No. 17-_____

IN THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

IN RE AMARIN PHARMA, INC. AND
AMARIN PHARMACEUTICALS IRELAND LTD.,

Petitioners.

On Petition for a Writ of Mandamus to the
United States International Trade Commission,
In the Matter of Certain Synthetically Produced, Predominantly EPA Omega-3 Products in Ethyl Ester or Re-esterified Triglyceride Form,
ITC Docket No. 3247.

PETITION FOR A WRIT OF MANDAMUS

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December 1, 2017

**Admission Pending*

CERTIFICATE OF INTEREST

Counsel for Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Ltd. certify the following:

1. The full name of every party or amicus represented herein:

Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Ltd.

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented us:

Not applicable.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented herein:

Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Ltd. are wholly-owned by Amarin Corporation plc., a publicly held corporation. No other publicly held corporation owns 10% or more of the stock of Amarin Pharma, Inc. or Amarin Pharmaceuticals Ireland Ltd.

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented herein in the trial court or agency or are expected to appear in this court (and who have not or will not enter an appearance in this case) are:

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5. The title and number of any case known to counsel to be pending in this or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal. See Fed. Cir. R. 47. 4(a)(5) and 47.5(b). (The parties should attach continuation pages as necessary).

Petitioners Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Ltd. are simultaneously filing both a petition for review and a petition for writ of mandamus, and have asked that the two cases be consolidated. Petitioners are not aware of any other cases that will be directly affected by this court's decision.

December 1, 2017

Respectfully submitted,

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TABLE OF CONTENTS

TABLE OF AUTHORITIES ii

STATEMENT OF RELIEF SOUGHT 1

ISSUE PRESENTED 2

STATEMENT OF JURISDICTION 3

INTRODUCTION AND SUMMARY OF ARGUMENT 4

STATEMENT OF FACTS AND PROCEDURAL HISTORY 7

STANDARD OF REVIEW 13

REASONS TO GRANT THE WRIT 13

I. The Commission Has A Non-Discretionary Obligation To Institute An Investigation When Presented With A Properly Pleaded Complaint. 14

II. The FDCA Does Not Preclude Amarin's Section 337 Claims. 20

A. The FDCA Does Not Preclude Suits Challenging The Labeling Of Products Subject To FDA Regulation. 21

B. The FDCA Does Not Preclude Section 337 Claims That Refer To Terms Defined In The FDCA. 26

III. Congress Anticipated That Other Agencies Will Participate In Section 337 Investigations And Required Them To Cooperate With The Commission. 31

CONCLUSION 41

CERTIFICATE OF COMPLIANCE WITH RULE 21(d)(1)

CERTIFICATE OF SERVICE

TABLE OF AUTHORITIES

CASES

Akzo N.V. v. U.S. Int'l Trade Comm'n,
808 F.2d 1471 (Fed. Cir. 1986) 26

Allergan, Inc. v. Athena Cosmetics, Inc.,
738 F.3d 1350 (Fed. Cir. 2013) 6, 30, 32

Amgen, Inc. v. Int'l Trade Comm'n,
565 F.3d 846 (Fed. Cir. 2009) 15

Amgen, Inc. v. U.S. Int'l Trade Comm'n,
902 F.2d 1532 (Fed. Cir. 1990) 3, 16

Athena Cosmetics, Inc. v. Allergan, Inc.,
135 S. Ct. 2886 (Mem.) (June 29, 2015) 31

Cheney v. United States Dist. Ct. for the Dist. of Columbia,
542 U.S. 367 (2004) 13

Farrel Corp. v. U.S. Int'l Trade Comm'n,
949 F.2d 1147 (Fed. Cir. 1991) 15

Gulfstream Aerospace Corp. v. Mayacamas Corp.,
485 U.S. 271 (1988) 3

In re Cray Inc.,
871 F.3d 1355 (Fed. Cir. 2017) 13

In re Halliburton Co.,
991 F.2d 810, 1993 WL 118929 (Fed. Cir. Mar. 12, 1993) 4

In re Link_A_Media Devices Corp.,
662 F.3d 1221 (Fed. Cir. 2011) 4

J.E.M. Ag Supply, Inc. v. Pioneer Hi–Bred Int'l, Inc.,
534 U.S. 124 (2001) 27

JHP Pharms., LLC v. Hospira, Inc.,
52 F. Supp. 3d 992 (C.D. Cal. 2014) 33

Kingdomware Techs., Inc. v. United States,
136 S. Ct. 1969 (2016) 16

L.A. Biomedical Research Inst. at Harbor-UCLA Med. Ctr. v. Eli Lilly & Co.,
849 F.3d 1049 (Fed. Cir. 2017) 17

Lexecon, Inc. v. Milberg Weiss Bershad Hynes & Lerach,
523 U.S. 26 (1998) 15

Miss. Chem. Corp. v. Swift Agric. Chems. Corp.,
717 F.2d 1374 (Fed. Cir. 1983) 3

POM Wonderful LLC v. Coca-Cola Co.,
134 S. Ct. 2228 (2014) ..... passim

Ricci v. Chicago Mercantile Exch.,
409 U.S. 289 (1973) 36

Roche v. Evaporated Milk Ass'n,
319 U.S. 21 (1943) 3, 13

Schlagenhauf v. Holder,
379 U.S. 104 (1964) 13

Syntex Agribusiness, Inc. v. U.S. Int'l Trade Comm'n,
659 F.2d 1038 (C.C.P.A. 1981) 19

Thermolife Int'l, LLC v. Gaspari Nutrition Inc.,
648 Fed. Appx. 609 (9th Cir. 2016) 25

Union Mfg. Co. v. U.S. Int'l Trade Comm'n,
826 F.2d 1071, 1987 WL 37901 (Fed. Cir. July 2, 1987) 19

Ventas, Inc. v. United States,
381 F.3d 1156 (Fed. Cir. 2004) 18

Wyandot Nation v. United States,
858 F.3d 1392 (Fed. Cir. 2017) 36

Wyeth v. Levine,
555 U.S. 555 (2009) 23

STATUTES

15 U.S.C. § 1125(a) 8

19 U.S.C. § 1334 ..... 6, 37

19 U.S.C. § 1337 ..... passim

19 U.S.C. § 1337(a) 15, 26, 36

19 U.S.C. § 1337(b) ..... passim

19 U.S.C. § 1337(c) 3

19 U.S.C. § 1337(f) 16

19 U.S.C. § 1337(j) 38

19 U.S.C. § 1673 18

21 U.S.C. § 321(f) 24

21 U.S.C. § 321(ff) 24, 29, 33, 34

21 U.S.C. § 321(g) 6

21 U.S.C. § 321(i) 6

21 U.S.C. § 332 10

28 U.S.C. § 1295 3

28 U.S.C. § 1651 4

28 U.S.C. § 1651(a) (1976) 3

LEGISLATIVE MATERIAL

S. Rep. No. 93-1298, 93 Cong. 2d Sess. 196 (Nov. 26, 1974) 26

OTHER AUTHORITIES

Br. of United States,
Albertson's v. Kanter,
No. 07-1327, 2008 WL 5151069 (Dec. 5, 2008) 11

Br. of United States,
Athena Cosmetics, Inc. v. Allergan,
No. 13-1379, 2015 WL 2457643 (May 26, 2015) 11, 31

Br. of United States,
POM Wonderful LLC v. The Coca Cola Co.,
No. 12-761, 2014 WL 827980 (U.S. Mar. 3, 2014) 11

Determination of the President
Regarding Certain Alkaline Batteries,
50 Fed. Reg. 1655 (Jan. 11, 1985) 38

ITC Trial Lawyers Association,
FAQs 18

Justice Department and Federal Partners Announce Enforcement
Actions of Dietary Supplement Cases, Nov. 17, 2015 35

Presidential Determination,
Welded Stainless Steel Pipe & Tube Indus.,
43 Fed. Reg. 17,789 (Apr. 26, 1978) 38

Section 337 Investigations Answers to
Frequently Asked Questions (Mar. 2009) 17

STATEMENT OF RELIEF SOUGHT

Petitioners Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Ltd. ("Amarin") filed a complaint requesting the International Trade Commission to institute an investigation into Amarin's allegations that the false labeling and deceptive description of certain imported products — synthetically produced, predominantly eicosapentaenoic acid ("EPA") omega-3 products in ethyl ester or re-esterified form ("synthetically produced omega-3 products") — marketed and sold as (or for use in) "dietary supplements" is an unfair act or unfair method of competition under Section 337 of the Tariff Act of 1930. Despite Congress's mandate that the Commission institute an investigation of complaints under Section 337, the Commission refused to institute the requested investigation. Amarin seeks a writ of mandamus that reverses the Commission's decision and directs the Commission to institute the requested investigation.

ISSUE PRESENTED

The Tariff Act imposes a mandatory obligation on the Commission to investigate allegations of unfair trade practices and unfair methods of competition, directing that "[t]he Commission *shall* investigate any alleged violation of" Section 337 "on complaint under oath." 19 U.S.C. § 1337(b)(1) (emphasis added). The Supreme Court has held that "Congress did not intend the" Federal Food, Drug and Cosmetic Act ("FDCA") "to preclude Lanham Act suits" alleging false and misleading advertising. *POM Wonderful LLC v. Coca-Cola Co.*, 134 S. Ct. 2228, 2241 (2014). The issue presented is:

Did the Commission clearly abuse its discretion, and/or fail to exercise authority that it has a duty to exercise, in refusing to institute an investigation into allegations raising cognizable claims of unfair trade practices under Section 337 of the Tariff Act, based in part on violations of Section 43(a) of the Lanham Act, on the view that "the Lanham Act allegations in this case are precluded by the Food, Drug and Cosmetic Act"?

STATEMENT OF JURISDICTION

Amarin has filed a petition for review of the Commission's decision refusing to institute an investigation. This Court has jurisdiction over the appeal under 28 U.S.C. § 1295(a)(6) because the decision constitutes a final determination under 19 U.S.C. § 1337(c). *See Amgen, Inc. v. U.S. Int'l Trade Comm'n*, 902 F.2d 1532, 1535 (Fed. Cir. 1990).

Out of an abundance of caution, and to avoid any impediment to this Court's exercise of jurisdiction, Amarin is also filing this petition for writ of mandamus. The Court may issue a writ as "necessary or appropriate in aid of [its] jurisdiction." *Miss. Chem. Corp. v. Swift Agric. Chems. Corp.*, 717 F.2d 1374, 1379 (Fed. Cir. 1983) (quoting 28 U.S.C. § 1651(a) (1976) (internal quotation marks omitted)). A writ of mandamus is necessary and appropriate when an administrative agency or lower court has committed a "demonstrable abuse of discretion" or failed to exercise "authority when it is its duty to do so." *Gulfstream Aerospace Corp. v. Mayacamas Corp.*, 485 U.S. 271, 289 (1988) (quoting *Roche v. Evaporated Milk Ass'n*, 319 U.S. 21, 26 (1943)); *see also In re Halliburton Co.*, 991 F.2d 810, 1993 WL 118929, at *1–2

(Fed. Cir. Mar. 12, 1993) (unpublished) (providing examples). The Court has jurisdiction to grant mandamus relief under the All Writs Act. *See* 28 U.S.C. § 1651; s*ee also, e.g.*, *In re Link_A_Media Devices Corp.*, 662 F.3d 1221 (Fed. Cir. 2011) (granting mandamus).

INTRODUCTION AND SUMMARY OF ARGUMENT

This petition asks the Court to direct the Commission to institute an investigation into the merits of Amarin's claims under Section 337 of the Tariff Act challenging the unlawful importation and sale of certain synthetically produced omega-3 products that are falsely labeled and deceptively described as (or for use in) "dietary supplements." The marketing and sale of these products, which do not meet the definition of "dietary supplement" and are therefore unapproved drugs, is an unfair trade practice that is causing substantial harm to the domestic industry and for which Congress intended to provide a remedy under Section 337. The statute imposes a mandatory, non-discretionary duty on the Commission to institute an investigation where, as here, it is presented with a complaint under oath. Nonetheless, the Commission declined to investigate on the erroneous view that Amarin's allegations are precluded by the FDCA, which is administered by the Food & Drug

Administration ("FDA"). That decision reflects a clear abuse of discretion.

First, the Commission has no discretion not to institute an investigation where, as here, it is presented with a complaint that properly invokes its jurisdiction. Section 337 unequivocally states that "[t]he Commission *shall* investigate any alleged violation . . . on complaint under oath." 19 U.S.C. § 1337(b)(1) (emphasis added). The Commission's refusal to institute an investigation violates that clear statutory mandate.

Second, the Commission's reason for not instituting an investigation — that Amarin's allegations under the Lanham Act are precluded by the FDCA — cannot be reconciled with controlling Supreme Court precedent. The Supreme Court has rejected the view that FDA has exclusive authority over the labeling of FDCA-regulated products, holding that "Congress did not intend the" FDCA "to preclude Lanham Act suits" alleging false and misleading advertising. *POM Wonderful*, 134 S. Ct. 2241. Nor is the Commission stripped of jurisdiction merely because it is asked to apply the well-settled meaning of statutory terms, like "dietary supplement" and "drug." This Court's

decision in *Allergan, Inc. v. Athena Cosmetics, Inc.*, 738 F.3d 1350 (Fed. Cir. 2013), rejected the view that only FDA had authority to interpret and apply the FDCA's statutory terms and determine whether a manufacturer engaged in an unfair trade practice by improperly marketing an unapproved "drug" as a "cosmetic." *Cf.* 21 U.S.C. § 321(g)(1) (defining "drug"); *id.* § 321(i) (defining "cosmetic").

Third, the Commission erred in deferring to FDA. Nothing in Amarin's complaint requires the Commission to enforce the FDCA or resolve any issue that would require scientific expertise. The remedies Amarin seeks are unique to Section 337. And the statutory terms "drug" and "dietary supplement" carry meanings that are well understood in the market, and applying them to the facts is a straightforward exercise within the Commission's authority under Section 337, not a complicated scientific inquiry. In any event, when an agency's special expertise is required, the Tariff Act sets out a specific process by which the agency may participate in an investigation. Congress directed agencies to "cooperate fully with the [C]ommission for the purposes of aiding and assisting in its work," 19 U.S.C. § 1334 (emphasis added) — not to block the Commission from instituting the

investigation. The Commission cannot avoid its statutory obligation to enforce Section 337 of the Tariff Act when presented with a complaint merely because FDA has separate authority to enforce the FDCA.

STATEMENT OF FACTS AND PROCEDURAL HISTORY

Amarin markets Vascepa® capsules, a prescription drug that consists of 1 gram of eicosapentaenoic acid (the omega-3 acid commonly known as "EPA") in a 1-gram capsule. The EPA in Vascepa® is in ethyl ester form and is synthetically produced from common fish oil. When it developed Vascepa®, Amarin took care to comply with all applicable laws, including making the extensive investments necessary to obtain FDA approval to market and sell Vascepa® in the United States as an adjunct to diet to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. Appx32, Appx82–83, Appx117 ¶¶ 16, 131, 213. Vascepa® is the only purified ethyl ester E-EPA ("E-EPA") product sold in the United States as an FDA-approved drug. Appx32 ¶ 16.

Amarin's Complaint. In August 2017, Amarin filed a complaint with the Commission alleging that certain competitors are falsely labeling or deceptively describing synthetically produced omega-3 products as (or for use in) "dietary supplements" when the products are

in fact "drugs" that have not been approved for sale or use in the United States. Appx19–29. (Amarin's complaint applied only to a small group of synthetically modified products, not to the majority of fish oil dietary supplements.) Amarin alleged that those acts constitute unfair acts or unfair methods of competition under Section 337 of the Tariff Act. Appx24 ¶ 1; *see* 19 U.S.C. § 1337. Amarin also asserted that those unfair acts violate Section 43(a) of the Lanham Act because falsely labeling or deceptively describing drugs as (or for use in) dietary supplements deceives consumers and others in the supply chain regarding the nature of the product. Appx24 ¶ 1; *see* 15 U.S.C. § 1125(a)(1). Amarin alleged that its domestic-industry commercial interests were being injured as a result of certain competitors' false and deceptive representations concerning the nature and characteristics of their imported products. Appx115–126.

FDA's Letter. After Amarin filed its complaint, FDA submitted a letter urging the Commission not to institute an investigation. FDA did not claim any authority to enforce either the Tariff Act or the Lanham Act. Nor did it dispute that the Commission is tasked by Congress to protect the domestic industry from unfair trade practices. It also did

not dispute that, as set forth in Amarin's complaint, the terms "dietary supplement" and "drug" have unambiguous, well-accepted meanings that are understood in the market and reflected in definitions set forth in the FDCA and decades of administrative precedent. Appx163–165.

Nonetheless, FDA asserted that because Amarin has no private right of action to enforce the FDCA, and because "FDA is the expert agency responsible for determining whether products comply with the FDCA," the Commission should not consider Amarin's Section 337 claims. According to FDA, the FDCA "preclude[s]" any claim that "require[s] the Commission to directly apply, enforce, or interpret the FDCA." Appx167. FDA also stated that "the Commission should decline to initiate an investigation under principles of comity to FDA — the federal agency that has the congressionally-delegated authority to determine the status of the products at issue." Appx165.

But Amarin's complaint does not seek any relief under the FDCA. Nor does it require FDA (or the Commission) to take action to enforce the FDCA. *See* Appx34, Appx51–53, Appx106–107 ¶ 18, 67, 185 (describing FDA's enforcement tools). Nor does anything in the FDCA give FDA a monopoly over the "appl[ication]" or "interpret[ation]" of

statutory terms, like "dietary supplement" or "drug." Appx49, Appx53–54, Appx63–64, Appx71–72, Appx126–128 ¶ 1, 62, 68, 86, 107, § XII. FDA does not pre-approve dietary supplements, so these statutory terms are interpreted and applied on a daily basis by manufacturers as they self-police by ensuring that products they wish to sell as dietary supplements qualify as dietary supplements and are not unapproved drugs. Moreover, FDA cannot take an enforcement action to restrain a company from selling an unapproved drug as a dietary supplement without a court interpreting those terms for itself and deciding *de novo* the status of the product. *See* 21 U.S.C. § 332. Accordingly, in response to FDA's letter, Amarin urged the Commission to institute its investigation, as required by statute, and not to defer to FDA's request under principles of comity.

As Amarin explained, FDA's letter attempts to resurrect the same field-preclusion arguments that the Supreme Court rejected in *POM Wonderful*. *See* 134 S. Ct. at 2241. FDA's letter also contradicts and disregards positions taken by the United States in briefing before the Supreme Court. In *POM Wonderful*, the Solicitor General argued that Lanham Act claims are barred by the FDCA "only to the extent the

FDCA or FDA regulations specifically *require* or *authorize* the challenged aspects of respondent's . . . label" — circumstances that are not present here. Br. of United States, *POM Wonderful LLC v. The Coca Cola Co.*, No. 12-761, 2014 WL 827980, at *9 (U.S. Mar. 3, 2014) (emphasis added). In taking that position, the Solicitor General recognized that "[c]ourts are called upon to interpret FDA regulations in various contexts." *Id.* at *10. The Solicitor General also made clear that "categorical preclusion [is not] warranted to prevent courts from interpreting the FDCA or FDA regulations[] to protect against 'backdoor' private FDCA enforcement actions, or to preserve FDA's regulatory authority." *Id.*; *see also* Br. of United States, *Athena Cosmetics, Inc. v. Allergan*, No. 13-1379, 2015 WL 2457643 (May 26, 2015); Br. of United States, *Albertson's v. Kanter*, No. 07-1327, 2008 WL 5151069 (Dec. 5, 2008).

Significantly, although the Solicitor General's position was not nearly as extreme as the position advanced by FDA's letter in this case, the Supreme Court rejected it as *too preclusive* and as "reorder[ing] federal statutory rights without congressional authorization." *POM Wonderful*, 134 S. Ct. at 2241. As the Court explained, the Solicitor

General's argument improperly assumed that "the FDCA and its regulations" are a "ceiling on the regulation" of labeling, when "Congress intended the Lanham Act and the FDCA to complement each other" with respect to labeling. *Id.* at 2240.

The Commission's Final Determination. On October 27, 2017, deferring to FDA, the Commission declined to institute an investigation. Appx1–2. The entirety of the Commission's determination reads:

> Under Commission Rules 210.9, 210.10 and 210.12(a)(2), (3) and (8), 19 C.F.R. §§ 210.9, 210.10, 210.12(a)(2), (3) and (8), the Commission has determined not to institute an investigation based on the complaint filed on behalf of Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Ltd. (collectively "Amarin") concerning Certain Synthetically Produced, Predominantly EPA Omega-3 Products in Ethyl Ester or Re-esterified Triglyceride Form, and has dismissed the complaint.
>
> Amarin's complaint does not allege an unfair method of competition or an unfair act cognizable under 19 U.S.C. § 1337(a)(1)(A), as required by the statute and the Commission's rules. The Commission notes that the Lanham Act allegations in this case are precluded by the Food, Drug and Cosmetic Act ("FDCA"). The Commission also notes that the Food and Drug Administration is charged with the administration of the FDCA.

Appx1; *see also* Appx3 (Comm'r Broadbent, concurring).

STANDARD OF REVIEW

A writ of mandamus should issue if (1) "no other adequate means [exists] to attain the relief" sought; (2) the right to mandamus is "clear and indisputable"; and (3) the court is "satisfied that the writ is appropriate under the circumstances." *Cheney v. United States Dist. Ct. for the Dist. of Columbia*, 542 U.S. 367, 380–81 (2004). As the Supreme Court has made clear, mandamus may be used to decide "basic [and] undecided" legal issues that a lower court has abused its discretion in deciding. *Schlagenhauf v. Holder*, 379 U.S. 104, 110 (1964); *see also In re Cray Inc.*, 871 F.3d 1355, 1359 (Fed. Cir. 2017) (granting mandamus because "the district court misunderstood the scope and effect of our decision in *Cordis*," which "led the court to deny the motion to transfer, which we find to have been an abuse of discretion"). Mandamus also may be used to compel a lower court or agency to "exercise its authority when it is its duty to do so." *Roche*, 319 U.S. at 26.

REASONS TO GRANT THE WRIT

Amarin is entitled to appeal the Commission's non-institution decision for reasons it will address in more detail in its opening brief on appeal. This mandamus petition is filed as a protective measure to avoid any impediment to the exercise of this Court's jurisdiction. If for

any reason the Court determines that Amarin is not entitled to appeal, then Amarin's only avenue for review is to seek mandamus relief. The Commission's non-institution decision is final and, if it is not reversed, Amarin will be improperly denied the remedies that Congress provided under the Tariff Act.

For reasons set forth below, the Commission's non-institution decision constitutes a clear abuse of discretion. Mandamus is warranted because (1) the Tariff Act mandates that the Commission institute an investigation where, as here, a complaint's properly pleaded allegations raise claims within the Commission's jurisdiction, and (2) the Commission's reasons for not instituting an investigation rest on a clear misunderstanding and violation of controlling precedent. The Court should therefore grant the writ and direct the Commission to exercise the jurisdiction that it has a duty to exercise and institute an investigation into the merits of Amarin's complaint.

I. The Commission Has A Non-Discretionary Obligation To Institute An Investigation When Presented With A Properly Pleaded Complaint.

The Tariff Act imposes a non-discretionary duty on the Commission to institute investigations into alleged unfair trade

practices and methods of competition. The statute directs that "[t]he Commission *shall* investigate any alleged violation of this section on complaint under oath . . . ." 19 U.S.C. § 1337(b)(1) (emphasis added). That mandatory command reinforces the statute's unequivocal requirement that unfair trade practices and unfair methods of competition "are unlawful, and when found by the Commission to exist *shall* be dealt with, in addition to any other provision of law . . . ." *Id.* § 1337(a)(1) (emphasis added).

In describing the Commission's statutory duties, this Court has noted that the Commission has both "the authority *and obligation* to investigate and prohibit importation based on unfair competition." *Amgen, Inc. v. Int'l Trade Comm'n*, 565 F.3d 846, 849 (Fed. Cir. 2009) (emphasis added). The Court has likened "shall" in this context to "the language of command," necessitating "strict compliance" and permitting termination of an investigation only in statutorily defined circumstances, "interpreted narrowly." *Farrel Corp. v. U.S. Int'l Trade Comm'n*, 949 F.2d 1147, 1153 (Fed. Cir. 1991); *see also Lexecon, Inc. v. Milberg Weiss Bershad Hynes & Lerach*, 523 U.S. 26, 35 (1998) ("The mandatory 'shall' . . . normally creates an obligation impervious to

judicial discretion"). Accordingly, this Court has recognized that when a complaint "on its face . . . [comes] within the jurisdiction of the Commission," the Commission "should assume jurisdiction" and address the complaint on its merits. *Amgen*, 902 F.2d at 1536.

In another area within this Court's exclusive jurisdiction, the Supreme Court recently emphasized that when a statute uses "may" and "shall" in different provisions, the word "shall" denotes a "requirement" and "imposes a mandatory duty" on the agency. *Kingdomware Techs., Inc. v. United States*, 136 S. Ct. 1969, 1977 (2016) (holding that the Small Business Act imposes a mandatory obligation that the Department of Veterans Affairs "shall award" contracts to veteran-owned small businesses). It is therefore significant that several of Section 337's subsections use permissive language. *See, e.g.*, 19 U.S.C. § 1337(b)(3) (stating that "the Commission *may* suspend its investigation" in certain circumstances); *id.* § 1337(f) (granting the Commission discretion to issue cease and desist orders). These permissive grants of authority highlight that Congress made a deliberate decision to use "shall" in Section 1337(b)(1), directing that the Commission must initiate an investigation when presented with a

complaint under oath. The statute provides no room for administrative leeway.

The Commission's historic practice confirms that the statute means what it says. Although the Commission does not keep public statistics on which cases it has declined to investigate, independent research suggests that in the last twenty years well over a thousand Section 337 cases were filed. The Commission declined to institute an investigation in only a small handful. *See, e.g.*, *Compl. of Prospera Corp. Concerning Certain Elec. Hand Held Pulse Massagers and Components Thereof* (ITC Docket No. 2997), issued Jan. 28, 2014; *Compl. of KV Pharm. Co. Concerning Hydroxyprogesterone Caproate and Prods. Containing Same* (ITC Docket No. 2919), issued Dec. 21, 2014; *see also L.A. Biomedical Research Inst. at Harbor-UCLA Med. Ctr. v. Eli Lilly & Co.*, 849 F.3d 1049, 1061 n.6 (Fed. Cir. 2017) ("We can properly take judicial notice of the records of related court proceedings."). As the Commission's public representations confirm, "[d]ecisions not to institute an investigation are rare." *Section 337 Investigations Answers to Frequently Asked Questions* 16 (Mar. 2009), https://www.usitc.gov/intellectual_property/documents/337_faqs.pdf.

The ITC Trial Lawyers Association offers the same assessment: "Only in extremely rare circumstances does the ITC decide not to institute an investigation." *FAQs*, http://www.itctla.org/resources/faqs.

There are only a few specifically enumerated and narrowly drawn exceptions to the Commission's mandatory obligation to institute an investigation. For example, in cases within the purview of the antidumping and countervailing laws, Congress has expressly directed that the Commission *shall not* institute an investigation. *See* 19 U.S.C. § 1337(b) ("the Commission shall terminate, or not institute, any investigation" into acts that constitute dumping and are solely within the purview of 19 U.S.C. § 1673). Congress's decision to enact an express provision that exempts antidumping and countervailing duty claims is strong evidence that it did not intend to carve out other categories of claims, such as those involving FDA-regulated products, from Section 337's requirements. *See Ventas, Inc. v. United States*, 381 F.3d 1156, 1161 (Fed. Cir. 2004) ("Where Congress includes certain exceptions in a statute, the maxim *expressio unius est exclusio alterius* presumes that those are the only exceptions Congress intended.").

Courts have also recognized a narrow exception to the Commission's obligation to institute an investigation in "unique circumstances" when a complaint's allegations are so inadequate that they do not provide a sufficient factual basis for the Commission to take action. *See Union Mfg. Co. v. U.S. Int'l Trade Comm'n*, 826 F.2d 1071, 1987 WL 37901, at *3 (Fed. Cir. July 2, 1987) (finding that Commission could decline to institute a second investigation when presented with no new material allegations that had not already been investigated). In *Syntex*, for instance, the Court of Customs and Patent Appeals concluded that the Commission was not required to institute an investigation because the "petitioner's allegations are no more than conclusory," *Syntex Agribusiness, Inc. v. U.S. Int'l Trade Comm'n*, 659 F.2d 1038, 1044–45, 1047 (C.C.P.A. 1981) (Nies, J., concurring), and did not include "an adequate factual basis" for its claims. *Id.* at 1045–46 (majority).

None of these narrow exceptions applies in this case. Amarin's complaint, as well as the numerous exhibits and other materials attached to the complaint, contains sufficient allegations and factual support to invoke the Commission's jurisdiction. Significantly, unlike

in one of the few other cases where the Commission has declined to institute an investigation, the Commission did not identify any allegations lacking sufficient information or give Amarin an opportunity to re-file its complaint. *Cf. Compl. of Prospera Corp.* (ITC Docket No. 2997) (dismissing a complaint without prejudice and permitting the complainant to re-file with sufficient allegations). Instead, the only ground the Commission identified for not complying with its statutory obligations was its conclusion that "the Lanham Act allegations in this case are precluded by the Food, Drug and Cosmetic Act," which FDA has authority to administer. Appx1. That conclusion is contrary to controlling precedent and a clear abuse of any discretion the Commission may have.

II. The FDCA Does Not Preclude Amarin's Section 337 Claims.

The Supreme Court in *POM Wonderful* rejected the view that the FDCA precludes Lanham Act claims challenging a product's false and deceptive labeling, even though the product is regulated by FDA under the FDCA. As the Supreme Court held, "Congress did not intend the FDCA to preclude Lanham Act suits" challenging the labeling of products subject to FDA regulation. *POM Wonderful*, 134 S. Ct. at

2241. The Commission's decision here cannot be reconciled with *POM Wonderful*.

A. The FDCA Does Not Preclude Suits Challenging The Labeling Of Products Subject To FDA Regulation.

In *POM Wonderful*, the plaintiff alleged that the labeling of the defendant's "pomegranate blueberry" beverage product misled consumers into believing that the product consisted predominantly of pomegranate and blueberry juice, when in fact it contained only small amounts of those juices. In the Ninth Circuit, the defendant argued that the FDCA precluded the Lanham Act claim because FDA has authority to regulate food and beverage labels and, as a result, only FDA has authority to determine whether the product's labeling was appropriate. 134 S. Ct. at 2233. The Ninth Circuit accepted that argument, noting that FDA exercised "comprehensive regulation" of juice labeling and expressing concern that permitting the Lanham Act claim to proceed "would risk undercutting" FDA's "expert judgments and authority." *Id.* at 2236.

The Supreme Court reversed, holding that "Congress did not intend the FDCA to preclude Lanham Act suits like POM's." *Id.* at 2241. The Court noted that "the Lanham Act subjects to suit any

person who 'misrepresents the nature, characteristics, qualities, or geographic origin' of goods and services" and that "this comprehensive imposition of liability extends, by its own terms, to misrepresentations on labels, including food and beverage labels." *Id.* at 2237. The Court further noted that "neither the Lanham Act nor the FDCA, in express terms, forbids or limits Lanham Act claims challenging labels that are regulated by the FDCA." *Id.* The Court also considered the structure of the two statutes and recognized that they protect different interests: the Lanham Act protects commercial interests, while the FDCA protects public health and safety interests. *Id.* at 2238. As the Court concluded, "the FDCA and the Lanham Act complement each other in the federal regulation of misleading labels," *id.* at 2241, and "[a]llowing Lanham Act suits takes advantage of synergies among multiple methods of regulation" — consistent with Congress's "design to enact two different statutes, each with its own mechanisms to enhance the protection of competitors and consumers," *id.* at 2239.

Accordingly, the Supreme Court held that "[c]ompetitors, in their own interest, may bring Lanham Act claims like POM's that challenge food and beverage labels that are regulated by the FDCA." *Id.* at 2233.

It also criticized the same position that FDA urged the Commission to resurrect in this case: "A holding that the FDCA precludes Lanham Act claims challenging food and beverage labels would not only ignore the distinct functional aspects of the FDCA and the Lanham Act but also would lead to a result that Congress likely did not intend." *Id.* at 2239; *see also Wyeth v. Levine*, 555 U.S. 555, 575 (2009) (stating that "Congress did not intend FDA oversight" to be the "exclusive means" of regulating products subject to the FDCA). Because FDA "does not preapprove food and beverage labels . . . [and] does not necessarily pursue enforcement measures regarding all objectionable labels . . . [,] if Lanham Act claims were to be precluded then commercial interests — and indirectly the public at large — could be left with less effective protection in the food and beverage labeling realm than in many other, less regulated industries." *POM Wonderful*, 134 S. Ct. at 2239. As the Court explained, there is no reason to think that "Congress intended the FDCA's protection of health and safety to result in less policing of misleading food and beverage labels than competitive markets for other products." *Id.*

The Commission's non-institution decision in this case cannot be reconciled with *POM Wonderful*. "Dietary supplements," like beverages, are a type of "food" regulated by FDA. 21 U.S.C. § 321(f), (ff). And, just like beverages, FDA does not preapprove the distribution or the labeling of purported dietary supplements. Instead, manufacturers interpret and apply the statutory definitions of "drug" and "dietary supplement" to determine for themselves whether a product is a drug, which requires FDA approval, or a dietary supplement, which does not. When manufacturers incorrectly decide that a drug is a dietary supplement, FDA can only police the purported dietary supplement's lack of compliance with the FDCA by relying on enforcement actions, warning letters, and other measures taken after a product is brought to market. Because of limited resources, however, the agency cannot pursue every violation. *POM Wonderful,* 134 S. Ct. at 2239. To the contrary, FDA has only about 25 employees to oversee the more than 85,000 products that each year are sold as dietary supplements. *See* Appx130–155 (Frontline: Supplements and Safety, PBS and The New York Times).

Claims that a manufacturer has falsely labeled or deceptively described a product as a dietary supplement when, in reality, it is an unapproved drug — like claims that a manufacturer has falsely labeled a beverage as a type of juice — are not precluded under the FDCA. *See POM Wonderful*, 134 S. Ct. at 2237 ("food and beverage labels regulated by the FDCA are not . . . off limits to Lanham Act claims"); *see also Thermolife Int'l, LLC v. Gaspari Nutrition Inc.*, 648 Fed. Appx. 609, 612 (9th Cir. 2016) (holding that plaintiff's allegations that defendant had falsely advertised a "dietary supplement" as "safe," "natural," and "legal" were not precluded by the FDCA). FDA has authority to enforce the FDCA to protect public health (and it does so when it detects a violation and has adequate resources to pursue it), but FDA has no authority to enforce the Lanham Act to preserve fair competition by protecting against deceptive advertising. And as explained above, the Supreme Court has already held that Congress did not intend its grant of one type of authority to FDA to protect health and safety interests to limit Congress's separate grant of a different type of authority to competitors to bring private actions under the Lanham Act to protect fair competition.

B. The FDCA Does Not Preclude Section 337 Claims That Refer To Terms Defined In The FDCA.

POM Wonderful addressed Lanham Act claims brought by private parties in district court, but the legal principles it recognized and announced apply with full force here.

There is no indication that Congress intended the FDCA to preclude private-party claims under Section 337 of the Tariff Act seeking to enforce the Lanham Act before the Commission any more than it intended to preclude private-party claims seeking to enforce the Lanham Act before district courts. To the contrary, Congress made clear that Section 337's remedies for unfair competition through misleading advertising or labeling are "*in addition to* any other provision of law." 19 U.S.C. § 1337(a)(1) (emphasis added); *see also* S. Rep. No. 93-1298, 93 Cong. 2d Sess. 196 (Nov. 26, 1974) (noting that "[t]he relief provided for violations of section 337 is 'in addition to' that granted in 'any other provisions of law'"). Section 337 also serves different purposes and protects different interests than the FDCA. *See Akzo N.V. v. U.S. Int'l Trade Comm'n*, 808 F.2d 1471, 1488 (Fed. Cir. 1986) (noting that "the thrust of the statute" is to protect domestic industry against "unfair trade practices in international commerce").

Accordingly, allowing Section 337 claims based on the Lanham Act "takes advantage of synergies among multiple methods of regulation" — consistent with Congress's "design to enact . . . different statutes, each with its own mechanisms to enhance the protection of competitors and consumers," *POM Wonderful*, 134 S. Ct. at 2239.

Congress's grant of authority to the Commission under Section 337 also should be read to complement and to work in synergy with Congress's grant of authority to FDA under the FDCA. Amarin's claims under Section 337 of the Tariff Act, like the Lanham Act claims considered in *POM Wonderful*, seek to protect competitors against unfair competition and unfair trade practices. Both the Lanham Act and the Tariff Act complement the FDCA, and "it would show disregard for the congressional design to hold that Congress nonetheless intended one federal statute [the FDCA] to preclude the operation of the other[s]." *POM Wonderful*, 134 S. Ct. at 2238 (citing *J.E.M. Ag Supply, Inc. v. Pioneer Hi–Bred Int'l, Inc.*, 534 U.S. 124, 144 (2001) ("we can plainly regard each statute as effective because of its different requirements and protections")).

That the disposition of Amarin's claims turns on market participants' understanding of what products qualify as "dietary supplements" or "drugs," which is informed by the FDCA's statutory definitions and administrative guidance, does not change this analysis. Although *POM Wonderful* stopped short of rejecting the possibility that FDA could limit the scope of the Lanham Act as it relates to FDA-regulated products by promulgating a regulation carrying the force of law that so provided, *see* 134 S. Ct. at 2240–41, FDA has not promulgated any such regulation addressing dietary supplements. Similarly, although the Court cast doubt on whether a Lanham Act claim would be precluded even if it conflicted with the plain terms of an FDA regulation, the Court entertained that possibility. *See id*. at 2241. But that is irrelevant, because there is no such conflict here. As in *POM Wonderful*, this "is not a case where a lawsuit is undermining an agency's judgment," *id.*, or where there will be "any difficulty in fully enforcing each statute according to its terms," *id.* at 2240.

Amarin's claims do not conflict with the FDCA or FDA regulations. To the contrary, Amarin is asking the Commission to find that certain products do not qualify as "dietary supplements" because,

among other reasons, the substances in them are not "dietary ingredients," as confirmed by the statute's text. *See* 21 U.S.C. § 321(ff)(1) (listing substances that are dietary ingredients). If there were any doubt, it is dispelled by long-standing administrative precedent, which publicly announces FDA's interpretation of what the law requires. For more than 15 years, FDA has stated on numerous occasions that certain types of synthetically produced substances are not "dietary ingredients" and, therefore, cannot be sold as (or for use in) dietary supplements. Appx51–54 ¶¶ 67–68; *see also* 21 U.S.C. § 321(ff)(1); FDA Ltr. to AIBMR Life Sciences, Inc. (Mar. 19, 2014) (determining that synthetic fatty acid esters derived from fish oil "do not fit within the statutory definition of 'dietary ingredient' because they are not constituents of a dietary substance for use by man under section 201(ff)(1)(F)"). These earlier administrative determinations thus confirm that there is no conflict between Amarin's request that the Commission enforce the laws protecting against unfair trade practices and FDA's responsibility to protect public health and safety under the FDCA.

This Court has already rejected the argument that a claim under a different statute is barred merely because it entails referring to, applying, or interpreting terms defined in the FDCA. In *Allergan, Inc. v. Athena Cosmetics, Inc.*, 738 F.3d 1350 (Fed. Cir. 2013), the manufacturer of an FDA-approved eyelash growth drug alleged that a competitor unfairly competed by selling its eyelash growth product as a "cosmetic," without obtaining FDA approval of the product as a "drug." In short, Allergan alleged that Athena had engaged in an unfair trade practice by improperly marketing an unapproved "drug" as a "cosmetic."

This Court held that Allergan's claim under California's unfair competition law was not preempted by the FDCA and affirmed the grant of summary judgment in Allergan's favor. Applying and interpreting the FDCA's definition of "drug" (which had been incorporated into California law) to include "any article other than food that is used or intended to affect the structure . . . of the body of human beings," *id.* at 1356, the Court concluded that Athena intended its product to be used as a "drug" and, therefore, Athena violated the prohibitions on unfair competition by selling its unapproved drug as if it were a cosmetic. The Supreme Court called for the views of the

Solicitor General in response to Athena's petition for certiorari, and the government defended this Court's decision, explaining that Allergan's suit did not conflict with the FDCA or FDA's exclusive authority to enforce that statute. *See* Br. of United States, *Athena Cosmetics,* 2015 WL 2457643, at *10–14 (noting that the "state-law suit to enjoin the sale of an unapproved drug does not compromise FDA's objectives"). The Supreme Court denied certiorari. *See Athena Cosmetics, Inc. v. Allergan, Inc.*, 135 S. Ct. 2886 (Mem.) (June 29, 2015). Neither FDA's letter nor the Commission's decision mentioned this Court's binding precedent in *Allergan v. Athena* or the United States' defense of that decision before the Supreme Court.

III. Congress Anticipated That Other Agencies Will Participate In Section 337 Investigations And Required Them To Cooperate With The Commission.

FDA's letter urged the Commission to "decline to initiate an investigation under principles of comity to FDA," suggesting that investigating Amarin's claims might require resolving complex questions necessitating FDA's scientific expertise. Appx165. That is wrong on its own terms, as Amarin's claims raise straightforward legal and factual issues that the Commission and this Court are entirely

competent to decide. FDA's "comity" request is contrary to the statute in any event. The Tariff Act includes detailed provisions specifying the role that other agencies play in connection with Section 337 complaints filed with the Commission. That role is to participate in and cooperate with a Commission investigation — not to block the Commission from instituting an investigation in the first place.

As explained above, nothing in the FDCA ousts the courts or the Commission from deciding whether a product meets either definition when that issue arises in a claim pleaded under the Lanham Act or some other source of law. Nor is any specialized scientific expertise required to determine whether a product qualifies as a "dietary supplement" or "drug" as those terms are defined by statute. Just as this Court had no difficulty in *Athena* applying the statutory definition of "drug" to the product improperly marketed as a mere "cosmetic," no expertise beyond the ken of the Commission or this Court is required to apply the definitions of "drug" and "dietary supplement." *Athena*, 738 F.3d at 1355–56, 1359–60.

That distinguishes this case from those where *courts* have referred matters to FDA to resolve questions of scientific judgment falling within

FDA's special expertise. *See JHP Pharms., LLC v. Hospira, Inc.*, 52 F. Supp. 3d 992, 1001 (C.D. Cal. 2014). For example, courts have sometimes referred cases to FDA when asked to assess the safety or effectiveness of a drug — questions that require scientific expertise concerning the design of clinical trials and the analysis of clinical data. *See id.* at 1003–05.

Nothing in Amarin's complaint requires the Commission to undertake that type of scientific inquiry. The pivotal issue — whether certain products are falsely labeled and deceptively described as (or for use in) "dietary supplements" — is a question that can be readily resolved by the Commission. Indeed, the Commission is as capable of making that determination as this Court was in applying the definition of "drug" to the facts in *Athena*. To determine whether the challenged products are falsely labeled or deceptively described, the Commission need only consider whether the substances they contain qualify as "dietary ingredients" as that term is expressly defined in the statute, *see* 21 U.S.C. § 321(ff)(1), and, if they do, whether they are otherwise precluded from being sold as "dietary supplements" because they were first studied or approved as a "drug," as that term is defined in the

statute, *see id.* § 321(ff)(3)(B). Appx49–62. ¶¶ 61–83. Resolving those issues requires nothing more than looking at the statute itself and the many decisions that have interpreted the relevant statutory terms and set market expectations. As discussed, FDA has already determined that synthetic fatty acid esters derived from fish oil — substances exceedingly similar to the accused products in all material respects — "do not fit within the statutory definition of 'dietary ingredient' because they are not constituents of a dietary substance for use by man under section 201(ff)(1)(F)." Appx156–161 (Compl., Ex. 33).

Confirming that no special scientific expertise is involved, courts routinely decide similar questions — including whether a purported dietary supplement is an unapproved drug — in enforcement actions brought by FDA, so it cannot be that only FDA can venture into this area.[1] By the same logic, the fact that private parties cannot bring

[1] In 2015, the Department of Justice, which brings enforcement actions on behalf of FDA, filed suit against several companies selling unapproved "new drugs" mislabeled as "dietary supplements." In each case, the court, not FDA, had the responsibility to decide the issue based on its interpretation and application of the definitions of "dietary supplement" and "drug." *See* Justice Department and Federal Partners Announce Enforcement Actions of Dietary Supplement Cases, Nov. 17,

actions to enforce the FDCA does not mean that the Commission is forbidden from applying or interpreting the FDCA when private parties invoke rights of action under other statutes, such as Section 43(a) of the Lanham Act and Section 337 of the Tariff Act. Competitors do not have an open field to engage in unfair trade practices like falsely labeling unapproved drugs as dietary supplements merely because FDA lacks the resources to enforce the FDCA against every violator.

With its focus on the public health, FDA does not have the necessary "perspective or expertise in assessing market dynamics" that give rise to competitive harms. *POM Wonderful*, 134 S. Ct. at 2238. Instead, the reason Congress allowed private parties to invoke Section 337 and the Lanham Act is to police competitive harms that result when competitors fail to comply with the law and to "provide incentives for manufacturers to behave well." *Id.* at 2238–39 (internal quotation marks omitted). Policing unfair trade practices is not FDA's job — it is the Commission's. And Congress made clear that the Commission's duty to investigate claims of unfair trade practices is "*in addition to* any

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2015, https://www.justice.gov/opa/pr/justice-department-and-federal-partners-announce-enforcement-actions-dietary-supplement-cases.

other provision of law." 19 U.S.C. § 1337(a)(1) (emphasis added). The fact that FDA has separate authority to pursue claims under the FDCA therefore cannot justify the Commission's abdication of the duty Congress placed on it under the Tariff Act.

Because of the unique nature of the Commission's duty and authority under the Tariff Act, court decisions that refer matters to FDA for an exercise of its scientific expertise under the "primary jurisdiction" doctrine are not relevant in the context of Section 337. Courts have discretion (albeit limited) to decline to exercise jurisdiction in the first instance and instead to wait for an administrative agency where "a prior agency adjudication . . . will be a material aid." *Wyandot Nation v. United States*, 858 F.3d 1392, 1400 (Fed. Cir. 2017) (quoting *Ricci v. Chicago Mercantile Exch.*, 409 U.S. 289, 305 (1973)). But the Commission has no such discretion; Congress imposed a mandatory duty on the Commission, providing that it "*shall* investigate any alleged violation of" Section 337 "on complaint under oath." 19 U.S.C. § 1337(b)(1) (emphasis added).

Moreover, this congressional mandate to investigate makes perfect sense in the context of the Tariff Act. Congress recognized that

the Commission would sometimes need or benefit from input from other agencies and provided a specific process by which the Commission can obtain such input during its investigation. 19 U.S.C. § 1334 (stating that the "Commission shall in appropriate matters act in conjunction and cooperation with . . . any other department . . . of the Government"). Indeed, Congress specifically mandated that during each investigation the Commission "shall consult with, and seek advice and information from, the Department of Health and Human Services," which includes FDA, as well as "such other departments and agencies as it considers appropriate." 19 U.S.C. § 1337(b)(2).

Congress even recognized that other agencies might not always be eager to provide the input requested by the Commission and specifically chose not to leave that decision to the agencies themselves, instead mandating that such other "departments . . . *shall cooperate fully* with the [C]ommission for the purposes of aiding and assisting in its work[.]" *Id.* § 1334 (emphasis added). Rather than allow another agency to block the institution of an investigation at the front end or to thwart the successful conduct of the investigation by withholding cooperation, Congress built in a process to address any inter-agency conflict at the

back end. Under the Tariff Act, all Commission decisions finding a violation of section 337 are submitted to the President for review during a 60-day period following the investigation's conclusion. *See id.* § 1337(j)(1). The President may disapprove of any Commission decision for "policy reasons," draining the decision of any force or effect. *Id.* § 1337(j)(2). The President has used this authority on two occasions to ensure that Commission decisions did not intrude on the prerogatives of another agency. *See* Presidential Determination, *Welded Stainless Steel Pipe & Tube Indus.*, 43 Fed. Reg. 17,789 (Apr. 26, 1978) (disapproving a cease-and-desist order issued by the Commission on the ground that the Antidumping Act administered by the Treasury Department provided complainant with adequate relief); *Determination of the President Regarding Certain Alkaline Batteries*, 50 Fed. Reg. 1655 (Jan. 11, 1985) (disapproving Commission determination on the ground that the Treasury Department's interpretation of the gray market goods provision of the Lanham Act controlled).

FDA's call for "comity," and the Commission's heeding of that call, cannot be reconciled with the text or structure of the Tariff Act. If any "comity" is owed in this context, it is owed *by* FDA *to* the Commission

under Congress's directive that other agencies "shall cooperate fully with the [C]ommission for the purposes of aiding and assisting in its work." If any special agency expertise were needed in the investigation of Amarin's claims — and none is, as explained above — the statute makes clear that that is not a basis for the Commission to abdicate its duty to institute an investigation. The Commission's job is to enforce the Tariff Act by investigating complaints that the domestic industry is being harmed by unfair trade practices, and to obtain whatever input from FDA or any other agency may be necessary or appropriate in the course of that investigation. In allowing FDA's desire to protect its prerogative to enforce the FDCA to serve as a basis to refuse to institute an investigation into Amarin's claims, the Commission lost sight of the obligations Congress imposed on it.

* * * *

When Amarin brought Vascepa® to market, it made the significant investments needed to comply with U.S. law and sell its product as an FDA-approved drug. The company is now facing unfair competition from a small group of omega-3 products that are in reality unapproved, imported drugs that are being falsely sold and deceptively described "dietary supplements." The Commission has a mandatory obligation to investigate Amarin's allegations on their merits, and it cannot avoid that obligation merely because the imported products are subject to regulation under the FDCA. Because the Commission's refusal to institute an investigation is a clear abuse of discretion, this Court should direct the Commission to comply with its statutory obligations.

CONCLUSION

If the Court concludes that it lacks jurisdiction over Amarin's petition for review appealing the Commission's final decision, it should grant a writ of mandamus ordering the Commission to institute an investigation into the merits of Amarin's claims, as Congress required under Section 337 of the Tariff Act.

Respectfully submitted,

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December 1, 2017

**Admission Pending*

CERTIFICATE OF COMPLIANCE WITH RULE 21(d)(1)

This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 21(d)(1). The brief contains 7,639 words, excluding the parts of the brief exempted by Federal Rules of Appellate Procedure 32(a)(7)(A) and 32(f), as well as Federal Circuit Rule 32(b).

This brief complies with requirements of Federal Rule of Appellate Procedure 32(c)(2). This brief has been prepared in a proportionally spaced typeface using Microsoft Office Word Version 2013 in 14-point Century Schoolbook font.

Respectfully submitted,

/s/ *Ashley C. Parrish*
Ashley C. Parrish

Counsel for Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Ltd.

Dated: December 1, 2017

CERTIFICATE OF SERVICE

I hereby certify that on December 1, 2017, I served or caused to be served copies of this Petition for a Writ of Mandamus via Hand Delivery or Overnight Mail to the following:

The Honorable Lisa R. Barton
Secretary
U.S. INTERNATIONAL TRADE COMMISSION
500 E Street, S.W.
Washington, DC 20436
Telephone: (202) 205-2000

Respectfully submitted,

/s/ *Ashley C. Parrish*
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Counsel for Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Ltd.

Dated: December 1, 2017

No. 17-_____

IN THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

IN RE AMARIN PHARMA, INC. AND
AMARIN PHARMACEUTICALS IRELAND LTD.,

Petitioners.

On Petition for a Writ of Mandamus to the United States International Trade Commission, *In the Matter of Certain Synthetically Produced, Predominantly EPA Omega-3 Products in Ethyl Ester or Re-esterified Triglyceride Form*, ITC Docket No. 3247.

APPENDIX TO PETITION FOR A WRIT OF MANDAMUS

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December 1, 2017

**Admission Pending*

TABLE OF CONTENTS FOR APPENDIX

File Date	Description	Appx. No.
10/27/2017	The Commission's Final Determination (with Commissioner Meredith M. Broadbent's Concurring Memorandum)	Appx1
	Docket Sheet for ITC Investigation No. 337-3247	Appx4
08/30/2017	Complaint of Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Ltd., filed with the U.S. International Trade Commission (Docket No. 3247)	Appx8
08/30/2017	Frontline: Supplements and Safety, PBS and The New York Times (Complaint, Exhibit 29)	Appx130
08/30/2017	FDA Warning Letter to AIBMR Life Sciences, Inc., (Mar. 19, 2014) (Complaint, Exhibit 33)	Appx156
10/06/2017	FDA Action Request To The ITC	Appx163
03/11/1993	*In re Halliburton Co.*, 1993 U.S. App. LEXIS 14271 (Fed. Cir. Mar. 12, 1993)	Appx174
04/14/2016	*Thermolife Int'l, LLC v. Gaspari Nutrition Inc.*, 648 F. App'x 609 (9th Cir. 2016)	Appx176
11/14/2017	*Allergan USA Inc. v. Imprimis Pharmaceuticals, Inc.*, Order Denying Mot. to Dismiss, (C.D. Cal. Nov. 14, 2017)	Appx182

UNITED STATES INTERNATIONAL TRADE COMMISSION

WASHINGTON, D.C. 20436

October 27, 2017

Jeffrey M. Telep, Esq.
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Re: Complaint Filed by Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Ltd. Concerning Certain Synthetically Produced, Predominantly EPA Omega-3 Products in Ethyl Ester or Re-esterified Triglyceride Form (Docket No. 3247)

Dear Mr. Telep:

Under Commission Rules 210.9, 210.10 and 210.12(a)(2), (3) and (8), 19 C.F.R. §§ 210.9, 210.10, 210.12(a)(2), (3) and (8), the Commission has determined not to institute an investigation based on the complaint filed on behalf of Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Ltd. (collectively "Amarin") concerning Certain Synthetically Produced, Predominantly EPA Omega-3 Products in Ethyl Ester or Re-esterified Triglyceride Form, and has dismissed the complaint.

Amarin's complaint does not allege an unfair method of competition or an unfair act cognizable under 19 U.S.C. § 1337(a)(1)(A), as required by the statute and the Commission's rules. The Commission notes that the Lanham Act allegations in this case are precluded by the Food, Drug and Cosmetic Act ("FDCA"). The Commission also notes that the Food and Drug Administration is charged with the administration of the FDCA.

Documents relating to this institution determination, including comments from the complainant, proposed respondents, and the public, can be found on the Commission's Electronic Document Information System (EDIS) under Docket Number 3247.

Sincerely,

Lisa R. Barton
Secretary to the Commission

cc: Proposed respondents

UNITED STATES INTERNATIONAL TRADE COMMISSION

WASHINGTON, DC 20436

CO84-PP-001

October 27, 2017

CONCURRING MEMORANDUM

TO: THE SECRETARY[1]

FROM: Commissioner Meredith M. Broadbent

SUBJECT: Complaint of Amarin Pharma, Inc. concerning Certain Synthetically Produced, Predominantly EPA Omega-3 Products in Ethyl Ester or Re-Esterified Triglyceride Form (Docket No. 3247)

Commissioner Broadbent concurs with the Commission's finding that Amarin's complaint does not allege an unfair method of competition or an unfair act under section 337(a)(1)(A) of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337(a)(1)(A). She notes, however, that she does not reach the issue of whether properly pleaded claims based on the Food, Drug, and Cosmetic Act may be cognizable under section 337(a)(1)(A).

[1] This is a public document to be filed in EDIS.

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Searched for: Investigation Number: "337-3247"

Doc ID	Doc Type	Order No.	Inv #	Phase	Security	Official Receive Date	Filed By	Firm/Org	On Behalf Of	Score
627055 (1 File)	Correspondence - USITC		337-3247	Violation	Public	10/27/2017 04:48 PM	Lisa R. Barton	USITC	Office of the Secretary	100%
Inv Title:	Certain Synthetically Produced, Predominantly EPA Omega-3 Products In Ethyl Ester Or Re-Esterified Triglyceride Form, DN 3247									
Doc Title:	Determination Not to Institute an Investigation; and Concurring Memorandum from Commissioner Broadbent									
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627040 (1 File)	Other		337-3247	Violation	Public	10/27/2017 04:00 PM	Frank Pallone, Jr.	U.S. House of Representatives	U.S. House of Representatives	100%
Inv Title:	Certain Synthetically Produced, Predominantly EPA Omega-3 Products In Ethyl Ester Or Re-Esterified Triglyceride Form, DN 3247									
Doc Title:	Written Comments									
Show Excerpt [+] :										
626429 (1 File)	Voting Sheet		337-3247	Violation	Public	10/23/2017 02:26 PM	Lisa R. Barton	USITC	Office of the Secretary	100%
Inv Title:	Certain Synthetically Produced, Predominantly EPA Omega-3 Products In Ethyl Ester Or Re-Esterified Triglyceride Form, DN 3247									
Doc Title:										
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626079 (1 File)	Correspondence - USITC		337-3247	Violation	Public	10/18/2017 04:05 PM	Lisa R. Barton	USITC	Office of the Secretary	100%
Inv Title:	Certain Synthetically Produced, Predominantly EPA Omega-3 Products In Ethyl Ester Or Re-Esterified Triglyceride Form, DN 3247									
Doc Title:	Letter to Jeffery Telep Granting Request for Leave to File out of Time									
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625581 (1 File)	Correspondence - USITC		337-3247	Violation	Public	10/13/2017 10:34 AM	Lisa R. Barton	USITC	Office of the Secretary	100%
Inv Title:	Certain Synthetically Produced, Predominantly EPA Omega-3 Products In Ethyl Ester Or Re-Esterified Triglyceride Form, DN 3247									
Doc Title:	2nd Postponement Letter									
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625575 (1 File)	Comments/Response to Comments		337-3247	Violation	Public	10/13/2017 08:57 AM	Jeffrey M. Telep	King and Spalding	Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Ltd.	100%
Inv Title:	Certain Synthetically Produced, Predominantly EPA Omega-3 Products In Ethyl Ester Or Re-Esterified Triglyceride Form, DN 3247									
Doc Title:	Amarin's Response to FDA's October 6, 2017 Submission									
Show Excerpt [+] :										
625038 (1 File)	Action Request		337-3247	Violation	Public	10/06/2017 03:35 PM	Rebecca Wood	U.S. Food and Drug Administration	U.S. Food and Drug Administration	100%
Inv Title:	Certain Synthetically Produced, Predominantly EPA Omega-3 Products In Ethyl Ester Or Re-Esterified Triglyceride Form, DN 3247									
Doc Title:	U.S. Food and Drug Administration's Request to Not Institute									
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624510 (1 File)	Voting Sheet		337-3247	Violation	Public	10/03/2017 09:23 AM	Lisa R. Barton	USITC	Office of the Secretary	100%
Inv Title:	Certain Synthetically Produced, Predominantly EPA Omega-3 Products In Ethyl Ester Or Re-Esterified Triglyceride Form, DN 3247									
Doc Title:										
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624188 (1 File)	Correspondence - USITC		337-3247	Violation	Public	09/28/2017 02:07 PM	Lisa R. Barton	USITC	Office of the Secretary	100%
Inv Title:	Certain Synthetically Produced, Predominantly EPA Omega-3 Products In Ethyl Ester Or Re-Esterified Triglyceride Form, DN 3247									
Doc Title:	Granting Request to Reply to Request Not to Institute									
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623759 (1 File)	Correspondence - USITC		337-3247	Violation	Public	09/25/2017 04:02 PM	Lisa R. Barton	USITC	Office of the Secretary	100%
Inv Title:	Certain Synthetically Produced, Predominantly EPA Omega-3 Products In Ethyl Ester Or Re-Esterified Triglyceride Form, DN 3247									
Doc Title:	Postponement Letter to Jeffrey M. Telep, Esq. of King & Spalding LLP									
Show Excerpt [+] :										
623705 (1 File)	Other		337-3247	Violation	Public	09/25/2017 10:08 AM	Jeffrey M. Telep	King and Spalding	Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Ltd.	100%
Inv Title:	Certain Synthetically Produced, Predominantly EPA Omega-3 Products In Ethyl Ester Or Re-Esterified Triglyceride Form, DN 3247									
Doc Title:	Complainant's Reply Brief on Jurisdiction									
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623534 (2 Files)	Complaint		337-3247	Violation	Public	09/21/2017 04:49 PM	Jeffrey M. Telep	King and Spalding	Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Ltd.	100%
Inv Title:	Certain Synthetically Produced, Predominantly EPA Omega-3 Products In Ethyl Ester Or Re-Esterified Triglyceride Form, DN 3247									
Doc Title:	Amended Exhibit 70 to the Complaint									
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623533 (2 Files)	Complaint		337-3247	Violation	Confidential	09/21/2017 04:49 PM	Jeffrey M. Telep	King and Spalding	Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Ltd.	100%
Inv Title:	Certain Synthetically Produced, Predominantly EPA Omega-3 Products In Ethyl Ester Or Re-Esterified Triglyceride Form, DN 3247									
Doc Title:	Amended Exhibit 70 to the Complaint									
Show Excerpt [+] :										
623336 (2 Files)	Action Request		337-3247	Violation	Public	09/18/2017 04:46 PM	Jordan L. Coyle	Orrick, Herrington & Sutcliffe LLP	Respondents Royal DSM NV, DSM Marine Lipids Peru S.A.C., DSM Nutritional Products LLC, DSM Nutritional Products Canada, Inc., and Pharmavite LLC	100%
Inv Title:	Certain Synthetically Produced, Predominantly EPA Omega-3 Products In Ethyl Ester Or Re-Esterified Triglyceride Form, DN 3247									
Doc Title:	Request Not to Institute and Brief on Jurisdiction of Respondents DSM and Pharmavite									
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623313 (1 File)	Comments/Response to Comments		337-3247	Violation	Public	09/18/2017 02:53 PM	Jeffrey M. Telep	King and Spalding	Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Ltd.	100%
Inv Title:	Certain Synthetically Produced, Predominantly EPA Omega-3 Products In Ethyl Ester Or Re-Esterified Triglyceride Form, DN 3247									
Doc Title:	Complainant's Reply Comments on the Public Interest									
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623140 (1 File)	Comments/Response to Comments		337-3247	Violation	Public	09/14/2017 05:11 PM	Deanna Tanner Okun	Adduci, Mastriani and Schaumberg	Council for Responsible Nutrition	100%
Inv Title:	Certain Synthetically Produced, Predominantly EPA Omega-3 Products In Ethyl Ester Or Re-Esterified Triglyceride Form, DN 3247									
Doc Title:	Council for Responsible Nutrition Public Interest Comments									
Show Excerpt [+] :										

623138 (1 File)	Comments/Response to Comments		337-3247	Violation	Public	09/14/2017 05:09 PM	Andrew F. Pratt	Venable LLP	Nordic Naturals and Nordic Pharma, Inc.	100%
Inv Title:	Certain Synthetically Produced, Predominantly EPA Omega-3 Products In Ethyl Ester Or Re-Esterified Triglyceride Form, DN 3247									
Doc Title:	Response to Commission's Request for Comments on Public Interest									
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623134 (1 File)	Comments/Response to Comments		337-3247	Violation	Public	09/14/2017 04:59 PM	Jay Sirois	Consumer Healthcare Products Association	Consumer Healthcare Products Association	100%
Inv Title:	Certain Synthetically Produced, Predominantly EPA Omega-3 Products In Ethyl Ester Or Re-Esterified Triglyceride Form, DN 3247									
Doc Title:	Statement of The Consumer Healthcare Products Association on Solicitation of Public Interest									
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623113 (1 File)	Action Request		337-3247	Violation	Public	09/14/2017 04:13 PM	Joseph Cwik	Amin Talati Upadhye LLP	Global Organization for EPA and DHA Omega	100%
Inv Title:	Certain Synthetically Produced, Predominantly EPA Omega-3 Products In Ethyl Ester Or Re-Esterified Triglyceride Form, DN 3247									
Doc Title:	Letter to Chairman Rhonda K. Schmidtlein in Support of Request Not to Institute									
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623111 (1 File)	Comments/Response to Comments		337-3247	Violation	Public	09/14/2017 04:12 PM	Joseph Cwik	Amin Talati Upadhye LLP	Global Organization for EPA and DHA Omega	100%
Inv Title:	Certain Synthetically Produced, Predominantly EPA Omega-3 Products In Ethyl Ester Or Re-Esterified Triglyceride Form, DN 3247									
Doc Title:	Global Organization for EPA and DHA Omega Public Interest Statement									
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623099 (1 File)	Comments/Response to Comments		337-3247	Violation	Public	09/14/2017 04:02 PM	Jordan L. Coyle	Orrick, Herrington & Sutcliffe LLP	Royal DSM NV, DSM Marine Lipids Peru S.A.C., DSM Nutritional Products LLC, DSM Nutritional Products Canada, Inc., and Pharmavite LLC	100%
Inv Title:	Certain Synthetically Produced, Predominantly EPA Omega-3 Products In Ethyl Ester Or Re-Esterified Triglyceride Form, DN 3247									
Doc Title:	Statement of Respondents DSM and Pharmavite Concerning the Public Interest									
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623080 (2 Files)	Action Request		337-3247	Violation	Public	09/14/2017 02:57 PM	Deanna Tanner Okun	Adduci, Mastriani and Schaumberg	Council for Responsible Nutrition	100%
Inv Title:	Certain Synthetically Produced, Predominantly EPA Omega-3 Products In Ethyl Ester Or Re-Esterified Triglyceride Form, DN 3247									
Doc Title:	Letter to Chairman Rhonda K. Schmidtlein Requesting the Complaint Not Be Instituted									
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623041 (1 File)	Comments/Response to Comments		337-3247	Violation	Public	09/14/2017 12:38 PM	Jennifer Hale	Jennifer Hale	Hale Oswick Family and Friends	100%
Inv Title:	Certain Synthetically Produced, Predominantly EPA Omega-3 Products In Ethyl Ester Or Re-Esterified Triglyceride Form, DN 3247									
Doc Title:	Public Interest Comments									
Show Excerpt [+] :										
623031 (7 Files)	Complaint		337-3247	Violation	Confidential	09/14/2017 11:44 AM	Jeffrey M. Telep	King & Spalding	Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Ltd.	100%
Inv Title:	Certain Synthetically Produced, Predominantly EPA Omega-3 Products In Ethyl Ester Or Re-Esterified Triglyceride Form, DN 3247									
Doc Title:	Supplemental Letter with Revised Confidential Exhibits									
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623030 (27 Files)	Complaint		337-3247	Violation	Public	09/14/2017 11:44 AM	Jeffrey M. Telep	King & Spalding	Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Ltd.	100%
Inv Title:	Certain Synthetically Produced, Predominantly EPA Omega-3 Products In Ethyl Ester Or Re-Esterified Triglyceride Form, DN 3247									
Doc Title:	Supplemental Letter with Revised Public Exhibits									
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622365 (1 File)	Notice		337-3247	Violation	Public	09/06/2017 05:00 PM	Lisa A. Barton	USITC	Office of the Secretary	100%
Inv Title:	Certain Synthetically Produced, Predominantly EPA Omega-3 Products In Ethyl Ester Or Re-Esterified Triglyceride Form, DN 3247									
Doc Title:	F.R. Notice of Receipt of Complaint; Solicitation of Comments Relating to the Public Interest									
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621633 (1 File)	Notice		337-3247	Violation	Public	08/30/2017 02:16 PM	Lisa R. Barton	USITC	Office of the Secretary	100%
Inv Title:	Certain Synthetically Produced, Predominantly EPA Omega-3 Products In Ethyl Ester Or Re-Esterified Triglyceride Form, DN 3247									
Doc Title:	Notice of Receipt of Complaint; Solicitation of Comments Relating to the Public Interest									
Show Excerpt [+] :										
621611 (36 Files)	Complaint		337-3247	Violation	Public	08/30/2017 11:39 AM	Jeffrey M. Telep	King and Spalding	Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Ltd.	100%
Inv Title:	Certain Synthetically Produced, Predominantly EPA Omega-3 Products In Ethyl Ester Or Re-Esterified Triglyceride Form, DN 3247									
Doc Title:	Complaint and Exhibits									
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621610 (9 Files)	Complaint		337-3247	Violation	Confidential	08/30/2017 11:39 AM	Jeffrey M. Telep	King and Spalding	Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Ltd.	100%
Inv Title:	Certain Synthetically Produced, Predominantly EPA Omega-3 Products In Ethyl Ester Or Re-Esterified Triglyceride Form, DN 3247									
Doc Title:	Confidential Exhibits									
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August 30, 3017

The Honorable Lisa R. Barton
Secretary
U.S. International Trade Commission
500 E Street, SW, Room 112A
Washington, DC 20436

Re: In the Matter of Certain Synthetically Produced, Predominantly EPA Omega-3 Products In Ethyl Ester Or Re-esterified Triglyceride Form

Dear Madam Secretary:

Enclosed for filing, please find documents in support of a request by Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Ltd. ("Complainants") that the U.S. International Trade Commission institute an investigation pursuant to Section 337 of the Tariff Act of 1930, as amended, concerning certain synthetically produced, predominantly EPA omega-3 products in ethyl ester or re-esterified triglyceride form. Complainants' submission includes the following documents.

1. One (1) original and eight (8) copies of the Verified non-confidential Complaint and Public Interest Statement pursuant to 19 C.F.R. §§ 210.4(f)(2), 210.8(a)(1)(i) and 210.8(b);

2. One (1) CD containing a copy of the non-confidential exhibits to the Verified Complaint pursuant to 19 C.F.R. §§ 210.8(a)(1)(i) and 210.4(f)(2);

3. One (1) CD containing a copy of the confidential exhibits to the Verified Complaint pursuant to 19 C.F.R. §§ 201.6(c) and 210.8(a)(1)(ii);

4. One (1) additional copy each – eighteen (18) additional copies total – of the Verified Complaint, the Public Interest Statement and accompanying electronic copies of the public exhibits, for service upon Proposed Respondents, pursuant to 19 C.F.R. §§ 210.6(c), 210.8(a)(1)(iii) and 210.8(b); and one (1) additional copy each – eighteen (18) additional copies total – of electronic copies of the confidential exhibits to the Verified Complaint for service upon Proposed Respondents' counsel after they have subscribed to the protective order;

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5. One (1) additional hard copy of the Verified Complaint and Public Interest Statement for the Embassies of Canada, the People's Republic of China, the Kingdom of the Netherlands, Peru, Norway, Chile and the United Kingdom – seven (7) additional copies total - pursuant to 19 C.F.R. §§ 210.8(a)(1)(iv) and 210.8(b); and

6. A letter and certification requesting confidential treatment for the information contained in Confidential Exhibits Nos. 23, 24, 70, 78, and 79.

Thank you for your assistance in this matter. Please contact me if you have any questions about this submission.

Respectfully submitted,

Jeffrey M. Telep
Lisa M. Dwyer
David J. Farber
Kevin M. Dinan
Patrick J. Togni
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Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Ltd.

Enclosures

30714986

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August 30, 2017

The Honorable Lisa R. Barton
Secretary
U.S. International Trade Commission
500 E Street, SW, Room 112A
Washington, DC 20436

Re: In the Matter of Certain Synthetically Produced, Predominantly EPA Omega-3 Products In Ethyl Ester Or Re-esterified Triglyceride Form/Request for Confidential Treatment

Dear Madam Secretary:

Pursuant to 19 C.F.R. § 201.6, Complainants Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Ltd. (collectively, "Complainants"), who are currently filing a Complaint pursuant to Section 337 of the Tariff Act of 1930, as amended, respectfully request confidential treatment of certain confidential business information contained in Confidential Exhibits Nos. 23, 24, 70, 78, and 79 to the Verified Complaint.

The information in these Confidential Exhibits for which Complainants seek confidential treatment consists of proprietary commercial secrets, including:

1. Proprietary commercial information regarding domestic industry expenses, various commercial agreements between Amarin and its suppliers, and proprietary prescription drug costs (Exhibit 23);

2. Proprietary commercial information about prescription drug costs (Exhibit 24);

3. Proprietary commercial information regarding Amarin's production volumes and inventories (Exhibit 70);

4. Proprietary commercial information regarding market research (Exhibit 78); and

5. Proprietary commercial information regarding market research (Exhibit 79).

The business information for which confidential treatment is sought consists of proprietary commercial and technical information that is not otherwise publicly available. The information described herein qualifies as confidential business information pursuant to 19 C.F.R.

§ 201.6(a) because: (1) it is not available to the general public; (2) unauthorized disclosure of such information could cause substantial harm to the competitive position of Complainants; and (3) disclosure of the information could impair the Commission's ability to obtain information necessary to perform its statutory function.

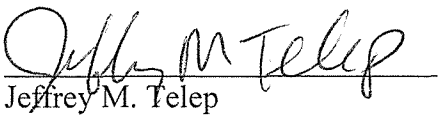
In accordance with 19 C.F.R. § 201.6(b)(iv), copies of Confidential Exhibits Nos. 23, 24, 70, 78, and 79 are enclosed with an indication on the cover that these exhibits are confidential. There are no non-confidential versions of Exhibits Nos. 24, 78, and 79, as confidential information is located throughout these exhibits. Non-Confidential versions of Exhibits 23 and 70 are being provided.

For good cause shown, I respectfully request confidential treatment of Confidential Exhibits Nos. 23, 24, 70, 78, and 79 in support of the Complaint. Please contact me if you have any questions about this request or if this request is not granted in full.

By my signature below, I certify that the confidential business information in Confidential Exhibits Nos. 23, 24, 70, 78, and 79 or substantially identical information is not reasonably available to the public and warrants confidential treatment under Commission Rule 201.6.

Thank you for your assistance in this matter. Please contact me if you have any questions about this submission.

Respectfully submitted,



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Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Ltd.

Enclosures

UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, D.C.

In the Matter of	)	
	)	
Certain Synthetically Produced, Predominantly EPA Omega-3 Products In Ethyl Ester Or Re-esterified Triglyceride Form	)	**Investigation No. 337-TA- ___**
	)	
	)	
	)	
	)	

CERTIFICATION

I, Jeffrey M. Telep, counsel for Complainants Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Ltd. (collectively, "Complainants"), declare:

1. I am duly authorized by Complainants to execute this certification.

2. I have reviewed Confidential Exhibits 23, 24, 70, 78, and 79 to Complainants' Verified Complaint, for which Complainants seek confidential treatment.

3. To the best of my knowledge, information, and belief, founded after a reasonable inquiry, substantially identical information that is contained in the Confidential Exhibits is not available to the public.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this 30th day of August, 2017 in Washington, District of Columbia.

Respectfully submitted,

Jeffrey M. Telep

Jeffrey M. Telep
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Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Ltd.

UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, D.C.

In the Matter of	)	
	)	
Certain Synthetically Produced, Predominantly EPA Omega-3 Products In Ethyl Ester Or Re-esterified Triglyceride Form	)	**Investigation No. 337-TA- ___**

COMPLAINANTS' STATEMENT ON THE PUBLIC INTEREST

Respectfully submitted,

Jeffrey M. Telep
Lisa M. Dwyer
David J. Farber
Kevin M. Dinan
Patrick J. Togni
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Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Ltd.

August 30, 2017

31044332

Pursuant to Commission Rule 210.8(b), Complainants, Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Ltd. (collectively "Amarin"), submit this Statement on the Public Interest regarding the remedial orders they seek against the Proposed Respondents' importing and selling certain synthetically produced, predominantly EPA omega-3 products in ethyl ester or re-esterified triglyceride form that are falsely labeled and/or promoted for use in, or as "dietary supplements," when they are actually illegal unapproved "new drugs" under the Federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 321 *et seq.* This false labeling and/or promotion constitutes an unfair method of competition or an unfair act under Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337 ("Section 337") because it violates the Lanham Act, 15 U.S.C. § 1125(a), and the standards established by the FDCA.

The large majority of omega-3 products that are imported or sold in the United States are legally marketed "dietary supplements" comprised of common fish oil and are not subject to this investigation. Common fish oil typically includes a mixture of saturated and unsaturated fats, including a variety of omega fatty acids in their natural triglyceride ("nTG-OM3") form. The products at issue here contain purified eicosapentaenoic acid ("EPA") or omega-3 fatty acid mixtures (that are predominantly EPA) in the ethyl ester form (respectively, "E-EPA" and "E-OM3") or in the re-esterified form (respectively, "rTG-EPA" and "rTG-OM3") (collectively, "Synthetically Produced Omega-3 Products"). Chemical synthesis enables higher EPA concentration and potency and removal of unwanted components, like saturated fat.

Amarin developed Vascepa®, a prescription drug that lists purified E-EPA as its active ingredient – legally – by investing the necessary resources to conduct clinical trials to show that the drug is safe and effective. Vascepa® is approved by the Food and Drug Administration ("FDA") for use as an adjunct to diet to reduce triglyceride levels in adult patients with severe

hypertriglyceridemia. Although Vascepa® is the only FDA-approved drug that contains purified E-EPA, FDA has approved branded and generic drugs that contain E-OM3, for the same use.

As explained in the Complaint, since the launch of these FDA-approved drugs, products that contain E-EPA or E-OM3, or chemically modified versions of those active ingredients, rTG-EPA or rTG-OM3, have increasingly been falsely labeled or promoted for use in, or as "dietary supplements" – even though they are illegal unapproved "new drugs." This constitutes an unfair trade practice or unfair method of competition because such false statements have the capacity to deceive a substantial segment of potential consumers, and that deception is material to purchasing decisions, in violation of Section 43(a) of the Lanham Act. False labeling and/or promotion also misbrands the products in violation of the standards set forth in Section 502 of the FDCA. 21 U.S.C. § 352(f), (n).

In addition, the false labeling and/or promotion of Synthetically Produced Omega-3 Products as "dietary supplements" enables the Proposed Respondents to avoid the drug approval process and the associated time and investment necessary to conduct clinical trials to show that their products are safe and effective for each intended use, *see* 21 U.S.C. § 355. And, by flouting the drug approval process, the Proposed Respondents are able to promote their products for a broader array of uses, *see id.*, and skirt prescription requirements as well, *see id.* § 353(b). This is unfair to pharmaceutical companies who have invested the necessary resources to bring drugs to market – legally – and it disincentivizes future investment in drug development.

Investment in drug development in this area is critical to advance the public health. Amarin, for example, is currently conducting the REDUCE-IT cardiovascular outcomes trial, an 8,175-patient clinical trial, to evaluate whether treatment with Vascepa® will reduce major cardiovascular events in patients who, despite stabilized statin therapy, have elevated triglyceride

levels and other cardiovascular risk factors. If successful, the trial has the potential to significantly change the treatment paradigm for cardiovascular risk reduction, the leading cause of death in the United States. Indeed, as John Jenkins, M.D., the former Director of the Office of New Drugs, at FDA has observed, the data from REDUCE-IT will be of "significant public health value." *See* **Complaint, ¶ 215.**

I. Use Of The Synthetically Produced Omega-3 Products In The United States

The Synthetically Produced Omega-3 Products are intended to be used for the purposes in which they are promoted, namely to affect the structure or function of the body and/or to affect disease. *See* **Complaint, § VI.A.1**. Presumably, they are purchased and used for those purposes. Structure/function claims that have been made for these products include, for example: support cardiovascular health; promote healthy immune responses; provide mood support; promote joint flexibility; and support healthy brain function. ***Id.* § VII.** Further, many are intended to affect disease, as evidenced by claims comparing the products to FDA-approved drugs (21 C.F.R. § 101.93(g)(vi) (disease claims include comparison claims)), and statements such as, "bring your triglyceride levels down naturally," and "anti-inflammatory for soothing arthritis." *Id.*

The Synthetically Produced Omega-3 Products are sold through multiple channels of distribution, including at retail establishments, such as grocery stores, pharmacies, and big box stores, as well as over the Internet. Moreover, unlike Vascepa® and other E-EPA and E-OM3 drug products that have been proven to be safe and effective for their intended uses, the Synthetically Produced Omega-3 Products can be accessed without a prescription.

II. Public Health, Safety, Or Welfare Concerns Relating To The Requested Order

An exclusion order in this case will not raise any public health, safety, or welfare concerns. Rather, removal of the purported "dietary supplements" will further the public interest because

those products are actually drugs that evade FDA regulation. Absent such an exclusion order, Proposed Respondents will continue to operate outside of the FDCA's drug regime, which was established by Congress to protect and promote the public health. 21 U.S.C. § 393(b). These activities will undermine incentives to invest in drug development, as explained above, and they may more immediately affect the public health. As mentioned in the complaint, former-Attorney General Loretta Lynch has observed that "dietary supplements" are not reviewed by FDA "before they reach the store shelves," and those that are illegally marketed can – not only abuse consumer trust by promising "results that they can't deliver" – but also "endanger public health" by leading consumers to use them as a substitute of proven therapies they may need," among other things. *See* **Complaint, ¶ 18**.

III. Directly Competitive Articles That Could Replace The Products At Issue

As mentioned, FDA has approved Vascepa® for use as an adjunct to diet to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. Although Vascepa® is the only FDA-approved purified E-EPA product on the United States market, FDA has approved one branded drug and several generic drugs containing E-OM3 for the same use. If the purported "dietary supplements" are removed from the market, consumers who took those products could consult a healthcare professional to determine whether prescription drugs are appropriate. Fish oil would also remain available to supplement diet and support body structures or functions.

IV. Amarin And Third-Parties Have The Capacity To Replace The Volume Of Articles At Issue In A Commercially Reasonable Period Of Time

As mentioned in the complaint, Amarin has the capacity and/or inventory to supply through prescription the entire U.S. market demand for the purported "dietary supplements," in a commercially reasonable period of time, if necessary. *See* **Complaint, ¶ 229.** The demand for these products, however, also may shift to: (1) FDA-approved prescription drugs containing E-

OM3, and (2) legally marketed "dietary supplements" that contain common fish oil, where prescription drugs are not appropriate. We have no reason to believe that the manufacturers of these products could not increase production as necessary, in a commercially reasonable time.

V. Impact of the Requested Remedial Orders on Consumers

Amarin does not believe that the issuance of the requested remedial orders will adversely affect patient access to omega-3 products. Vascepa® is a low-cost drug from a consumer perspective. *See* **Complaint, ¶¶ 16, 237.** The monthly cost of Vascepa® is typically less than $200, and this cost is mostly covered by insurance plans. *Id.* In addition, the majority of patients covered by insurance who obtain prescriptions for Vascepa® pay a monthly co-pay charge of $9.99 or less. *Id.* In fact, a consumer with commercial insurance can pay as little as $9.00 for a 90-day supply prescription of Vascepa®. *Id.* Therefore, patients who need drugs to reduce triglyceride levels will still be able to access Vascepa®, or drugs containing E-OM3, including generics. Common fish oil would also remain available to supplement the diet or support certain structures or functions of the body.

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Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Ltd.

UNITED STATES INTERNATIONAL TRADE COMMISSION

In The Matter Of	)	
	)	
Certain Synthetically Produced, Predominantly EPA Omega-3 Products In Ethyl Ester Or Re-esterified Triglyceride Form	)	**Investigation No. 337-TA- ___**

VERIFIED COMPLAINT UNDER SECTION 337 OF THE TARIFF ACT OF 1930, AS AMENDED

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TABLE OF CONTENTS

I. INTRODUCTION....1

II. COMPLAINANTS....12

III. PROPOSED RESPONDENTS....13

A. Manufacturers/Importers....13

B. Distributors....15

IV. THE PRODUCTS AT ISSUE....16

V. JURISDICTION....23

VI. UNLAWFUL AND UNFAIR ACTS OF PROPOSED RESPONDENTS....23

A. Proposed Respondents' Importation And Sale Of The Synthetically Produced Omega-3 Products Violate The Lanham Act....23

1. Proposed respondents are making false statements about the Synthetically Produced Omega-3 Products by labeling and/or promoting them as "dietary supplements" when they are actually unapproved "new drugs"....25

a. The Synthetically Produced Omega-3 Products cannot meet the definition of "dietary supplement" in the FDCA....26

i. The Synthetically Produced Omega-3 Products do not meet the definition of "dietary supplement" because they do not bear or contain a "dietary ingredient"....26

a) The Synthetically Produced Omega-3 Products do not fall under subsection 201(ff)(1)(E) of the "dietary ingredient" definition....27

b) The Synthetically Produced Omega-3 Products do not fall under subsection 201(ff)(1)(F) of the "dietary ingredient" definition....31

ii. Certain Synthetically Produced Omega-3 Products are excluded from the definition of "dietary supplement" under the exclusionary clause contained in subsection 321(ff)(3)(B) of the FDCA....32

b. Synthetically Produced Omega-3 Products are actually unapproved "new drugs" under the FDCA 39

i. All of the Synthetically Produced Omega-3 Products meet the definition of "drug" in the FDCA 43

a) Encapsulated E-OM3 43

b) E-OM3 in Oil Form 45

c) E-EPA, rTG-EPA, and rTG-OM3, as well as other forms of E-OM3 46

ii. All of the Synthetically Produced Omega-3 Products are unapproved "new drugs" 46

2. The other elements for false advertising and contributory false advertising under the Lanham Act are met 47

B. Proposed Respondents' Importation And Sale Of The Synthetically Produced Omega-3 Products Violate Section 337 Based On The Standards Set Forth In The FDCA 48

VII. INSTANCES OF UNFAIR IMPORTATION AND SALE 52

A. Manufacturers 52

B. Distributor Respondents 72

VIII. CLASSIFICATION OF THE RESPONDENTS' PRODUCTS UNDER THE HARMONIZED TARIFF SCHEDULE 91

IX. RELATED LITIGATION 91

X. DOMESTIC INDUSTRY 92

XI. SUBSTANTIAL INJURY 95

A. Damage To The Vascepa® Brand 96

B. Lost Sales And Market Share 98

C. Lost Profits And Price Erosion 100

XII. RELIEF 103

I. INTRODUCTION

1. Amarin Pharma, Inc. ("Amarin Pharma") and Amarin Pharmaceuticals Ireland Ltd. ("Amarin Ireland") (collectively, "Amarin" or "Complainants") file this Complaint pursuant to Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337 ("Section 337"). Amarin manufactures and markets Vascepa® capsules, a drug approved by the Food and Drug Administration ("FDA") consisting of 1 gram of eicosapentaenoic acid (the omega-3 acid commonly known as "EPA") in a 1-gram capsule. The EPA in Vascepa® is in ethyl ester form and is synthetically produced. Amarin respectfully requests that the U.S. International Trade Commission (the "ITC" or "Commission") commence an investigation into the unlawful importation or sale in the United States of synthetically produced omega-3 products that are predominantly comprised of EPA in either ethyl ester ("EE") or re-esterified ("rTG") form and are falsely labeled, and/or promoted for use as, or in "dietary supplements" (the "Synthetically Produced Omega-3 Products" (as defined with more particularity in paragraph 8, below)). **Exhibits 1-12.** These products are cloaked as "dietary supplements" but are actually unapproved "new drugs" under the Federal Food, Drug and Cosmetic Act ("FDCA"). The false labeling or promotion of these products constitutes an unfair act and/or unfair method of competition under Section 337 because, among other things, these acts violate Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), and the standards established by the FDCA.

2. A large majority of omega-3 products that are imported or sold in the United States are legally marketed "dietary supplements" comprised of common fish oil. *See* Global Organization for EPA and DHA Omega-3s ("GOED") Blog, June 5, 2014, (noting that, for example, "[e]thyl esters represented 12% of the US dietary supplement market in 2013"), **Exhibit 13**. Common fish oil typically includes a mixture of saturated and unsaturated fats,

including a variety of omega fatty acids in their natural triglyceride ("nTG") form. *See* R. Preston Mason and Samuel C.R. Sherratt, Omega-3 fatty acid fish oil dietary supplements contain saturated fats and oxidized lipids that may interfere with their intended biological benefits, Biochemical and Biophysical Research Communications (2016), **Exhibit 14**. Common fish oil is not synthetically produced. Amarin is not alleging that the import or sale in the United States of common fish oil, *i.e.,* for use in, or as "dietary supplements," violates Section 337, or other U.S. laws *per se*, and Amarin is not requesting an investigation into the import or sale of those natural products. Nor is Amarin requesting an investigation into synthetically produced omega-3 products in EE or rTG form that are not predominantly comprised of the omega-3 acid, EPA.

3. The Synthetically Produced Omega-3 Products are being sold in the United States as ingredients for finished products, and as finished products themselves. Certain of the Proposed Respondents are selling synthetically produced omega-3 oil, or encapsulated synthetically produced omega-3 oil, *for use in or as* finished products marketed as "dietary supplements"– namely:

- Royal DSM NV ("DSM NV"), **Exhibit 1**;
- DSM Marine Lipids Peru S.A.C. ("DSM-Peru"), **Exhibit 1**;
- DSM Nutritional Products LLC in the United States ("DSM-US"), **Exhibit 1**;
- DSM Nutritional Products Canada Inc., ("DSM-Canada"), **Exhibit 1**;
- Ultimate Biopharma Corp. ("Ultimate"), **Exhibit 2**;
- Marine Ingredients AS, **Exhibit 3**;
- Marine Ingredients LLC, **Exhibit 3**;

- Golden Omega S.A., **Exhibit 4**;
- Golden Omega USA LLC, **Exhibit 4**;
- Nordic Pharma Inc., **Exhibit 5**;
- Croda Europe Ltd., **Exhibit 6**;
- Croda, Inc., **Exhibit 6**; and
- Technologica de Alimentos S.A., **Exhibit 7**

(collectively the "Manufacturers").

4. The other Proposed Respondents are selling finished products containing synthetically produced omega-3 oil *as* "dietary supplements" directly to consumers – namely:

- The Nature's Bounty Co. ("Nature's Bounty"), **Exhibit 8**;
- Nordic Naturals, **Exhibit 9**;
- Pharmavite LLC, **Exhibit 10**;
- Innovix Pharma Inc. ("Innovix Pharma"), **Exhibit 11**; and
- J. R. Carlson Laboratories ("Carlson"), **Exhibit 12**

(collectively, the "Distributors").

5. The Synthetically Produced Omega-3 Products, like Vascepa®, are derived from common fish oil. Common fish oil includes omega-3 fatty acids in their natural triglyceride form ("nTG-OM3"), such as EPA (eicosapentaenoic acid) in its natural triglyceride form ("nTG-EPA") and docosahexaenoic acid ("DHA") in its natural triglyceride form ("nTG-DHA"). Although the Synthetically Produced Omega-3 Products are derived from common fish oil, they are not the same as common fish oil. As discussed in more detail in paragraphs 42-51, typically,

common fish oil is extracted from oily fish by using physical, not chemical processes, such that no chemical bonds are broken or created.

6. Depending upon the fish from which the oil was extracted and the environmental conditions in which the fish were raised, the ratio of nTG-EPA and nTG-DHA can differ. However, typically, 30% of common fish oil by weight is nTG omega-3 fatty acids, or nTG-OM3. The remaining 70% of the oil has other constituents, most predominantly, saturated fat, other omega-3 fatty acids, and omega-6 and omega-9 fatty acids. *See* Figure 1 (below).

Figure 1. Leading Common Fish Oil Supplement with 30% nTG-OM3*

See* R. Preston Mason and Samuel C.R. Sherratt, Omega-3 fatty acid fish oil dietary supplements contain saturated fats and oxidized lipids that may interfere with their intended biological benefits, Biochemical and Biophysical Research Communications (2016), 1-5. **Exhibit 14.

7. It is not possible to produce natural marine oil with a collective concentration of nTG-EPA and nTG-DHA that is greater than approximately 30% by weight of the oil. Oils with a higher collective concentration of EPA and DHA must be chemically synthesized, *i.e.*, synthetically produced. Many of the Synthetically Produced Omega-3 Products are chemically altered to deliver heightened levels of EPA and/or DHA – well beyond the levels that are found

in nature, *see, e.g.,* **Exhibits 8-I, 9-T, 9-V, 11-A, 12-D**. Some are also chemically altered to remove less valuable or unwanted components of common fish oil, such as saturated fat. *See* Figure 2 (below).

8. Common molecular forms and mixtures of Synthetically Produced Omega-3 Products include the following:

(i) purified EPA in its ethyl ester form ("E-EPA"),

(ii) purified EPA in its re-esterified form ("rTG-EPA"),

(iii) omega-3 mixtures in their ethyl ester form ("E-OM3"), and

(ii) omega-3 mixtures in their re-esterified form ("rTG-OM3").

Amarin believes that all of the Synthetically Produced Omega-3 Products identified in this complaint contain E-EPA, rTG-EPA, E-OM3 (where E-EPA is the predominant component), or rTG-OM3 (where rTG-EPA is the predominant component). **Exhibits 8-A – 12-M**[1]; *see also* Section VII.

9. To synthesize omega-3 fatty acid mixtures, or their EPA or DHA components, from their natural triglyceride form into their ethyl ester form, the natural triglyceride molecules undergo chemical reactions. First, the glycerol backbone of each triglyceride molecule in the common fish oil is removed. Second, the resulting free fatty acids are reacted with ethanol through a process known as esterification. This ethyl ester form allows for the substantial heightening of the level of the E-EPA and/or E-DHA in the synthetically produced oil. The

[1] Throughout this document, when a range of exhibits is given, it refers to all like subparts within the given range, unless otherwise noted.

manufacturer can choose which fatty acid levels to heighten, and either to manipulate the ratio of E-EPA to E-DHA or to purify the product into E-EPA or E-DHA.

10. The differences between the complex mixture of multiple constituents that comprise common fish oil products and the various pharmacologically designed and chemically synthesized products is illustrated by comparing Figure 1 (above) to Figure 2 (below).

Figure 2. Vascepa® (Purified E-EPA)*

*Vascepa® Full Prescribing Information, **Exhibit 15** (reflecting that FDA has labeled Vascepa® 1 gram capsules as containing 1 gram of E-EPA. The capsules also contain trace amounts of inactive ingredients including, tocopherol, an anti-oxidation agent designed to protect the fragile active ingredient).

11. Vascepa®, the product highlighted in Figure 2, is the only drug approved by the FDA that contains purified E-EPA. *See* List of FDA-Approved Icosapent Ethyl (E-EPA) Drugs in Orange Book, **Exhibit 16** (icosapent ethyl is an alternate name for eicosapentaenoic acid in ethyl ester form). Vascepa® is manufactured and marketed by Amarin. There are also branded and generic FDA-approved drugs that contain omega-3 mixtures in their ethyl ester form (E-OM3). *See* List of FDA-Approved Omega-3 Ethyl Ester Drugs in the Orange Book, **Exhibit 17**. FDA has approved these drugs for use as an adjunct to diet to reduce triglyceride levels in adult

patients with severe hypertriglyceridemia. *See, e.g.*, Vascepa® Full Prescribing Information, **Exhibit 15**; Lovaza® Full Prescribing Information, **Exhibit 18**. Severe hypertriglyceridemia (too much fat in the blood) is a disease that can lead to inflammation of the pancreas, which can cause life-threatening complications. *See* Pancreatitis, Patient Care & Health Information, Mayo Clinic (accessed August 4, 2017), **Exhibit 19**. Severe hypertriglyceridemia can also raise or indicate increased risk of heart disease. *See* High Cholesterol-Medicines To Help You, FDA Website (accessed August 4, 2017) (noting that "[t]riglycerides are another form of fat in your blood that can raise your risk for heart disease"), **Exhibit 20.**

12. Since the launch of these FDA-approved drugs, companies have been increasingly falsely labeling and promoting products that contain chemically heightened levels of EPA as "dietary supplements." *See* Jennifer Grebow, Ultra-High Concentrates and the Next Omega-3, Supply Side West Report, Nutritional Outlook, Oct. 14, 2015, **Exhibit 21** ("Omega-3 suppliers . . . are now taking omega-3 concentrates for dietary supplements into near-pharmaceutical territory . . . . "); *see also* Hank Schultz, EPA-only nutraceuticals ride pharma's coattails into marketplace, NUTRA Ingredients-usa.com, Oct. 21, 2013, **Exhibit 22**. This recent free-riding is not surprising, and it is likely that it has occurred ever since E-EPA first gained recognition in the marketplace as a "drug" in the mid-1980s, as discussed in paragraphs 80-83.

13. The ethyl ester components of the FDA-approved drugs (*i.e.,* E-OM3, E-EPA, and E-DHA) can also be *further* chemically altered into the re-esterified triglyceride (rTG) form using enzymes in a chemical process called glycerolysis. Food-grade enzymes separate the ethanol molecule from the fatty acid, creating a free fatty acid ("FFA") molecule and a free ethanol molecule. When glycerol is reintroduced to the solution, the enzymes then re-esterify the

fatty acids back onto a glycerol backbone, creating re-esterified triglyceride (rTG) oil. The molecular distinctions between omega-3 fatty acids in their natural triglyceride forms (*e.g.,* nTG-OM3 and nTG-EPA), in their ethyl ester forms (*e.g.,* E-OM3 and E-EPA), and in their re-esterified forms (*e.g.,* rTG-OM3 and rTG-EPA) are further explained in paragraphs 49-50, and in Figure 3, in Section IV.

14. The Proposed Respondents are falsely labeling and/or promoting Synthetically Produced Omega-3 Products for use in, or as "dietary supplements." **Exhibits 1-B – 7-B, 8-A-ii – 12-M-ii**. As explained in paragraphs 58-105, labeling and/or promoting these products as "dietary supplements" is false because E-OM3, E-EPA, rTG-OM3, and rTG-EPA do not meet the definition of "dietary supplement" in the FDCA, 21 U.S.C. § 321(ff), and these products are actually unapproved "new drugs" under the FDCA. This false labeling and/or promotion of the Synthetically Produced Omega-3 Products constitute unfair trade practices or unfair methods of competition in violation of Section 337 because they deceive or have the capacity to deceive a substantial segment of potential consumers, and that deception is material to purchasing decisions in violation of Section 43(a) of the Lanham Act. False labeling and/or promotion also misbrands the products under the standards set forth in Section 502 of the FDCA. 21 U.S.C. § 352.

15. Moreover, such false labeling and/or promotion is unfair to Amarin and other pharmaceutical companies that have invested the necessary resources to bring competing drug products to market, and it serves as a disincentive for drug companies to invest resources in drug development in the future. In particular, falsely labeling and/or promoting products as "dietary supplements" enables the Proposed Respondents to avoid the drug approval process and the

associated time and investment necessary to conduct clinical trials to show that their products are safe and effective for each intended use and to obtain FDA approval for each intended use. *See* 21 U.S.C. § 355. Disregarding the FDA drug approval process also enables the Proposed Respondents to avoid the following: (i) limiting the indications for their products to those that have been approved by FDA, *see id.* § 355(a); (ii) applicable user fee costs associated with manufacturing drugs, *id.* § 379h; and (iii) applicable costs associated with complying with FDA's drug registration, *id.* § 360, listing, *id.*, and labeling and manufacturing requirements, *id.* §§ 502(f), 501(a)(2)(B). In addition, it allows the Distributors to avoid the need to sell their products pursuant to a prescription by a licensed healthcare professional, *see id.* § 353(b).

16. Amarin has a domestic industry. Amarin specializes in developing effective therapies, approved by FDA, to treat disease, with a focus on hypertriglyceridemia and cardiovascular disease. Amarin developed Vascepa®, a prescription drug that lists icosapent ethyl as the drug's active pharmaceutical ingredient ("API") – legally – by investing the necessary resources to conduct clinical trials to show that the drug is safe and effective. Amarin then obtained FDA approval for the drug. *See* List of FDA-Approved Icosapent Ethyl Drugs (E-EPA) in Orange Book, **Exhibit 16**. Icosapent ethyl, Vascepa®'s API, is the ethyl ester form of EPA, namely E-EPA. The FDA approved Vascepa® for use as an adjunct to diet to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. *See* Vascepa® Full Prescribing Information, **Exhibit 15**. Amarin markets and sells Vascepa® in the United States as a prescription drug. Vascepa® is the only FDA-approved purified E-EPA mixture on the United States market. *See* List of FDA-Approved Icosapent Ethyl Drugs (E-EPA) in Orange Book, **Exhibit 16**. Vascepa® is a low-cost drug from a consumer perspective. According to Amarin's

records, on average, the monthly cost of Vascepa® is typically less than $200, and this cost is mostly covered by insurance plans. **Exhibit 23**. In addition, the majority of patients covered by insurance who obtain prescriptions for Vascepa® pay a monthly co-pay charge of $9.99 or less. **Confidential Exhibit 24.** In fact, a consumer with commercial insurance can pay as little as $9.00 for a 90-day supply prescription of Vascepa®. **Exhibit 25.** Finally, Amarin makes substantial investments in encapsulation, packaging, logistics, sales and marketing, along with substantial investments in labor conducting clinical trials in support of Vascepa®. **Exhibit 23**.

17. The Synthetically Produced Omega-3 Products compete with Vascepa® and injure Amarin because, like Vascepa®, they are chemically modified to deliver heightened levels of EPA. **Exhibits 9-O, 9-V, 9-T, 11-A, 12-D**. Indeed, all the Synthetically Produced Omega-3 products in ethyl ester form (*i.e.*, E-OM3 and E-EPA) actually contain E-EPA – Vascepa's active ingredient. Moreover, the Synthetically Produced Omega-3 Products are often marketed and used to treat the same diseases for which Vascepa® has been, and is being, developed. *See* **Tables 1 and 2.** The Proposed Respondents' importation and sale of Synthetically Produced Omega-3 Products has injured and/or threatened Amarin with substantial injury by (i) damaging the Vascepa® brand by exploiting Vascepa®'s status as an FDA-approved drug, (ii) causing lost sales and market share to Vascepa, and (iii) diminishing profitability and eroding prices. Amarin also has the capacity and/or inventory to supply the entire U.S. market demand for the Synthetically Produced Omega-3 Products (and similarly situated products), and Proposed Respondents' unfair acts prevent Amarin from making these sales, as discussed in paragraphs 225-229.

18. Finally, because false labeling and promotion enables purported "dietary supplement" products to evade the drug approval process, it also endangers the public health. Indeed, former-Attorney General Lynch observed the following with regard to "dietary supplements":

> What many Americans don't know is that dietary supplements are *not* subject to testing [by FDA] before they reach the store shelves – meaning that every day, millions of Americans are ingesting substances whose safety and efficacy are not guaranteed. Some of these supplements are simply a waste of money, promising results that they can't deliver or advertising ingredients that they don't contain. And too often, these supplements don't just abuse consumer trust – they also endanger public health. Some contain harmful ingredients, causing consumers to fall ill. Others falsely claim to cure illness and disease, leading patients to use them as a substitute of proven therapies they may need. But whether these supplements are deceptive or dangerous, the fact remains that too many companies are making profits by misleading – and in some cases harming – American consumers.

Former-Attorney General Lynch Discusses Department's Efforts to Protect Consumers From Unsafe Dietary Supplements, Department of Justice, Office of Public Affairs, March 8, 2016 (emphasis added), **Exhibit 26**. Then-Attorney General Lynch's remarks were in reference to the Department of Justice's ("DOJ's") "dietary supplement" enforcement sweep in November 2015, which it conducted with the FDA and other federal partners. *See* Justice Department and Federal Partners Announce Enforcement Actions of Dietary Supplement Cases, Nov. 18, 2015, **Exhibit 27**.

19. Although Section 337 and the Lanham Act are both designed to protect commercial interests against unfair methods of competition by authorizing private parties to sue competitors – they can also indirectly protect the public, particularly where FDA and other government entities have not acted, or have not acted to the full extent of their authority. Given

the government's limited resources, it simply cannot pursue all deceptively labeled and deceptively promoted products.

20. Indeed, FDA has primary responsibility for policing the "labeling" of "dietary supplements" and the "labeling" and "advertising" of unapproved "new drugs." *See* Memorandum of Understanding Between the Federal Trade Commission and the Food and Drug Administration, 225-71-8003, Sept. 9, 1971, **Exhibit 28**; *see also* 21 U.S.C. § 321(m) (defining "labeling"); 21 C.F.R. § 202.1(l) (providing examples of "labeling" and "advertising"). Yet, according to a recent PBS "Frontline" documentary, produced in collaboration with *The New York Times*, FDA has only about 25 people in the division that oversees products positioned as "dietary supplements," and more than 85,000 of these products are sold each year. As reported in that program, "[FDA] target[s] companies they consider the most risky, but agree the problem remains much bigger than that." *See* Frontline: Supplements and Safety, PBS and *The New York Times*, **Exhibit 29**; *see also* Complainant's Brief On Jurisdiction, **Confidential Exhibit 30**.

II. COMPLAINANTS

21. Complainant Amarin Pharma is incorporated under the laws of Delaware with its primary office located at 1430 Route 206, Bedminster, NJ 07921. Amarin Pharma runs Amarin's United States operations, including sales, marketing, research and development, and regulatory affairs, among other things.

22. Complainant Amarin Ireland is organized under the laws of the Republic of Ireland with its principal offices at 2 Pembroke House, Upper Pembroke Street 28-32, Dublin 2 Ireland. Amarin Ireland is a biopharmaceutical company specializing in developing effective, approved therapies to improve cardiovascular health. Amarin Ireland and Amarin Pharma are

both wholly owned subsidiaries of Amarin Corporation plc, a public limited liability company organized under the laws of England and Wales.

23. Amarin developed Vascepa®, a prescription drug that lists icosapent ethyl as the drug's API. Icosapent ethyl is another name for E-EPA. Amarin Ireland is the holder of NDA No. 202057 for Vascepa® (icosapent ethyl) Capsules, for oral use. The FDA approved Vascepa® for use as an adjunct to diet to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. Amarin markets and sells Vascepa® in the United States as a prescription drug.

III. PROPOSED RESPONDENTS

A. Manufacturers/Importers

24. Proposed Respondent Royal DSM NV ("DSM NV") is a manufacturer of Synthetically Produced Omega-3 Products. DSM NV's headquarters are located at Het Overloon 1 6411 TE, Heerleen, The Netherlands.

25. Proposed Respondent DSM Marine Lipids Peru S.A.C. ("DSM-Peru") is a manufacturer of Synthetically Produced Omega-3 Products. DSM-Peru's headquarters are located at Calle Principal S/N Caserio la Legua, Catacaos Piura, Peru.

26. Proposed Respondent DSM Nutritional Products LLC ("DSM-US") is a manufacturer of Synthetically Produced Omega-3 Products. DSM-US's headquarters are located at 45 Waterview Blvd., Parsippany, NJ 07054.

27. Proposed Respondent DSM Nutritional Products Canada, Inc. ("DSM-Canada") is a manufacturer of Synthetically Produced Omega-3 Products. DSM-Canada is located at 105 Neptune Crescent, Dartmouth, NS B2Y4T6.

28. Proposed Respondent Ultimate Biopharma (Zhongshan) Corporation ("Ultimate") is a Chinese foreign joint venture limited company that manufactures softgel capsules containing Synthetically Produced Omega-3 Products. Ultimate's headquarters are located at 10 Jiankang Road, National Health Technology Park, Zhongshan, Guandong, People's Republic of China.

29. Proposed Respondent Marine Ingredients AS is a manufacturer of Synthetically Produced Omega-3 Products. Marine Ingredients AS's headquarters are located at Strandgata 60, 6270 Brattvag, Norway.

30. Proposed Respondent Marine Ingredients LLC is a U.S. importer of Synthetically Produced Omega-3 Products. Its headquarters are located at 794 Sunrise Blvd., Mt. Bethel, Pennsylvania 18343.

31. Proposed Respondent Golden Omega S.A. is a manufacturer of Synthetically Produced Omega-3 Products. Its headquarters are located at Avenida Apoquindo Ote. 5550, Piso 8, Las Condes, Santiago, Chile.

32. Proposed Respondent Golden Omega USA LLC is a U.S. importer of Synthetically Produced Omega-3 Products. Its headquarters are located at 65 Enterprise, Aliso Viejo, California, 92656.

33. Proposed Respondent Nordic Pharma, Inc. is a manufacturer of Synthetically Produced Omega-3 Products. Its headquarters are located at Ropnesveien 71, 9107 Kvaløya, Norway.

34. Proposed Respondent Croda Europe Ltd. is a manufacturer of Synthetically Produced Omega-3 Products. Its headquarters are located at Cowick Hall, Snaith Goole, East Yorkshire DN14 9AA, United Kingdom.

35. Proposed Respondent Croda Inc. is a U.S. importer of Synthetically Produced Omega-3 Products. Its headquarters are located at 300-A Columbus Circle, Edison, NJ 08837.

36. Proposed Respondent Tecnologica de Alimentos S.A. is a manufacturer of Synthetically Produced Omega-3 Products. Its headquarters are located at Las Begonias 441, Of. 352, San Isidro, Lima 27, Peru.

B. Distributors

37. Proposed Respondent The Nature's Bounty Co. ("Nature's Bounty"), is a U.S. distributor of imported Synthetically Produced Omega-3 Products. In 2010, a Nature's Bounty subsidiary acquired Ultimate. **Exhibit 2-E-ii**. Nature's Bounty's headquarters are located at 2100 Smithtown Avenue, Ronkonkoma, New York 11779.

38. Proposed Respondent Nordic Naturals, Inc. is a U.S. distributor of imported Synthetically Produced Omega-3 Products. Nordic Naturals' headquarters are located at 111 Jennings Drive, Watsonville, California 95076.

39. Proposed Respondent Pharmavite LLC is a U.S. distributor of Nature Made-branded imported Synthetically Produced Omega-3 Products. Its headquarters are located at 8510 Balboa Blvd. # 100, Northridge, California 91325.

40. Proposed Respondent Innovix Pharma Inc. is a U.S. distributor of OmegaVia-branded imported Synthetically Produced Omega-3 Products. Its headquarters are located at 26500 Agoura Road, Suite 102790, Calabasas, CA 91302.

41. Proposed Respondent J.R. Carlson Laboratories, Inc. is a U.S. distributor of imported Synthetically Produced Omega-3 Products. Its headquarters are located at 600 W. University Dr., Arlington Heights, Illinois, 60004.

IV. THE PRODUCTS AT ISSUE

42. The Proposed Respondents' Synthetically Produced Omega-3 Products that are the subject of this investigation contain derivatives of naturally occurring omega-3 fatty acids. Omega-3 fatty acids are a category of polyunsaturated fatty acids that include EPA and DHA. Omega-3 fatty acids are marketed, legally and illegally, in the United States in a number of different mixtures and molecular forms. Common mixtures and molecular forms include the following: (i) common fish oil (*i.e.,* a natural omega-3 mixture ("nTG-OM3")), (ii) purified EPA mixtures in their ethyl ester form ("E-EPA"), (iii) purified EPA mixtures in their re-esterified form ("rTG-EPA"), (iv) omega-3 mixtures in their ethyl ester form ("E-OM3"), and (v) omega-3 mixtures in their re-esterified form ("rTG-OM3"). Although common fish oil contains omega-3 fatty acids in their natural triglyceride form (nTG-OM3) – E-EPA, rTG-EPA, E-OM3, and rTG-OM3 are synthetically produced through processes involving a number of chemical reactions.

43. Upon information and belief, all of the Synthetically Produced Omega-3 Products identified in this complaint contain E-EPA, rTG-EPA, E-OM3 (where the predominant component is E-EPA) or rTG-OM3 (where the predominant component is rTG-EPA). **Exhibits 8-A – 12-M**; *see also* Section VII.

44. Omega-3 fatty acids are found in fish and are most prevalent in oily fish, such as salmon, tuna, lake trout, mackerel, menhaden, sardines, anchovies, and herring. Oil in these fatty acids can be extracted by: (1) cooking and pressing the fish to separate the water and oil from the proteins and solids, (2) removing the water from the oil, and (3) polishing the oil (*i.e.,* deacifying, degumming, and washing the oil several times). When this oil is used for human consumption, it is also bleached and deodorized. At this point, the nTG-OM3 has been extracted

from the fish through physical processes only – no chemical bonds have been broken or created. The resulting oil is common fish oil in nTG form, and depending upon the fish from which the oil was derived and the environmental conditions in which the fish were raised, the ratio of nTG-EPA and nTG-DHA can differ. Before it is sold, however, common fish oil is generally blended and standardized to contain approximately 180 mg of nTG-EPA and 120 mg of nTG-DHA per gram (1000 mg) of oil. Though the ratio of EPA to DHA may vary slightly, this oil is often referred to as 18:12 fish oil. The numbers 18:12 represent the approximate ratio of nTG-EPA to nTG-DHA by weight: 18% of the oil, by weight, is nTG-EPA; and 12% of the oil, by weight, is nTG-DHA (therefore, 30% of the oil, by weight is nTG omega-3 fatty acids). The remaining 70% of the oil has other constituents, typically, most predominantly, saturated fat, other omega-3 fatty acids, and omega-6 and omega-9 fatty acids. *See* Figure 1 (in Section I, and repeated below).

45. It is not possible to produce natural marine oil with a collective concentration of nTG-EPA and nTG-DHA that is greater than approximately 30% by weight of the oil. Oils with a higher concentration of EPA and DHA than approximately 30% must be chemically synthesized. Synthetic oils with higher concentrations of EPA and/or DHA that are available today are commonly in either the ethyl ester form or the re-esterified triglyceride form.

46. The first step in the process of synthesizing common fish oil to yield higher concentrations of EPA and DHA involves a chemical reaction wherein the glycerol backbone of each triglyceride molecule in the fish oil is removed, resulting in "free fatty acids" ("FFA"), including FFA-EPA and FFA-DHA, and a "free glycerol" molecule. The FFA-EPA and FFA-DHA are then chemically reacted with ethanol through a process known as esterification.

Esterification changes the fatty acids into ethyl ester form, such that FFA-EPA becomes E-EPA, and FFA-DHA becomes E-DHA.

47. The resulting ethyl ester form allows for substantial heightening of the level of the E-EPA or other components. The fatty acid level can be heightened using a number of different physical procedures, the two most common of which are molecular distillation and supercritical fluid technology. These technologies allow the manufacturer to choose which fatty acid levels to heighten, and to either manipulate the ratio of E-EPA to E-DHA or to purify the product into substantially only E-EPA.

48. Synthetically produced ethyl ester fatty acids, such as E-EPA, can also be chemically converted to the re-esterified triglyceride form using enzymes in a chemical process called glycerolysis. Food-grade enzymes separate the ethanol molecule from the fatty acid, creating a FFA and a free ethanol molecule. When glycerol is reintroduced to the solution, the enzymes then re-esterify the fatty acids back onto a glycerol backbone, creating re-esterified triglyceride (rTG) oil.

49. Omega-3 mixtures in their ethyl ester form, regardless of whether they are characterized as E-OM3 mixtures or more purified E-EPA or E-DHA mixtures, are different from omega-3 mixtures in their natural triglyceride, or nTG, form in a number of ways. For example, the ratio of EPA to DHA in ethyl ester mixtures is often significantly different from the ratio in naturally occurring (nTG) mixtures. In addition, the EPA and DHA levels in the ethyl ester mixtures typically are much higher than they are in natural mixtures. Also, the E-EPA and E-DHA molecules are chemically altered from the nTG-EPA and nTG-DHA molecules and become chemically distinct as a result of such alteration. These types of differences are material

because they can affect the efficacy and safety of the ethyl ester mixture, compared to the nTG mixture (*e.g.*, concentration can lead to greater efficacy and, for example, higher levels of DHA have been associated with certain unwanted effects, particularly in diseased patients with severely high levels of triglycerides in the blood). The differences between the complex mixture of multiple constituents that comprise common fish oil products and the pharmacologically designed highly pure synthesized E-EPA product, Vascepa®, are illustrated in Figures 1 and 2. The differences between the E-OM3 and nTG-OM3 molecules, and their components, are illustrated in Figure 3.

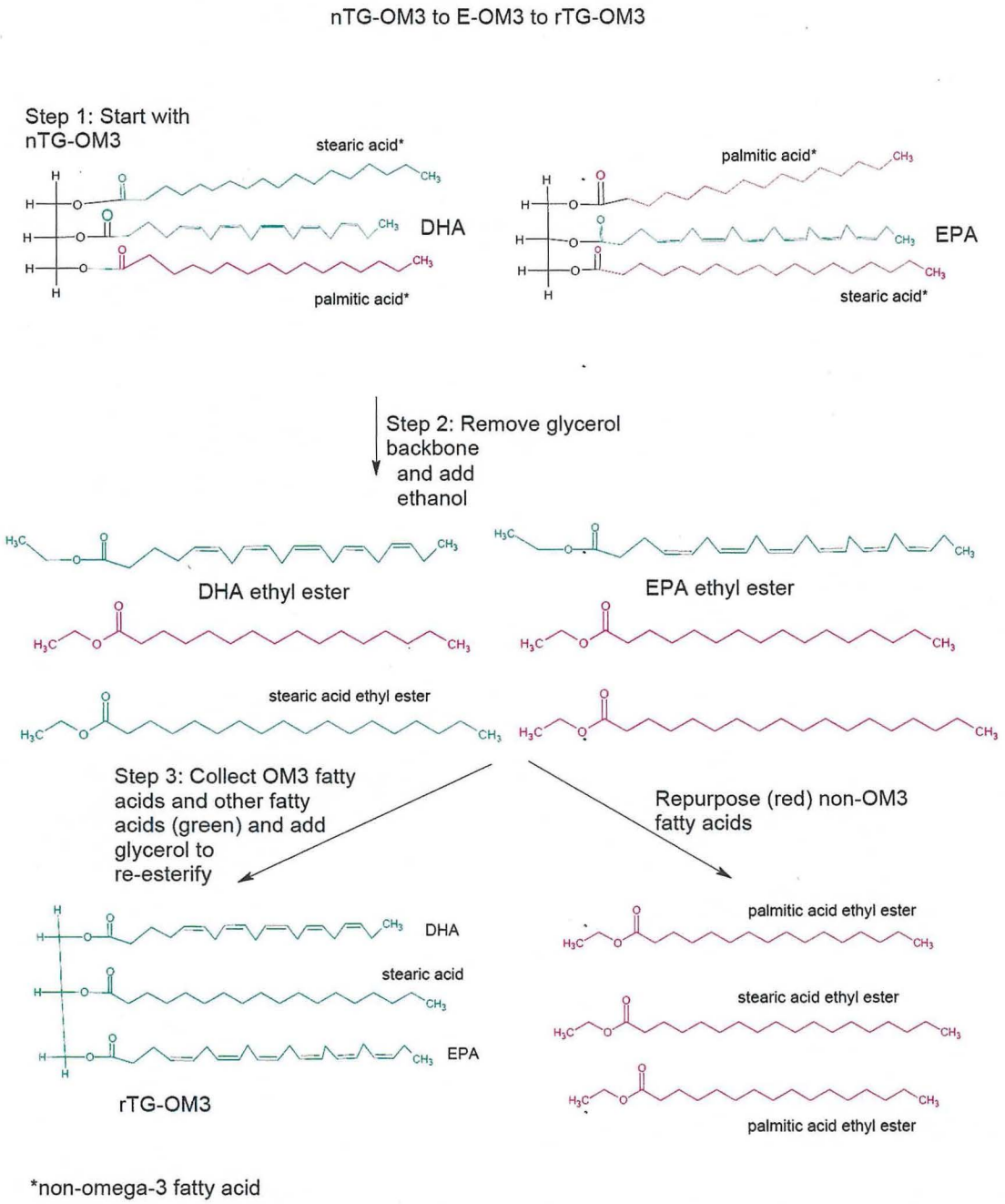
Figure 1. Leading Common Fish Oil Supplement with 30% nTG-OM3.*

See* R. Preston Mason and Samuel C.R. Sherratt, Omega-3 fatty acid fish oil dietary supplements contain saturated fats and oxidized lipids that may interfere with their intended biological benefits, Biochemical and Biophysical Research Communications (2016), 1-5. **Exhibit 14.

Figure 2. Vascepa® (E-EPA)*

*Vascepa®, Full Prescribing Information, **Exhibit 15** (reflecting that FDA has labeled Vascepa® 1 gram capsules as containing 1 gram of E-EPA. The capsules also contain trace amounts of inactive ingredients including, tocopherol, an anti-oxidation agent designed to protect the fragile active ingredient).

Figure 3. Conversion of nTG-OM3 to E-OM3 to rTG-OM3



*non-omega-3 fatty acid

Disclaimer - The triglyceride molecules shown in the scheme are merely representative of certain molecular species that would be expected to be present in both natural fish oil and rTG oil. They do not represent the only molecular species in these mixtures. These mixtures would contain a variety of fatty acid residues, inaddition to DHA, EPA, stearic and palmitic acid. The scheme is intended to represent, qualitatively, the type of chemical transformation that occurs in each step.

50. Omega-3 mixtures in their rTG form, regardless of whether they are characterized as rTG-OM3 mixtures or the more purified rTG-EPA or rTG-DHA mixtures, are also different from omega-3 mixtures in their natural triglyceride, or nTG, form in a number of ways. For example, the ratio of EPA to DHA in rTG-OM3 mixtures is often different from the ratio in naturally occurring (nTG) mixtures. In addition, the EPA and DHA levels in the rTG mixtures are typically much higher than they are in natural mixtures. This is because the re-esterification process adds, on average, one extra fatty acid to each triglyceride molecule. Further, nTG and rTG typically have different molecular structures. When the EPA, DHA, and other fatty acids, are re-attached to the glycerol molecule, during the chemical re-esterification process, they randomly attach to one of three different points on the glycerol molecule: SN-1, SN-2, or SN-3. Even though the pattern of attachment is random, based on statistical probability, more EPA, DHA, and other fatty acids attach to the SN-1 and SN-3 points than the SN-2 point. In nTG, however, the EPA and DHA are typically bound to the SN-2 position. Finally, during the re-esterification process, not all fatty acids, such as EPA and DHA, reattach to the glycerol molecule as triglycerides. Thus, large percentages of the oil, often approximately 40%, are in di-glyceride or mono-glyceride form. Notably, di-glycerides and mono-glycerides are not components of natural fish oil, nTG, at all. In nTG-OM3 mixtures (common fish oil), 100% of the oil is in triglyceride form. As described above, these types of differences are material because they can affect the efficacy and safety of the rTG mixture, compared to the nTG mixture (*e.g.,* concentration can lead to greater efficacy and, for example, higher levels of DHA have been associated with unwanted effects, particularly in some diseased patients with abnormally high levels of triglycerides in the blood). The differences between the rTG-EPA and nTG-EPA

molecules, as well as the differences between the rTG-DHA and nTG-DHA molecules are illustrated in Figure 3.

51. Upon information and belief, all of the Proposed Respondents' Synthetically Produced Omega-3 Products contain E-EPA, rTG-EPA, E-OM3, or rTG-OM3. **Exhibits 1 – 12.** Upon information and belief, all of these products are synthesized (*i.e.*, chemically altered) using the same basic chemical processes described above, and as such, they are distinct from common fish oil, *i.e.*, nTG-OM3.

V. JURISDICTION

52. The Commission had jurisdiction over this investigation for the reasons set forth in Complainant's Brief On Jurisdiction. **Exhibit 30.**

VI. UNLAWFUL AND UNFAIR ACTS OF PROPOSED RESPONDENTS

A. Proposed Respondents' Importation And Sale Of The Synthetically Produced Omega-3 Products Violate The Lanham Act

53. The Proposed Respondents' importation and sale of the Synthetically Produced Omega-3 Products, and their false or misleading representations about those products, constitute unfair acts or unfair methods of competition under Section 337, and violate Section 43(a) of the federal Lanham Act, 15 U.S.C. § 1125(a), and the federal common law of unfair competition.

54. Section 43(a) of the Lanham Act provides that:

> [a]ny person who, on or in connection with any goods or services, or any container for goods, uses in commerce any word, term, name, symbol, or device, or any combination thereof, or any false designation of origin, false or misleading description of fact, or false or misleading representation of fact, which – . . . (B) in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities, shall be liable in a civil action by any person who believes that he or she is or is likely to be damaged by such act.

15 U.S.C. § 1125(a).

55. The elements of a false advertising/promotion claim under the Lanham Act are (i) a false or misleading statement of fact is being made by the defendant about a product; (ii) the statement is deceiving or has the capacity to deceive a substantial segment of potential consumers; (iii) the deception is material, in that it is likely to influence a purchasing decision; (iv) the defendant is causing the false statement to enter interstate commerce; and (v) the complainant has been or is likely to be injured as a result of the statement. *See Hewlett-Packard Co. v. NU-Kote Int'l, Inc.*, 155 F.3d 571 (Fed. Cir. 1998) (*citing Southland Sod Farms v. Stover Seed Co.*, 108 F.3d 1134, 1139 (9th Cir. 1997)); *see also Marcinkowska v. IMG Worldwide, Inc.*, 342 F. App'x 632, 636 (Fed. Cir. 2009) (*citing Scotts Co. v. United Indus. Corp.*, 315 F.3d 264, 272 (4th Cir.2002)).

56. When a complainant can show that a statement is "literally false," or false on its face, however, the consumer deception is presumed, such that proving the third element is not necessary. *See Clock Spring, L.P. v. Wrapmaster, Inc.*, 560 F.3d 1329, n. 10 (Fed. Cir. 2009). A statement may be "literally false" due to a material omission, among other reasons. *See, e.g., Pfizer Inc. v. Miles Inc.*, 868 F.Supp. 437 (D. Ct. 1994) (holding that an omission that is likely to deter physicians from using an FDA approved drug is material and makes the advertisement's statement "a literal falsity").

57. In addition, parties other than those making false statements can be contributorily liable for Lanham Act violations. *See, e.g., Duty Free Ams., Inc. v. Estee Lauder Co.*, 797 F.3d 1248, 1273 (11th Cir. 2015); *Merck Eprova AG v. Gnosis S.p.A.*, 901 F. Supp. 436, 456 (S.D.N.Y. 2012) (finding company liable to Merck for contributory false advertising). The

elements of a contributory false advertising/promotion claim include showing that (1) a third party directly engaged in false advertising/promotion that injured the plaintiff and (2) the respondent at issue contributed to that conduct by knowingly inducing or causing the conduct, or by materially participating in it. *See Duty Free Ams.*, 797 F.3d at 1277.

1. Proposed respondents are making false statements about the Synthetically Produced Omega-3 Products by labeling and/or promoting them as "dietary supplements" when they are actually unapproved "new drugs"

58. The Distributors of the Synthetically Produced Omega-3 Products are unlawfully importing or selling their products with labeling, advertising and/or other promotional materials ("Promotional Materials") that are literally false. Among other things, the labeling for all of the Distributors' Synthetically Produced Omega-3 Products falsely asserts that the products are "dietary supplements," or it falsely implies that they are "dietary supplements" by using some modification of that term (*e.g.,* "Omega-3 Supplement"). **Exhibits 8-A-ii – 12-M-ii**. Indeed, the term "dietary supplement" or a modification of that term using the name of the ingredient in the product is required to appear on "dietary supplement" labeling by law. 21 U.S.C. §§ 321(ff)(2)(C), 343(s)(2)(B).

59. In addition, all of the Manufacturers (except Ultimate) are unlawfully importing or selling their products with Promotional Materials that are literally false because they assert that the products are for use in, or as "dietary supplements." **Exhibits 1-B – 7-B**.

60. Labeling and/or promoting Synthetically Produced Omega-3 Products for use in, or as "dietary supplements" is literally false because these products (i) cannot meet the definition of "dietary supplement" in Section 201(ff) of the FDCA, 21 U.S.C. § 321(ff) and (ii) are being

referred to as "dietary supplements" to hide the fact that they are actually unapproved "new drugs."

a. The Synthetically Produced Omega-3 Products cannot meet the definition of "dietary supplement" in the FDCA

61. None of the Synthetically Produced Omega-3 Products meets the definition of "dietary supplement" in the FDCA because none of the products bears or contains a "dietary ingredient." 21 U.S.C. § 321(ff)(1). Moreover, although the failure to bear or contain a "dietary ingredient" is sufficient to preclude a product from being a "dietary supplement," the Synthetically Produced Omega-3 Products that emphasize E-EPA in their manufacture or marketing are also excluded from the definition of "dietary supplement" by the definition's "exclusionary clause." *See id.* § 321(ff)(3)(B).

i. The Synthetically Produced Omega-3 Products do not meet the definition of "dietary supplement" because they do not bear or contain a "dietary ingredient"

62. The definition of "dietary supplement" in the FDCA applies only to products that, among other things, bear or contain one or more of the following "dietary ingredients": "(A) a vitamin, (B) a mineral, (C) an herb or other botanical, (D) an amino acid, (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake, or (F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E)." 21 U.S.C. § 321(ff)(1). Products marketed with ingredients that do not fall within the categories of "dietary ingredients" listed in Section 201(ff)(1) of the FDCA, 21 U.S.C. § 321(ff)(1), cannot be marketed as, or for use in, "dietary supplements." *See id.*

63. The Synthetically Produced Omega-3 Products are not "dietary supplements" because E-EPA, rTG-EPA, E-OM3, and rTG-OM3 do not fall into any of the categories of

"dietary ingredients" under the Section 201(ff)(1) of the FDCA. As an initial matter, E-EPA, rTG-EPA, E-OM3, E-EPA, and rTG-OM3 are not vitamins, minerals, herbs, or other botanicals, and therefore, they do not fall under subsections 201(ff)(1)(A)-(D). Moreover, they do not fall under subsections 201(ff)(1)(E) or (F) either.

a) The Synthetically Produced Omega-3 Products do not fall under subsection 201(ff)(1)(E) of the "dietary ingredient" definition

64. Unlike nTG-OM3 and nTG-EPA, which naturally occur in fish oil, E-EPA, rTG-EPA, E-OM3, and rTG-OM3 do not fall under subsection (E). They are not "dietary substance[s] for use by man to supplement the diet by increasing the total dietary intake." 21 U.S.C. § 321(ff)(1)(E). According to FDA, when the chemical structure of a dietary ingredient is altered, for example, by the "addition of new chemical groups as in *esterification*," it:

> creates a new substance that is different from the original dietary ingredient. The new dietary ingredient is not considered to be a dietary ingredient merely because it has been altered from a substance that is a dietary ingredient, and therefore, is in some way related to the dietary ingredient.

Dietary Supplements: New Dietary Ingredient Notifications and Related Issues: Guidance for Industry (Draft), August 2016 (NDI Guidance), at 41 (emphasis added), **Exhibit 31**. This is a well-settled FDA policy that previously has been articulated in Federal Register notices and implemented in rejections of new dietary ingredient notifications. *See*, *e.g.*, 81 Fed. Reg. 61700, 61702 (Sept. 7, 2016), **Exhibit 32**, (noting that vinpocetine "is a synthetic compound, derived from vincamine, an alkaloid found in the *Vinca minor* plant" because it undergoes transesterification and/or dehydration of vincamine in ethanol); FDA Letter to AIBMR Life

Sciences, Inc., dated March 19, 2014, **Exhibit 33** (finding that synthetic fish oil fatty acid esters were "not constituents of a dietary substance for use by man under Section 201(ff)(1)(F)").

65. FDA refers to these chemically altered ingredients – these new substances – as "synthetic" or "synthetically produced" ingredients, and it uses those terms interchangeably to refer to ingredients that are synthesized from natural starting materials as well as unnatural starting materials. *See, e.g.,* NDI Guidance, at 37-41, **Exhibit 31**; *see also* 81 Fed. Reg. at 61702, **Exhibit 32**; FDA Warning Letter to Quincy Bioscience Manufacturing Inc., dated Oct. 16, 2012, **Exhibit 34** (concluding that synthetic apoaequorin manufactured from "rapidly dividing host cells," which are natural materials, is not a "dietary ingredient"); FDA Letter to Syntech (SSPF) International, dated December 6, 2004, **Exhibit 35** (finding that betaphrine, an ingredient chemically synthesized from substances that are themselves "dietary ingredients," is not a "dietary ingredient" under any subsection in Section 201(ff)(1)(A)-(F) of the Act).

66. Because E-EPA, rTG-EPA, E-OM3, and rTG-OM3 are each chemically altered, or synthesized from common fish oil, they are synthetically produced, or synthetic. As such, they cannot fall under subsection 201(ff)(1)(E), unless they themselves are commonly used in conventional food.

67. For more than 15 years, FDA has consistently found that synthetic substances do not fall under subsection 201(ff)(1)(E), or subsections 201(ff)(1)(C) and (F) of the "dietary ingredient" definition for that matter, unless the synthetic substance itself is commonly used in conventional food. And when purported "dietary supplements" have contained a synthetic ingredient that is not common in conventional foods, FDA has taken action. For example, the agency has

(i) brought enforcement actions on this basis, *see, e.g.,* 69 Fed. Reg. 6787, 6793 (Feb. 11, 2004), **Exhibit 36** (citing *United States v. 1009 Cases* * * * No. 2:01CV-820C (D. Utah filed October 22, 2001));

(ii) denied citizen petitions on this basis, *see, e.g.,* Letter from FDA to Ullman, Shapiro, & Ullman LLP, Docket No. FDA-2009-P-0298, dated Feb. 23, 2011, **Exhibit 37** (citizen petition response stating that synthetic homotaurine may not be marketed as a "dietary supplement" because it is not a "dietary ingredient");

(iii) advised other federal agencies on this basis, *see, e.g.,* Letter from Dennis E. Baker, Associate Commissioner of Regulatory Affairs, FDA, to Laura M. Nagel, Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, June 21, 2001 (Nagel Letter), **Exhibit 38** (concluding that synthetic ephedrine alkaloids are not "dietary ingredients");

(iv) announced in the Federal Register that certain ingredients cannot be sold as "dietary supplements" on this basis, 69 Fed. Reg. 6793, **Exhibit 36** (acknowledging that synthetic ephedrine hydrochloride "and other synthetic sources of ephedrine cannot be dietary ingredients because they are not constituents or extracts of a botanical, nor do they qualify as any other type of dietary ingredient");

(v) issued warning letters on this basis, *see, e.g.*, FDA Warning Letter to ATS Labs, LLC, dated February 3, 2016, **Exhibit 39** (finding that 1,3-dimethylbutylamine ("DMBA") is not a "dietary ingredient" because it is synthetic and to the best of FDA's knowledge it is not used in conventional foods); FDA Warning Letter to DBM Nutrition, dated Nov. 30, 2015, **Exhibit 40** (finding that picamilon, "a unique chemical entity synthesized from the

dietary ingredients niacin and aminobutyric acid" does not fall within any of the "dietary ingredients" categories in the statute, and therefore, is not a "dietary ingredient"); FDA Warning Letter to Quincy Bioscience Manufacturing Inc., dated Oct. 16, 2012, **Exhibit 34** (finding that synthetic apoaequorin is not a "dietary ingredient"); FDA Warning Letter to Supplementstogo.com LLC, dated March 8, 2006, **Exhibit 41** (finding that methasterone, a synthetic steroid, is not a "dietary ingredient"); and

(vi) rejected new dietary ingredient notifications on this basis, *see*, *e.g.*, FDA Letter to Syntech (SSPF) International, dated December 6, 2004, **Exhibit 35** (finding that betaphrine, a chemically synthesized substance is not a "dietary ingredient"). In addition, FDA recently reiterated this position in 2016 draft guidance on "new dietary ingredients." *See* NDI Guidance at 38, **Exhibit 31**.

68. The FDA's long-standing position is based on a plain language interpretation of the definition of "dietary supplement" in the text in subsection 201(ff)(1)(E) – namely, "a dietary substance for use by man to supplement the diet by increasing the total dietary intake." *See* NDI Guidance, at 38, **Exhibit 31**; Nagel Letter, **Exhibit 38**. According to FDA, *Webster's II New Riverside University Dictionary*, provides that the term "dietary" means "of or relating to the diet" and "diet" means "an organism's usual food and drink." *See* NDI Guidance, at 38, **Exhibit 31**; Nagel Letter, **Exhibit 38**. Reading those definitions in conjunction with the phrase, "for use by man," FDA construes the term "dietary substance" to mean "a substance commonly used as human food or drink." *See* NDI Guidance, at 38, **Exhibit 31**; Nagel Letter, **Exhibit 38**. FDA also maintains that the last phrase in subsection (E), "to supplement the diet by increasing the total dietary intake," provides further evidence that Congress intended the term "dietary

substance" to refer to "foods and food components that humans eat as part of their usual diet" because "[o]ne cannot increase the 'total dietary intake' of something that is not part of the human diet in the first place." *See* NDI Guidance, at 38, **Exhibit 31**; Nagel Letter, **Exhibit 38**.

69. Upon information and belief, E-EPA, rTG-EPA, E-OM3, and rTG-OM3 are not common in conventional food in the United States. Each is synthetically produced.

b) The Synthetically Produced Omega-3 Products do not fall under subsection 201(ff)(1)(F) of the "dietary ingredient" definition

70. Similarly, E-EPA, rTG-EPA, E-OM3, and rTG-OM3 do not fall under subsection 201(ff)(1)(F) because each is a synthetically produced substance, and upon information and belief, none of the ingredients is a concentrate, constituent, extract, or combination of a "dietary substance" that falls under subsection 201(ff)(1)(E), or subsections 201(ff)(1)(A)-(D) for that matter. Notably, in 2014, FDA specifically rejected a new dietary ingredient notification for a product dubbed "synthetic fish oil fatty acid esters"– in part, because the proponent of the ingredient had not submitted evidence sufficient for FDA to determine whether it met the definition of "dietary ingredient." *See* FDA Letter to AIBMR Life Sciences, Inc., dated March 19, 2014, **Exhibit 33**. In reaching this conclusion, FDA stated that the synthetic fish oil fatty acid esters at issue were "not constituents of a dietary substance for use by man under Section 201(ff)(1)(F)." *Id.* This approach by FDA is consistent with its conclusion that "[o]ne cannot increase the 'total dietary intake' of something that is not part of the human diet in the first place." NDI Guidance, at 38, **Exhibit 31**; Nagel Letter, **Exhibit 38**.

ii. Certain Synthetically Produced Omega-3 Products are excluded from the definition of "dietary supplement" under the exclusionary clause contained in subsection 321(ff)(3)(B) of the FDCA

71. Subsection 201(ff)(3)(B) of the FDCA (*i.e.,* the exclusionary clause) also excludes from the definition of "dietary supplement" any "article" that is approved as a "new drug" or authorized for study as a "new drug" (where substantial clinical investigations have been instituted), that was not before such approval or authorization legally marketed as a "dietary supplement" or as a food. 21 U.S.C. § 321(ff)(3)(B). As explained below in paragraphs 80-83, E-EPA first gained recognition in the market place by being studied as a drug in the mid-1980s, and upon information and belief it was not legally marketed as a "dietary supplement" or a food prior to that time. Thus, as explained below, E-EPA products, as well as products containing E-OM3 that emphasize E-EPA in the way that they are manufactured or promoted, are excluded from the definition of "dietary supplement" under subsection 201(ff)(3)(B) of the FDCA.

72. The relevant "article" for the purposes of the exclusionary clause is dictated by the circumstances surrounding the manufacture and marketing of the purported "dietary supplements" at issue. *See Pharmanex v. Shalala ("Pharmanex III")*, 2001 WL 741419 (D. Utah 2001), *2, *4-*5 (upholding FDA's administrative determination); FDA Administrative Determination on Cholestin, dated May 20, 1998, at 10, **Exhibit 42**. In the seminal case on the exclusionary clause, Pharmanex, Inc. ("Pharmanex") marketed a product that contained red yeast rice as a "dietary supplement." *See* FDA Administrative Determination on Cholestin, dated May 20, 1998, at 1, **Exhibit 42**. FDA, however, determined that Cholestin was not a "dietary supplement," but rather an unapproved "new drug" under the FDCA. *See id.* FDA reasoned that Cholestin did not meet the definition of "dietary supplement" because Cholestin contained

lovastatin, an active ingredient in an FDA-approved drug. *See id.* at 7, 10. As such, products containing lovastatin were excluded from the definition of "dietary supplement" by the exclusionary clause. *See id.* According to FDA, lovastatin was the relevant "article" for the purposes of the exclusionary clause, as opposed to the finished Cholestin product, because of the "particular circumstances surrounding the Cholestin product, which indicate[d] that Pharmanex, in marketing and manufacturing Cholestin, [was] marketing and manufacturing lovastatin, not the traditional food product red yeast rice." *Id.* at 10.

73. Notably, the Tenth Circuit upheld FDA's determination that an "article" for the purposes of the exclusionary clause can be either a finished drug product or a component of a drug product. *See Pharmanex v. Shalala ("Pharmanex II")*, 211 F.3d 1151 (10th Cir. 2000); FDA Administrative Determination on Cholestin, dated May 20, 1998, **Exhibit 42**. This interpretation ensures that substances that have gained recognition in the marketplace as drugs cannot be marketed as, or incorporated into, "dietary supplements." *See* FDA Administrative Determination on Cholestin, dated May 20, 1998, at 6, **Exhibit 42**.

74. The exclusionary clause encourages and protects investment in drug development and the resulting innovation. The Tenth Circuit and FDA have observed, respectively, that permitting "manufacturers to market dietary supplements with components identical to the active ingredients in prescription drugs" would undermine the FDCA's incentive structures for drug development, *see Pharmanex II*, 211 F.3d at 1159, and it would "serve as a disincentive to the often significant investment needed to gain FDA approval of new drugs." *See* FDA Administrative Determination on Cholestin, dated May 20, 1998, at 4-5, **Exhibit 42**. Protecting drug innovation is such a critical underpinning of the FDCA that Congress later enacted a

separate exclusionary clause to prohibit substances that have gained recognition in the marketplace by being studied as, or approved as drugs, from being incorporated into conventional food as well, unless those substances were first marketed in a food. *See* 21 U.S.C. § 331(ll)).

75. In this case, consistent with the FDA's decision in *Pharmanex* and the underlying principle of the exclusionary clause, E-EPA is the relevant "article" when the purported "dietary supplements" at issue (i) contain E-EPA and (ii) emphasize E-EPA in the way that they are manufactured or promoted. In those instances, it is clear that the Proposed Respondents are importing or selling E-EPA, not common fish oil, or nTG-EPA. To adequately protect investment in drug development and the resulting innovation, E-EPA, which gained recognition in the marketplace as a "new drug", as explained in paragraphs 80-83, cannot be marketed as, or incorporated into, "dietary supplements."

76. The affected products are identified in **Exhibits 1-A – 4-A, 6-A – 7-A, 8-A – 8-C, 8-E – 8-F, 8-H – 8-N, 10-A – 10-G, 12-C – 12-F, 12-J – 12-K**. By pharmacological design, E-EPA is the most predominant component in these purified E-EPA products and E-OM3 mixtures. *Id.* Upon information and belief, these products are manufactured by following the same basic steps that drug companies follow, as summarized in paragraphs 42-51 of the complaint. In addition, as demonstrated in the attached charts, these products are typically promoted not just for their EPA content – but for their *chemically concentrated EPA content* – which would not be possible but for the ethyl ester form. **Tables 3 and 4**. The chemical cleaving of the glycerol backbone from the nTG-OM3 and the reaction with the ethanol to form E-EPA or E-OM3

enables EPA to be substantially heightened to a level beyond that which exists in nature. EPA in its natural triglyceride form cannot be heightened to the same level.

77. Moreover, the esterification of EPA – *i.e.,* the ethyl ester form – allows these products to be concentrated and differentiates these products from common fish oil or other natural sources of EPA. A consumer would have to consume a likely intolerable amount of common fish oil or common krill oil in an effort to even get the same dosage of E-EPA in Vascepa®, a highly pure form of E-EPA. For example, a 300 mg capsule of MegaRed® Omega-3 Krill Oil contains approximately 50 mg of natural EPA in each capsule, *see* MegaRed Website, **Exhibit 43**, whereas a 1 gram capsule of Vascepa® contains 1000 mg of E-EPA. *See* Vascepa® Full Prescribing Information. **Exhibit 15**. Given that the FDA-approved dose of Vascepa® to reduce triglyceride levels in adult patients with severe hypertriglyceridemia is 4000 mg per day (*e.g.,* two, 1 gram capsules twice a day), consumers would have to take approximately 80 capsules of MegaRed® Omega-3 Krill Oil daily to get a similar dose of EPA from that product as they would get from four, 1 gram capsules of Vascepa®.

78. For this reason, companies often tout their chemically manipulated products containing E-EPA as being comparable to drugs that contain E-EPA (*e.g.*, "Most fish oils are not the same as Lovaza. But some Are! A few over-the counter pharmaceutical grade fish oils [sic] are just as potent, pure and effective at reducing triglycerides as Lovaza," *see* OmegaVia Website, **Exhibit 44**; *see also* OmegaVia Website 2, **Exhibit 45** (making implicit comparisons of OmegaVia's so-called "pharmaceutical grade fish oil" products to both Vascepa® and Lovaza® (another FDA-approved drug product)).

79. The Synthetically Produced Omega-3 Products that contain E-EPA, and emphasize that component in the manufacture and/or promotion of the product, are excluded from the definition of "dietary supplement" under subsection 201(ff)(3)(B) of the FDCA, 21 U.S.C. § 321(ff)(3)(B), because the relevant "article" – E-EPA – gained recognition in the marketplace by being studied as a "drug," as explained below. And upon information and belief, Synthetically Produced Omega-3 Products that incorporate E-EPA are not saved from exclusion from the "dietary supplement" definition by the "prior market clause" because E-EPA was never legally marketed as food or as a "dietary supplement."

80. E-EPA first gained recognition in the marketplace as a drug when it was clinically studied as a drug in the United States in the mid-1980s, if not earlier. Studies on E-EPA, in E-OM3 mixtures, began to proliferate after the Biomedical Test Materials Program ("BTM Program") was created in 1986. *See* Sylvia B. Galloway, Ph.D., Biomedical Test Materials Program: Drug Master Files for Biomedical Test Materials, Produced From Refined Menhaden Oil, and Their Placebos, United States Department of Commerce, October 1989 (1989 BTM Report), **Exhibit 46**, at 1-1, 2-1, 2-2. The BTM Program was created by the National Oceanographic and Atmospheric Administration ("NOAA") and the National Institutes of Health ("NIH")/Alcohol, Drug Abuse, and Mental Health Administration ("ADAMHA"), and it provided standardized test materials to help researchers better identify the role of different forms of omega-3 fatty acids on health and disease. *See id.* at 1-1. The standardized test materials included an E-OM3 mixture that contained E-EPA as its principal component. *See id.* at 2-3. Specifically, the E-OM3 mixture contained approximately 80% omega-3 fatty acid ethyl esters, 44% E-EPA and 24% E-DHA, and 10-12% other omega-3 fatty acid ethyl esters, as well as other

components. *See id.* Notably, the test materials, by chemically converting the EPA to ethyl ester form, increased the level of EPA in the mixture by approximately 26%. Typically, common fish oil contains 18% EPA. The availability of the test materials was announced on a number of occasions in the NIH Guide for Grants and Contracts, starting on May 29, 1987; requests from researchers were received by June 1987; and the BTM Program began shipping materials by September 1987. *See id.* at 2-1. Notably, in a February 1988 announcement, the program was explicit that "[i]n accordance with federal regulations, an [investigational new drug ("IND")] number will be required for the use of these materials in human studies." NIH Guide for Grants and Contracts, Vol. 17, No. 5, Feb. 12, 1988, **Exhibit 47** at 1; *see also* 1989 BTM Report, **Exhibit 46**, at 2-1. In 1989, the BTM Program also made purified mixtures of E-EPA and E-DHA available for study. *See* P.H. Fair, Biomedical Test Materials Program: Distribution Management Manual, Department of Commerce, Dec. 1989 (1989 BTM Distribution Manual), **Exhibit 48**. The E-EPA mixture contained >95% ethyl esters (of the ethyl esters, EPA was 97%, other omega-3 fatty acids were < 1% and omega-6 fatty acids were < 1%). *See id.* at 5.

81. Upon information and belief, no "dietary supplement" or food containing E-EPA was legally marketed prior to these studies. In the late 1980s, FDA was skeptical that any omega-3 products, even those containing common fish oil (*i.e.*, nTG-OM3), were marketed legally. Many, if not all, of the omega-3 products at the time, were marketed with promotional claims that rendered them unapproved new drugs. In 1988, FDA sent more than 50 letters to manufacturers and distributors of omega-3 products citing them for that illegal practice. *See, e.g.,* FDA Letter to Barth Vitamin Corp., dated April 1988 (and related letters), **Exhibit 49**. For example, an FDA letter to American Health Products stated that the promotional material

distributed with a product, known as SuperEPA (i) suggested that the product may be useful in "the prevention or treatment of cancer, arthritis, atherosclerosis, heart disease, platelet aggregation, immune system effects, and the lowering of blood levels of cholesterol and triglycerides" and (ii) rendered the product an unapproved "new drug" under the FDCA. *See* FDA Letter to American Health Products, dated May 18, 1988, **Exhibit 50**.

82. In addition, in the late 1980s and in the 1990s (at least before the Dietary Supplement Health and Education Act of 1994, P.L. 103-417, amended the FDCA), no omega-3 supplements had been authorized for use by FDA as food ingredients, and agency statements reveal that the agency considered them to be unsafe "food additives." *See* 21 U.S.C. §§ 321(s), 342(a)(2)(C). A "food additive" is "any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food" that is not (i) generally recognized as safe ("GRAS") or (ii) used in food prior to January 1, 1958, and shown to be safe through scientific procedures or common use. 21 U.S.C. § 321(s). Substances falling within the definition of "food additive" are deemed "unsafe" as a matter of law and marketing them is illegal when FDA has not approved them through regulation. 21 U.S.C. §§ 348(a)(2), 342(a)(1)(C)(i). In 1990, FDA sent a letter to a trade association stating that:

> We have continued concerns about any food use of omega-3 polyunsaturated fatty acids. We are unaware of any history of use of these substances as food ingredients prior to 1958, and FDA has not listed omega-3 polyunsaturated fatty acids as approved food additives or as being generally recognized as safe [GRAS]. Thus, addition of these substances to foods may render those foods adulterated under 21 U.S.C. 342(a)(2)(C).

See FDA Letter to R. William Soller, dated June 20, 1990, **Exhibit 51**. Further, when FDA affirmed natural menhaden oil to be GRAS in 1997, the agency noted that it declined to make the same determination in 1989 because the oil contained high levels of the omega-3 fatty acids, EPA and DHA, which were known to have physiologic effects, such as effects on blood clotting. 62 Fed. Reg. 30751, 30752 (June 5, 1997), **Exhibit 52**. In other words, in 1989, FDA did not believe that nTG-OM3 in menhaden oil, or its components nTG-EPA or nTG-DHA, were GRAS, and as such, nTG-OM3, nTG-EPA, and nTG-DHA could not have avoided the designation of "food additive" at that time. If nTG-OM3, nTG-EPA, and nTG-DHA in menhaden oil could not have avoided the designation of "food additive" until 1997, there is no basis to support the lawful marketing of E-OM3 and E-EPA as GRAS ingredients prior to that time.

83. Accordingly, for purported "dietary supplements" containing E-EPA to be saved from exclusion from the "dietary supplement" definition, a product must be identified that contained E-EPA that (i) was marketed before the proliferation of E-EPA clinical studies in the mid-1980s, (ii) was not an unapproved new drug, based on the manner in which it was promoted, (iii) did not contain an unsafe "food additive," and (iv) was not otherwise illegally marketed. Upon information and belief, no such "unicorn" exists.

b. Synthetically Produced Omega-3 Products are actually unapproved "new drugs" under the FDCA

84. Section 201(g)(1) of the FDCA defines the term "drug" as (A) "articles" recognized in the official United States Pharmacopeia ("USP") or official National Formulary ("NF") (which have now been combined into one publication, the "USP/NF"); (B) "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or

other animals;" (C) "articles (other than food) intended to affect the structure or any function of the body of man or other animals;" and/or (D) "articles intended for use as a component of any articles specified in clause (A), (B), or (C)." 21 U.S.C. § 321(g)(1)(A)-(D); *see also* 21 C.F.R. § 101.93(f) (further describing "structure/function" claims under subsection (C)), (g) (further describing "disease" claims under subsection (B)).

85. Products that meet the definition of "dietary supplement," however, are subject to a safe harbor – they may be promoted with claims indicating that they are intended to affect the structure or function of the body without invoking drug status. 21 U.S.C. § 321(g)(1). But, because the Synthetically Produced Omega-3 Products are not "dietary supplements," they are not subject to that safe harbor. Thus, the Synthetically Produced Omega-3 Products are "drugs" if they meet any of the four prongs of the "drug" definition contained in Section 201(g)(1)(A)-(D) of the FDCA – including if they are intended to affect the structure or function of the body. *See* 21 U.S.C. § 321(g)(1)(A)-(D).

86. FDA need not deem products to be "drugs," for them to be "drugs." Products are "drugs" if they meet any of the four prongs of the definition of "drug" in the FDCA. 21 U.S.C. § 321(g)(1). Drug sponsors often take steps toward drug approval before any FDA involvement at all. Typically, basic scientists collect data from animal studies. If the data look promising, the drug company develops a prototype drug, and it seeks permission from FDA to begin clinical testing in humans by way of an IND application. *See id.* § 355(i). Once the clinical trials are conducted, the sponsor may submit an NDA, and if FDA believes that the drug is safe and effective, that the proposed labeling is appropriate, and that manufacturing methods assure that the drug's identity, strength, quality, and purity, then the agency will approve the drug. *See id.* §

355(d). At that point, the drug may be legally marketed. In other words, it is incumbent upon the sponsor of a "drug" to recognize that a product is a "drug" pursuant to the definition in the FDCA, and to comply with FDA's regulatory requirements for "drugs" accordingly. *See generally*, Susan Thaul, How FDA Approves Drugs and Regulates Their Safety and Effectiveness, Congressional Research Service, June 25, 2012, **Exhibit 53**.

87. Sponsors of products that meet the definition of "drug," that fail to comply with FDA's *drug approval process* are engaging in a prohibited act. The FDCA expressly prohibits the introduction or delivery for introduction of an *unapproved "new drug"* into interstate commerce. 21 U.S.C. §§ 355(a), 331(d); *see also* 21 U.S.C. §§ 352(f), 331(a)-(c). And, as a practical matter, all unapproved "drugs" are also unapproved "new drugs." Products that meet the definition of "drug" are "new drugs" under Section 201(p) of the FDCA if they are not generally recognized by qualified experts as safe and effective for their intended uses. 21 U.S.C. § 321(p). To be so "generally recognized," the Supreme Court has found that, among other things, there must be a consensus of expert opinion that a drug is safe and effective based on "substantial evidence," as that term is defined in Section 505(d) of the FDCA. *See Weinberger v. Hynson, Wescott & Dunning Inc.*, 412 U.S. 609, 632 (1973) (citing 21 U.S.C. 355(d)). Notably, the *Hynson* decision effectively incorporates FDA's "new drug" approval standard for efficacy into the "new drug" definition. *See id.* Since 1975, FDA has opposed virtually every attempt to deem a "new drug" as generally recognized by qualified experts as safe for the uses mentioned in the labeling by any mechanism other than FDA approval. *See* David G. Adams, *et al.*, Food and Drug Law and Regulation (3d. 2015), at p. 298, **Exhibit 54**. In other words,

practically speaking, to avoid designation as a "new drug," a product that meets the definition of "drug," must be approved by FDA.

88. Some sponsors of products that are "drugs," pursuant to the "drug" definition, may attempt to illegally evade the drug approval requirements by hiding the identity of these products with false labels, such as "dietary supplement," or even "medical food" – because products that actually meet those definitions are exempt from certain "drug" requirements, including premarket review. *See id.* §§ 321(g), (ff), 360ee(b)(3). But if the products do not actually meet the definitions of those terms in the statute, and they meet the definition of the term "drug," then they are unapproved "new drugs." Because "dietary supplements" and "medical foods" are not subject to premarket review, FDA would not review the labeling of those products before the products are marketed or have the occasion to consider whether the products are actually unapproved "new drugs." And, once the products are on the market, FDA still may not be aware of the statements made in the labeling or have the occasion to consider whether the products are actually unapproved "new drugs." Accordingly, the sponsors' false statements may go undetected.

89. When FDA detects such false labeling and has the requisite resources to pursue the violation, it may send a warning letter to the violator. For example, in late May and early June of this year, FDA sent three separate warning letters to different companies that cited them for selling products containing synthetic steroids as "dietary supplements" when in fact (1) the products did not meet the definition of "dietary supplement," and (2) the products were actually unapproved "new drugs." *See* FDA Warning Letter to Flex Fitness Products and Big Dan's Fitness, dated May 25, 2017, **Exhibit 55**; FDA Warning Letter to Hardcore Formulations, dated

June 5, 2017, **Exhibit 56**; FDA Warning Letter to AndroPharm LLC, dated June 5, 2017, **Exhibit 57**.

90. FDA has taken similar actions against unapproved "new drugs" falsely labeled as "medical foods." For example, FDA took action in May 2017 against Enzymotec Ltd. (and one of its suppliers) for falsely positioning three *omega-3 fatty acid products* – Vayarol®, Varyarin®, and Vayacog® – as "medical foods," when they were actually unapproved "new drugs." *See* BRIEF-Enzymotec Ltd- FDA issued import alert that included vayarol, vayarin and vayacog products, Reuters.com, May 10, 2017, **Exhibit 58**; Import Alert 66-41, Detention Without Physical Examination of Unapproved New Drugs Promoted in the U.S., dated June 19, 2017, **Exhibit 59**; Enzymotec Ltd., SEC Form 6-K, dated May 2017, **Exhibit 60**; FDA Warning Letter to Rainbow Gold Products, Inc. dated May 4, 2017, **Exhibit 61** (citing Vayarin® as an unapproved "new drug").

91. The Synthetically Produced Omega-3 Products come in several molecular forms (*e.g.*, E-EPA, rTG-EPA, E-OM3, and rTG-OM3) and, typically, in two different physical forms (*i.e.,* in liquid form, as an oil for use in or as a "dietary supplement," or in an encapsulated form, for use as a "dietary supplement"). Each Synthetically Produced Omega-3 Product is a "drug" because it triggers one or more elements of the "drug" definition, and the elements in the "drug" definition triggered by each product depend on the molecular and physical form of the product.

i. All of the Synthetically Produced Omega-3 Products meet the definition of "drug" in the FDCA

a) Encapsulated E-OM3

92. The encapsulated E-OM3 products subject to this complaint are "drugs" because they meet at least one of the four prongs of the "drug" definition. *See id.* With regard to the first

prong, subsection 201(g)(1)(A) of the FDCA, "Omega-3-Acid Ethyl Ester Capsules" are named in the drug USP/NF, *see* USP/NF (USP40-NF35), Vol. 2 (2017), at 5430-5433. **Exhibit 62**. Notably, to be "recognized" in the USP, products need only meet the definition of a product named in the USP; they need not comply with compendial identity standards. *See* 21 U.S.C. §§ 351(b), 352(e)(3)(B); *see also* USP/NF (USP40-NF35), at xiii, § 2.30. **Exhibit 63**. (Recognized products that do not meet the compendial identity standards are "drugs" that are adulterated, misbranded or both. *See* 21 U.S.C. §§ 351(b), 352(e)(3)(B)). According to the USP, "Omega-3-Acid Ethyl Ester Capsules" are capsules that include E-EPA and E-DHA as well as five other omega-3 fatty acids in ethyl ester form (*e.g.,* alpha-linolenic acid in ethyl ester form). *See* USP/NF (USP40-NF35), Vol. 2 (2017), **Exhibit 62**, at 5430-5433. Upon information and belief, all of the encapsulated E-OM3 products identified in this complaint (and attachments hereto) meet that definition. Accordingly, they are all "recognized" in the USP, and therefore, are "drugs."

93. With regard to the second and third prongs of the "drug" definition, subsections 201(g)(1)(B) and 201(g)(1)(C) of the FDCA, all of the Proposed Respondents' E-OM3 capsules named in this complaint (except those sold by Ultimate) are clearly intended to affect disease and/or the structure/function of the body. Under FDA's regulations, evidence that a product is intended to be used as "drug" includes advertising, labeling, or "other oral or written statements" by the entities that are legally responsible for the labeling of the drug, as well as the circumstances surrounding the distribution of the product. 21 C.F.R. § 201.128. As set forth in Section VII below, the Promotional Materials associated with each of these products (except those sold by Ultimate) indicate that the products are intended to affect disease and/or the

structure function of the body. Moreover, upon information and belief, the circumstances of sale corroborate that intent.

94. With regard to the fourth prong of the "drug" definition, subsection 201(g)(1)(D) of the FDCA, upon information and belief, the encapsulated E-OM3 products sold by Ultimate are intended for use as a component of a "drug."

b) E-OM3 in Oil Form

95. The E-OM3 products in oil form are "drugs" because they meet at least one of the four prongs of the "drug" definition. With regard to the first prong, subsection 201(g)(1)(A) of the FDCA, "Omega-3-Acid Ethyl Esters" (in oil form) are named in the drug USP/NF, *see* USP/NF (USP40-NF35), Vol. 2 (2017), at 5428-5430, **Exhibit 64**. According to the USP/NF, "Omega-3 Acid Ethyl Esters" are mixtures of ethyl esters, principally E-EPA and E-DHA, that may also contain one of five other omega-3 fatty acids. *See id.* Upon information and belief, all E-OM3 sold by the Proposed Respondents in oil form meet this definition. Therefore, they are recognized in the USP/NF, and as such are "drugs."

96. With regard to the second and third prongs of the "drug" definition, subsections 201(g)(1)(B) and 201(g)(1)(C) of the FDCA, all of the Proposed Respondents' E-OM3 oil named in this complaint (except that sold by Ultimate) is clearly intended to affect disease and/or the structure/function of the body. As set forth in Section VII below, the Promotional Materials associated with each of these products (except those sold by Ultimate) indicate that the products are intended to affect disease and/or the structure function of the body. Moreover, upon information and belief, the circumstances of sale corroborate that intent.

97. With regard to the fourth prong of the "drug" definition, subsection 201(g)(1)(D) of the FDCA, upon information and belief, the E-OM3 oil sold by Ultimate is intended for use as a component of a "drug."

c) E-EPA, rTG-EPA, and rTG-OM3, as well as other forms of E-OM3

98. E-EPA, rTG-EPA, and rTG-OM3, as well as other forms of E-OM3, are "drugs" because they meet one or more of the prongs of the definition of "drug" in the FDCA. With regard to the second and third prong, namely subsections 201(g)(1)(B) and 201(g)(1)(C), most of these products are intended to affect disease and/or the structure/function of the body. As set forth in Section VII below, the Promotional Materials associated with each of these products (except those sold by Ultimate and Nordic Pharma) indicate that the products are intended to affect disease and/or the structure function of the body. Moreover, upon information and belief, the circumstances of sale corroborate that intent.

99. With regard to the fourth prong, subsection 201(g)(1)(D) of the FDCA, upon information and belief, when these substances are sold by Ultimate and Nordic Pharma, they are intended for use as a component of a "drug."

ii. All of the Synthetically Produced Omega-3 Products are unapproved "new drugs"

100. All of the Synthetically Produced Omega-3 Products are also "new drugs" under Section 201(p) of the FDCA because they are not generally recognized by qualified experts as safe and effective for their intended uses. 21 U.S.C. § 321(p).

101. As mentioned above, as a practical matter, for a drug to be generally recognized by qualified experts as safe and effective for its intended uses, it has to be FDA-approved. None

of the Synthetically Produced Omega-3 Products is an FDA-approved drug. *See* List of FDA-Approved Icosapent Ethyl Drugs (E-EPA) in Orange Book, **Exhibit 16** (listing none of the Synthetically Produced Omega-3 Products); List of FDA-Approved Omega-3 Ethyl Ester Drugs in the Orange Book, **Exhibit 17** (same). Thus, they are all "new drugs" – and indeed, *unapproved* "new drugs."

2. The other elements for false advertising and contributory false advertising under the Lanham Act are met

102. The Promotional Materials associated with all of the Synthetically Produced Omega-3 Products (except for those sold by Ultimate) indicate that the products are for use in, or as "dietary supplements," **Exhibits 1-B – 7-B, 8-A-ii – 12-M-ii**. As explained above, falsely labeling or promoting these products as "dietary supplements" is literally false for two reasons: (1) the products do not meet the definition of "dietary supplement" in 21 U.S.C. § 321(ff), and (2) calling the products "dietary supplements" hides the material fact that the products are actually unapproved "new drugs."

103. Because these statements are literally false, they have the capacity to deceive a substantial segment of potential consumers, and this deception is presumed to be material to consumer purchasing decisions. Indeed, the express use of a false moniker and the failure to disclose the unapproved "new drug" status of the products is undoubtedly material. If consumers knew that the products were illegally marketed unapproved "new drugs" and that, as such, it was unclear whether the products were safe and effective, it would influence the consumers' purchasing decisions.

104. All of the Proposed Respondents (except Ultimate) are causing the literally false statements to enter interstate commerce, **Exhibit 1-B – 7-B and 8-A-ii – 12-M-ii**. Finally, the

false statements of the Proposed Respondents (except Ultimate) about their products have injured, or are likely to injure, Amarin, as discussed in paragraphs 217-238.

105. Further, upon information and belief, as set forth in Section VII, Ultimate and Nordic Pharma Inc. are contributorily liable under the Lanham Act for knowingly inducing or causing the entities distributing their products, respectively, Nature's Bounty and Nordic Naturals, to falsely advertise their products as "dietary supplements," or for materially participating in that illegal conduct.

B. Proposed Respondents' Importation And Sale Of The Synthetically Produced Omega-3 Products Violate Section 337 Based On The Standards Set Forth In The FDCA

106. The importation and sale of the Proposed Respondents' Synthetically Produced Omega-3 Products constitute unfair acts or unfair methods of competition under Section 337 based upon the standards set forth in the FDCA. As discussed in paragraphs 61-83, none of Proposed Respondents' Synthetically Produced Omega-3 Products meets the definition of "dietary supplement" in the FDCA, 21 U.S.C. § 321(ff). In addition, as discussed in paragraphs 84-101, all of the products are actually unapproved "new drugs" under the FDCA. *Id.* §§ 321(g), (p), 355(a); *see also* 21 U.S.C. § 352(f). The introduction, or delivery for introduction, into interstate commerce of any unapproved "new drug" violates the standards set forth in Section 505(a) of the FDCA, *id.* § 355(a); *see also* 21 U.S.C. §§ 352(f), 331(a)-(c).

107. As explained in paragraphs 86-87, products that meet the definition of "drug" in the FDCA, *id.* § 321(g), must follow the requirements in the FDCA and its implementing regulations that apply to "drugs," regardless of whether FDA has acknowledged that the products are "drugs." As explained below, none of the Synthetically Produced Omega-3 Products follows

a number of these requirements, and as such, they are misbranded drugs in violation of the standards set forth in Section 502 of the FDCA, *id.* § 352, and adulterated drugs, in violation of Section 501 of the FDCA, *id.* § 351.

108. Section 502(a) of the FDCA prohibits "labeling" that is "false or misleading in any particular." *Id.* § 352(a); *see also* 21 U.S.C. § 321(m) (defining the term "labeling" as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article"). In addition, Section 502(n) of the FDCA similarly prohibits promotional material other than labeling from being false or misleading. 21 U.S.C. § 352(n); 21 C.F.R.§ 202.1(e)(6). The labeling for all of the Distributors' Synthetically Produced Omega-3 Products is false, at minimum, because it falsely asserts that the products are "dietary supplements," or it falsely implies that they are "dietary supplements" by using some modification of that term. **Exhibits 8-A-ii – 12-M-ii**. Similarly, the Promotional Materials associated with the Manufacturer's products (except for Ultimate's products) are false because they provide that the products at issue are for use in, or as "dietary supplements." **Exhibits 1-B – 7-B**.

109. Further, Section 502(f) of the FDCA provides that drugs are misbranded if their labeling fails to bear "adequate directions for use." 21 U.S.C. § 352(f). "Adequate directions for use" means "directions under which the layman can use a drug safely and for the purposes for which it is intended." 21 C.F.R. § 201.5. According to FDA,

> Prescription drugs can only be used safely at the direction, and under the supervision, of a licensed practitioner. Therefore, it is impossible to write "adequate directions for use" for prescription drugs. FDA-approved drugs which bear their FDA-approved labeling are exempt from the requirement that they bear adequate

> directions for use by a layperson. But otherwise, all prescription drugs by definition lack adequate directions for use by a layperson.

See, e.g., FDA Warning Letter to Flex Fitness Products and Big Dan's Fitness, dated May 25, 2017, **Exhibit 55** (citing 21 U.S.C. §§ 352(f)(1), 353(b)(2)). All of the Distributors' Synthetically Produced Omega-3 Products are "prescription drugs" as defined by the FDCA, 21 U.S.C. § 353(b)(1)(A), because of their toxicity or other potentiality for harmful effect, or the method of their use, or the collateral measures necessary for their use. *See id.* Indeed, all products containing synthetically produced omega-3 that have been approved by FDA are prescription drugs. *See* List of FDA-Approved Icosapent Ethyl (E-EPA) Drugs in Orange Book, **Exhibit 16**; List of FDA-Approved Omega-3 Ethyl Ester Drugs in the Orange Book, **Exhibit 17**. As explained in paragraphs 84-101, all of the Distributors' Synthetically Produced Omega-3 Products are intended for "drug" uses (*i.e.,* to affect the structure/function of the body and/or to affect disease), **Exhibits 8-A-iii – 12-M-iii, 8-A-iv – 12-M-iv**; **Table 1**. Those uses have not been approved by FDA, and therefore, the labeling for the products at issue does not, and cannot, contain adequate directions for those uses. Accordingly, those products are misbranded in violation of Section 502(f).

110. Further, upon information and belief, all of the Synthetically Produced Omega-3 Products are misbranded drugs under Section 502(o) of the FDCA because they were manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under Section 510 of the FDCA, *id.* § 360; and/or the products at issue were not included in a list as required by Section 510(j) of the FDCA, *id.* § 360(j). *Id.* § 352(o).

111. In addition, upon information and belief, all of the Synthetically Produced Omega-3 Products are adulterated for failure to comply with current good manufacturing

practices for drugs, in violation of the standards set forth in Section 501(a)(2)(B) of the FDCA, 21 U.S.C. § 351(a)(2)(B).

112. The introduction, or delivery for introduction, into interstate commerce of any unapproved "new drug" that violates Section 505(a) of the FDCA, and/or any adulterated or misbranded drug that violates Sections 501 and/or 502 of the FDCA, is prohibited by Section 301(d) and (a) of the FDCA. *Id.* § 331(a), (d).

113. Finally, the FDCA prohibits unapproved "new drugs," and adulterated and misbranded "drugs," from entering the United States under Section 801(a) of the FDCA, 21 U.S.C. § 381(a), when the "drugs" have been manufactured, prepared, propagated, compounded, or processed in a foreign establishment that is not registered in accordance with Section 510(i) of the FDCA. Upon information and belief all of the products sold by the Manufacturers were manufactured, prepared, propagated, compounded, or processed in such a foreign establishment. Section 801(a) requires FDA to (1) sample any drugs that have been manufactured in an unregistered establishment, and (2) examine samples to determine whether any appear to be misbranded, adulterated, or unapproved new drugs. *See Cook v. FDA*, 733 F.3d 1, 10 (D.C. Cir. 2013). If FDA finds an apparent FDCA violation (*e.g.*, that a product is an unapproved, misbranded, and adulterated "new drug"), it must refuse the drug admission to the United States. *See id.*

VII. INSTANCES OF UNFAIR IMPORTATION AND SALE

A. Manufacturers

DSM

114. Proposed Respondent Royal DSM NV ("DSM NV") and its corporate affiliates, DSM Marine Lipids Peru S.A.C. ("DSM-Peru"), DSM Nutritional Products Canada Inc., ("DSM-Canada") and "DSM Nutritional Products LLC" in the United States ("DSM-US") manufacture, import, and/or sell Synthetically Produced Omega-3 Products. Royal DSM NV acquired a fish oil concentration facility in Nova Scotia, Canada in 2012, to "strengthen its position in the North American dietary supplement market." Koninklijke DSM NV to Acquire Ocean Nutrition Canada to Expand Its Nutritional Lipids Growth Platform Conference Call – Final, May 18, 2012 FDA (Fair Disclosure) Wire, **Exhibit 65**. Upon information and belief, this facility is now DSM-Canada. At the time of acquisition, the facility manufactured fish oil concentrates of up to 70% EPA/DHA levels, and those supplements were sold in "Walmart, GNC, and Sam's Club." *Id.* Since that time, DSM has begun to use 3C technology, a new concentrating technology, to make "[u]ltra-pure, high potency EPA and DHA up to 85%," and it continues to manufacture those oils at the Nova Scotia facility. *See* The Modern Movement Forward In Omega-3, DSM Brochure, **Exhibit 66**; Meg-3, Business Opportunities, Accessed Aug. 8, 2017 ("DSM's flagship fish oil production facility is located in Mulgrave, Nova Scotia. In 2015, DSM invested $40 million to expand the facility, which refines and concentrates Omega-3 fish oil"), **Exhibit 67.** In April 2017, World Fishing & Aquaculture announced that DSM's Meg-3 ingredients "processed in DSM's facilities in Peru and Canada (DSM Marine Lipids Peru SAC and DSM Nutritional Products Canada Ltd [sic])," received a Friend of the Sea

seal of approval, and the article noted that Meg-3 is a "leading global brand containing omega-3 EPA and DHA. The ingredients are used in dietary supplement, pharmaceutical and food & beverage applications worldwide." World Fishing & Aquaculture, April 20, 2017, **Exhibit 68**. DSM also advertises Meg-3 as conforming to the quality and purity standards established for dietary supplements by the U.S. FDA. Meg-3, Business Opportunities, **Exhibit 67**. The Meg-3 product line sold by DSM includes E-OM3 concentrates and concentrates in the triglyceride form (upon information and belief, these concentrates are rTG-OM3 and rTG-EPA). *See* DSM in Food, Beverages & Dietary Supplements, **Exhibit 1-A-i**. Upon information and belief, DSM-Peru and DSM-Canada are manufacturing Meg-3 products that are Synthetically Produced Omega-3 Products, including E-OM3 oil and rTG-OM3 oil comprised predominantly of E-EPA or rTG-EPA.

115. Complainants have obtained data from Datamyne, Inc.[2] showing that DSM-Peru shipped to the United States, to DSM-US, "240 drums containing 45.60 MT of omega3T1000 [and] Meg-3 refined fish oil." **Exhibits 1-F-i.** Upon information and belief, DSM-Peru is supplying DSM-US with E-OM3 oil and/or rTG-OM3 oil comprised predominantly of E-EPA or rTG-EPA. In addition, DSM-Peru imported 191 MT of purified fish oil into the United States in bond for immediate export to consignee DSM-Canada. **Exhibit 1-F-i.** Based on the commercial relationships described above, DSM-Canada's concentrated production facility in Nova Scotia, and DSM-Canada's "focus on the North American Market" described in paragraph 114 above, and upon information and belief, DSM-Canada is supplying those products to DSM-US.

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[2] Datamyne, Inc. obtains trade data gathered from U.S. Customs and Border Protection's Automated Manifest System, customs declarations, and import-export Customs statistics. U.S. shipment data are updated daily upon receipt from U.S. Customs and Border Protection.

116. DSM violates Section 337 of the Tariff Act, because it violates the standards established in the FDCA. Specifically, the E-OM3 sold by DSM cannot meet the definition of "dietary supplement" because it is not a "dietary ingredient," 21 U.S.C. § 321(ff)(1), as explained in paragraphs 61-70, and it is excluded from the definition of "dietary supplement" by the exclusionary clause, *id.* § 321(ff)(3), as explained in paragraphs 71-83. As further explained in paragraph 95, it is a "drug" because, upon information and belief, it is a drug recognized in the USP/NF, **Exhibit 64**. It also is a "drug" because it is intended to affect the structure/function of the body and to affect disease, as evidenced by, among other things, structure/function and disease promotional claims made by DSM. For example, DSM makes the following structure/function claims: "Omega-3 fatty acids play a critical role in supporting human health across different stages. DHA . . . provides important brain and eye benefits, while DHA and EPA . . . together promote cardiovascular health." **Exhibit 1-C-i**; **Table 2**. In addition, DSM makes the following disease claims:

> The omega-3s EPA and DHA have been the focus of cardiovascular research for several decades. Numerous observational and randomized clinical trials have shown EPA/DHA intake reduces cardiovascular risk via reduction in blood triglycerides (TGs), resting heart rate, blood pressure and inflammation and improved vascular function. The strongest evidence for EPA/DHA is for reduction of coronary heart disease (CHD) death and sudden cardiac death (SCD), with the latter being attributed to the antiarrhythmic effects of omega-3s.

Exhibit 1-D-i; **Table 2**. As explained in paragraphs 100-101, this product is also an unapproved "new drug" under the FDCA. *Id.* §§ 321(g), (p), 355(a).

117. Similarly, the rTG-OM3 oil sold by DSM cannot meet the definition of "dietary supplement" because it is not a "dietary ingredient," 21 U.S.C. § 321(ff)(1), as explained in

paragraphs 61-83. As further explained in paragraphs 98-99, it is a drug because it is intended to affect the structure/function of the body and to affect disease, as evidenced by, among other things, the structure/function and disease claims identified in paragraph 116, above. As explained in paragraphs 100-101, this product is also an unapproved "new drug" under the FDCA. *Id.* §§ 321(g), (p), 355(a).

118. In addition, DSM's E-OM3 and rTG-OM3 oil are (1) falsely promoted for use in "dietary supplements" when they cannot legally be used for that purpose, and they are actually unapproved "new drugs," in violation of Section 502(n) of the FDCA, *id.* § 352(n), **Exhibits 1-B-i – 1-B-iii**; (2) upon information and belief, as explained in paragraph 110, misbranded drugs under Section 502(o) of the FDCA, *id.* § 352(o), because they were manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under Section 510 of the FDCA, *id.* § 360; and/or not included in a list as required by Section 510(j) of the FDCA, *id.* § 360(j); and (3) upon information and belief, as explained in paragraph 111, adulterated drugs because they were not manufactured in compliance with current good manufacturing practices for drugs, in violation of Section 501(a)(2)(B) of the FDCA, 21 U.S.C. § 351(a)(2)(B).

119. DSM also violates the standard set forth in Section 301 of the FDCA. Section 301 of the FDCA prohibits the introduction, or delivery for introduction, into interstate commerce of any unapproved "new drug" that violates Section 505(a) of the FDCA, and/or any adulterated or misbranded drug that violates Sections 501 and/or 502 of the FDCA. *Id.* § 331(a), (d).

120. In addition, DSM violates Section 337 of the Tariff Act, based upon violations of the Lanham Act. Specifically, DSM is falsely stating that its E-OM3 oil and its rTG-OM3 oil

can be used in "dietary supplements" when these products are actually unapproved "new drugs," **Exhibits 1-B-i – 1-B-iii**; these literally false statements have the capacity to deceive customers and are likely to influence purchasing decisions; DSM caused these false statements to enter interstate commerce; and as discussed in paragraphs 217-238, Amarin is likely to be injured as a result.

Ultimate BioPharma

121. Proposed Respondent Ultimate Biopharma (Zhongshan) Corporation ("Ultimate") is a Chinese company that manufactures softgel capsules containing E-OM3 and OM3 in triglyceride form, **Exhibit 2-A**. Upon information and belief, some, if not all, of the OM3 in triglyceride form is rTG-OM3 comprised predominantly of rTG-EPA.

122. **Exhibit 2-F** contains 30 Datamyne documents showing 29 shipments of fish oil (labeled, 2100 Fish Oil, 2340 Fish Oil, 2099 Fish Oil, 2370 Fish Oil, and 2333 Fish Oil), and one shipment of 2340 Fish Oil Softgels, from Ultimate to Nature's Bounty between September 15, 2016 – February 11, 2017. Upon information and belief, Ultimate is shipping E-OM3 comprised predominantly of E-EPA and rTG-OM3 comprised predominantly of rTG-EPA in oil and softgel form to Nature's Bounty.

123. As discussed in paragraphs 163-173 below, Proposed Respondent Nature's Bounty is a U.S. importer and distributor of Synthetically Produced Omega-3 Products under brand names Nature's Bounty®, Puritan's Pride®, and Solgar®, **Exhibit 2-E-i**. Nature's Bounty was the consignee on the import shipments described in paragraph 122 above. **Exhibit 2-F**. Ultimate is a subsidiary or affiliate of Nature's Bounty. **Exhibit 2-E-ii**.

124. Ultimate violates Section 337 of the Tariff Act, because it violates the standards set forth in the FDCA. Specifically, the E-OM3 oil and capsules sold by Ultimate cannot meet the definition of "dietary supplement" because E-OM3 is not a "dietary ingredient," 21 U.S.C. § 321(ff)(1), as explained in paragraphs 61-71, and it is excluded from the definition of "dietary supplement" by the exclusionary clause, *id.* § 321(ff)(3), as explained in paragraphs 71-83. As further explained in paragraphs 92 and 95, both the E-OM3 oil and capsules are "drugs" because, upon information and belief, they are drugs recognized in the USP/NF. **Exhibits 62 and 64**. Ultimate's E-OM3 capsules and oil are also drugs because, upon information and belief, as explained in paragraphs 94 and 97, they are intended for use in, or as, a final product that is a "drug" (*e.g.*, Nature's Bounty purported "dietary supplements," which are actually unapproved "new drugs"). **Exhibits 8-A-ii – 8-N-ii**; **Table 4**. As explained in paragraphs 100-101, these products are also unapproved "new drugs" under the FDCA. *Id.* §§ 321(g), (p), 355(a).

125. Similarly, the rTG-OM3 oil and capsules sold by Ultimate cannot meet the definition of "dietary supplement" because rTG-OM3 is not a "dietary ingredient," 21 U.S.C. § 321(ff)(1), as explained in paragraphs 61-71. Rather, Ultimate's rTG-OM3 oil and capsules are drugs because, upon information and belief, the rTG oil and capsules are intended for use in (or as) a final product that is a "drug" (*e.g.*, Nature's Bounty purported "dietary supplements," which are actually unapproved "new drugs"). **Exhibits 8-A-ii – 8-N-ii**; **Table 4**. As explained in paragraphs 100-101, these products are also unapproved "new drugs" under the FDCA. *Id.* §§ 321(g), (p), 355(a).

126. In addition, upon information and belief, Ultimate's E-OM3 oil and capsules are (1) as explained in paragraph 110, misbranded drugs under Section 502(o) of the FDCA, *id.* §

352(o), because they were manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under Section 510 of the FDCA, *id.* § 360; and/or not included in a list as required by Section 510(j) of the FDCA, *id.* § 360(j); and (2) upon information and belief, as explained in paragraph 111, adulterated drugs because they were not manufactured in compliance with current good manufacturing practices for drugs, as required by Section 501(a)(2)(B) of the FDCA, 21 U.S.C. § 351(a)(2)(B).

127. Ultimate also violates the standard set forth in Section 301 of the FDCA. Section 301 of the FDCA prohibits the introduction, or delivery for introduction, into interstate commerce of any unapproved "new drug" that violates Section 505(a) of the FDCA, and/or any adulterated or misbranded drug that violates Sections 501 and/or 502 of the FDCA. *Id.* § 331(a), (d).

128. In addition, Ultimate violates Section 337 of the Tariff Act, predicated upon violations of the provisions of the Lanham Act. Specifically, Ultimate is liable for contributory false advertising because Nature's Bounty is engaged in false advertising, as explained in paragraphs 163-173, and upon information and belief, Ultimate knowingly induced or caused that false advertising or otherwise materially participated in it.

Marine Ingredients

129. Marine Ingredients is a KD Pharma Group Company. **Exhibit 69**. Proposed Respondent Marine Ingredients AS is a manufacturer of Synthetically Produced Omega-3 Products. Complainants have obtained data from Datamyne, Inc. showing that Marine Ingredients AS, in Norway, shipped to Marine Ingredients LLC, in the United States: 17.06 metric tons of oil, including "Omevital 400200 EE Mix" and "Omevital 3322 EE," around July

23, 2017; in two separate shipments, 17.06 metric tons of oil (in each shipment), including "Omevital 400200 EE Mix," "Omevital 3322 EE," "4510 TG Ultra," and "Omevital 3322 TG," around July 17, 2017; 17.06 metric tons of oil, including "Omevital 4510 TG Ultra" and "Omevital 3322EE" in June 2017; and 22 Drums of "Omevital 3322 EE," in December 2016, **Exhibit 3-F-i**. Omevital 3322EE and Omevital 400200 EE are E-OM3, **Exhibit 3-F-i**, and upon information and belief, Omevital 4510 TG Ultra is rTG-OM3. *See id.* Thus, E-OM3 oils comprised predominantly of E-EPA and rTG-OM3 oils comprised predominantly of rTG-EPA are being imported into the United States from Marine Ingredients AS to Marine Ingredients LLC.

130. Proposed Respondent Marine Ingredients LLC is a U.S. importer of Synthetically Produced Omega-3 Products. Marine Ingredients LLC was the consignee on the import shipment described in paragraph 129 above. **Exhibit 3-F-i**. Marine Ingredients LLC markets its Synthetically Produced Omega-3 Products under the brand "Omevital." **Exhibit 3-A-i**. These products include E-OM3 oil comprised predominantly of E-EPA, and upon information and belief, they include rTG-OM3 oil comprised predominantly rTG-EPA as well. *See id.* Marine Ingredients LLC acquired BASF's concentrated fish oil production facility in 2014, which produces "Omevital" brand Synthetically Produced Omega-3 Products, and it merged with KD Pharma in 2016. **Exhibit 3-E-i**. Marine Ingredients AS is a subsidiary of Marine Ingredients LLC. **Exhibit 3-E-ii**.

131. Marine Ingredients violates Section 337 of the Tariff Act, because it violates certain standards in the FDCA. Specifically, the E-OM3 oil sold by Marine Ingredients cannot meet the definition of "dietary supplement" because E-OM3 is not a "dietary ingredient," 21

U.S.C. § 321(ff)(1), as explained in paragraphs 61-71, and it is excluded from the definition of "dietary supplement" by the exclusionary clause, *id.* § 321(ff)(3), as explained in paragraphs 71-83. In addition, as explained in paragraph 95, it is a "drug" because, upon information and belief, it is a drug recognized in the USP/NF, **Exhibit 64**. It also is a "drug" because it is intended to affect the structure/function of the body and to affect disease, as evidenced by, among other things, structure/function and disease promotional claims made by Marine Ingredients. Marine Ingredients' structure/function claims include the following:

> Together EPA & DHA play a critical role in our cell development, growth, and maintenance . . . [they] are necessary for several important body functions, such as •Essential building blocks for our brain, eyes, and nerves . . . • Building cell membrane [sic] in our brain . . . • Maintenance of normal brain function . . . . More than 20,000 clinical studies showing positive health benefits have been conducted on Omega-3 EPA & DHA.

Exhibit 3-C-ii; Table 2. In addition, Marine Ingredients' disease claims include:

> More than 20,000 clinical studies showing positive health benefits have been conducted on Omega-3 EPA & DHA. Many of these studies indicate that these vital nutrients may be of importance by themselves or in combination with other drugs for the management of the following disorders: • Cardiovascular Disease, • Inflammation and Rheumatoid Arthritis, • Developmental Disorders, • Psychiatric Disorders, •Cognitive Aging, • Coronary Heart Disease, • Lupus, • Cancer.

Exhibit 3-D-ii, **Table 2**. As explained in paragraphs 100-101, this product is also an unapproved "new drug" under the FDCA. *Id.* §§ 321(g), (p), 355(a).

132. Similarly, the rTG-OM3 oil sold by Marine Ingredients cannot meet the definition of "dietary supplement" because it is not a "dietary ingredient," 21 U.S.C. § 321(ff)(1), as explained in paragraphs 61-71. It also is a "drug" because it is intended to affect the structure/function of the body and to affect disease, as evidenced by, among other things, the

same structure/function and disease claims cited above. As explained in paragraphs 100-101, this product is also an unapproved "new drug" under the FDCA. *Id.* §§ 321(g), (p), 355(a).

133. In addition, Marine Ingredients' E-OM3 oil and rTG-OM3 oil are (1) falsely promoted for use in "dietary supplements" when they cannot legally be used for that purpose and they are actually unapproved "new drugs," in violation of the standards set forth in Section 502(n) of the FDCA, *id.* § 352(n), **Exhibits 3-B-i – 3-B-iv**; (2) upon information and belief, as explained in paragraph 110, misbranded drugs under Section 502(o) of the FDCA, *id.* § 352(o), because they were manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under Section 510 of the FDCA, *id.* § 360; and/or not included in a list as required by Section 510(j) of the FDCA, *id.* § 360(j); and (3) upon information and belief, as explained in paragraph 110, adulterated drugs because they were not manufactured in compliance with current good manufacturing practices for drugs, as required by Section 501(a)(2)(B) of the FDCA, 21 U.S.C. § 351(a)(2)(B).

134. Marine Ingredients also violates the standard set forth in Section 301 of the FDCA. Section 301 of the FDCA prohibits the introduction, or delivery for introduction, into interstate commerce of any unapproved "new drug" that violates Section 505(a) of the FDCA, and/or any adulterated or misbranded drug that violates Sections 501 and/or 502 of the FDCA. *Id.* § 331(a), (d).

135. In addition, Marine Ingredients violates Section 337 of the Tariff Act, because it violates the Lanham Act. Specifically, Marine Ingredients is falsely stating that its E-OM3 oil and rTG-OM3 oil can be used in "dietary supplements" when these products are actually unapproved "new drugs" **Exhibits 3-B-i – 3-B-iv**. These literally false statements have the

capacity to deceive consumers and are likely to influence purchasing decisions; Marine Ingredients caused these false statements to enter interstate commerce; and as discussed in paragraphs 216-237, Amarin is likely to be injured as a result.

Golden Omega

136. Proposed Respondent Golden Omega S.A. is a manufacturer of Synthetically Produced Omega-3 Products. Complainants have obtained data from Datamyne, Inc. showing that Golden Omega S.A. shipped to the United States 6.84 metric tons of "Fish Oil Omega-3 Concentrate Ethyl Ester (EE3322)," 6.84 metric tons of Fish Oil Omega-3 Concentrate Ethyl Ester (EE4020)," and 1.52 metric tons of "Fish Oil Omega-3 Concentrate Triglyceride (TG3624)" in October 2016. **Exhibit 4-F-i**. Proposed Respondent Golden Omega USA LLC is a U.S. importer of Synthetically Produced Omega-3 Products. In particular, it was the consignee on the import shipments described above. **Exhibit 4-F-i**. Golden Omega S.A. and Golden Omega USA LLC are affiliated entities. **Exhibit 4-E**.

137. Golden Omega identifies "EE3322" as a "balanced EPA+DHA EE concentrate" **Exhibit 4-A-iii**, "TG3624 as a balanced EPA+DHA TG concentrate," **Exhibit 4-A-iii**, and "EE4020" as a "high EPA EE concentrate" **Exhibit 4-A-iv**. The "EE," or E-OM3, products are Synthetically Produced Omega-3 Products, and upon information and belief the concentrated TG product is rTG-OM3.

138. Golden Omega violates Section 337 of the Tariff Act, because it violates certain standards of the FDCA. Specifically, the E-OM3 oil sold by Golden Omega cannot meet the definition of "dietary supplement" because it is not a "dietary ingredient," 21 U.S.C. § 321(ff)(1), as explained in paragraphs 61-71, and it is excluded from the definition of "dietary

supplement" by the exclusionary clause, *id.* § 321(ff)(3), as explained in paragraphs 71-83. In addition, as explained in paragraph 95, it is a "drug" because, upon information and belief, it is a drug recognized in the USP/NF, **Exhibit 64**. It also is a "drug" because it is intended to affect the structure/function of the body and to affect disease, as evidenced by, among other things, structure/function and disease promotional claims made by Golden Omega. For example, Golden Omega's structure/function claims include:

> Omega 3s and specifically EPA and DHA, are involved in the structure and function of cells in your body – from your head to your toes. There are more than 30,000 published studies on EPA and DHA Omega 3s, focused on the positive impact that the high consumption of Omega 3s has for the health of the heart, brain, and eye.

Exhibit 4-C-i; **Table 2.** In addition, disease claims include the following: "High EPA Omega-3 concentrates are commonly used in products to support . . . anti-inflammatory health." **Exhibit 4-D**; **Table 2**. As explained in paragraphs 100-101, this product is also an unapproved "new drug" under the FDCA. *Id.* §§ 321(g), (p), 355(a).

139. Similarly, rTG-OM3 oil sold by Golden Omega cannot meet the definition of "dietary supplement" because it is not a "dietary ingredient," 21 U.S.C. § 321(ff)(1), as explained in paragraphs 61-71. It also is a "drug" because it is intended to affect the structure/function of the body and to affect disease, as evidenced by, among other things, the same structure/function and disease claims cited in the paragraph above. As explained in paragraphs 100-101, this product is also an unapproved "new drug" under the FDCA. *Id.* §§ 321(g), (p), 355(a).

140. In addition, Golden Omega's E-OM3 oil and its rTG-OM3 oil are (1) falsely promoted for use in "dietary supplements" when they cannot legally be used for that purpose,

and they are actually unapproved "new drugs," in violation of Section 502(n) of the FDCA, *id.* § 352(n), **Exhibits 4-B-i – 4-B-iv**; (2) upon information and belief, as explained in paragraph 1109, misbranded drugs under Section 502(o) of the FDCA, *id.* § 352(o), because they were manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under Section 510 of the FDCA, *id.* § 360; and/or not included in a list as required by Section 510(j) of the FDCA, *id.* § 360(j); and (3) upon information and belief, as explained in paragraph 111, adulterated drugs because they were not manufactured in compliance with current good manufacturing practices for drugs, as required by Section 501(a)(2)(B) of the FDCA, 21 U.S.C. § 351(a)(2)(B).

141. Golden Omega also violates the standard set forth in Section 301 of the FDCA. Section 301 of the FDCA prohibits the introduction, or delivery for introduction, into interstate commerce of any unapproved "new drug" that violates Section 505(a) of the FDCA, and/or any adulterated or misbranded drug that violates Sections 501 and/or 502 of the FDCA. *Id.* § 331(a), (d).

142. In addition, Golden Omega violates Section 337 of the Tariff Act, because it violates the Lanham Act. Specifically, Golden Omega is falsely stating that its E-OM3 oil and its rTG-OM3 oil can be used in "dietary supplements" when these products are actually unapproved "new drugs" **Exhibits 4-B-i – 4-B-iv**; these literally false statements have the capacity to deceive consumers and are likely to influence purchasing decisions; Golden Omega caused these false statements to enter interstate commerce; and as discussed in paragraphs 217-238, Amarin is likely to be injured as a result.

Nordic Pharma

143. Proposed Respondent Nordic Pharma, Inc. ("Nordic Pharma") is a manufacturer of Synthetically Produced Omega-3 Products. Complainants have obtained data from Datamyne, Inc., that show that Nordic Pharma imported into the United States: "Fish Oil, TG90 2050" on or about July 30, 2017; "Fish Oil TG90 3525" also on or about July 30, 2017; "Fish Oil TG90 3525" on or about May 19, 2017; "Fish Oil TG90 3525" and "Fish Oil TG 2050" on or about May 7, 2017; and "Fish Oil TG90 4020 80 drums" and "Fish Oil TG90 3525 37 Drums" in December 2016. **Exhibit 5-F**. Nordic Pharma is "exclusively dedicated to manufacturing Nordic Naturals omega oils" and the company is "privately owned by Nordic Naturals." **Exhibit 5-E**. Nordic Naturals, as explained in paragraphs 174-181, sells a large number of concentrated omega-3 products in triglyceride form. Upon information and belief, the products sold by Nordic Naturals and the products referenced in Datamyne, Inc. are rTG-OM3 oil comprised predominantly of rTG-EPA.

144. Nordic Pharma violates Section 337 of the Tariff Act, because it violates certain standards of the FDCA. The rTG-OM3 oil sold by Nordic Pharma cannot meet the definition of "dietary supplement" because it is not a "dietary ingredient," 21 U.S.C. § 321(ff)(1), as explained in paragraphs 61-71. Rather Nordic Pharma's rTG-OM3 oil is a drug because, as explained in paragraph 99, upon information and belief, the rTG-OM3 oil is intended for use in a final product that is a "drug" (*e.g.*, the purported "dietary supplements" sold by Nordic Naturals that are actually unapproved "new drugs"). **Exhibits 9-A-ii – 9-UU-ii**. As explained in paragraphs 100-101, these products are also unapproved "new drugs" under the FDCA. *Id.* §§ 321(g), (p), 355(a).

145. In addition, Nordic Pharma's rTG-OM3 oil is (1) falsely promoted for use in "dietary supplements" when it cannot legally be used for that purpose and it is actually an unapproved "new drug," in violation of the standards set forth in Section 502(n) of the FDCA, *id.* § 352(n), **Exhibits 9-A-ii – 9-UU-ii**; (2) upon information and belief, as explained in paragraph 110 a misbranded drug under Section 502(o) of the FDCA, *id.* § 352(o), because it was manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under Section 510 of the FDCA, *id.* § 360; and/or not included in a list as required by Section 510(j) of the FDCA, *id.* § 360(j); and (3) upon information and belief, as explained in paragraph 111, an adulterated drug because it was not manufactured in compliance with current good manufacturing practices for drugs, in violation of the standards set forth in Section 501(a)(2)(B) of the FDCA, 21 U.S.C. § 351(a)(2)(B).

146. Nordic Pharma also violates the standard set forth in Section 301 of the FDCA. Section 301 of the FDCA prohibits the introduction, or delivery for introduction, into interstate commerce of any unapproved "new drug" that violates Section 505(a) of the FDCA, and/or any adulterated or misbranded drug that violates Sections 501 and/or 502 of the FDCA. *Id.* § 331(a), (d).

147. In addition, Nordic Pharma violates Section 337 of the Tariff Act, because it violates the Lanham Act. Specifically, Nordic Pharma is liable for contributory false advertising because Nordic Naturals is engaged in false advertising, as explained in paragraphs 174-181, and upon information and belief, Nordic Pharma knowingly induced or caused that false advertising or otherwise materially participated in it.

Croda

148. Proposed Respondent Croda Europe Ltd. is a manufacturer of Synthetically Produced Omega-3 Products. Complainants have obtained data from Datamyne, Inc. showing that Croda Europe Ltd. shipped to the United States: 13.6 metric tons of oil, including TG 3322, in March 2017; 17.29 metric tons of "Crodamol/Incromega" in January 2017; 16.08 metric tons of Incromega E3322-LQ in August 2016; and 16.07 metric tons of oil including Incromega E3322-LQ in May 2016. **Exhibit 6-F.**

149. Proposed Respondent Croda Inc. is a U.S. importer of Synthetically Produced Omega-3 Products. In particular, it was the consignee on the import shipment described in paragraph 148 above. **Exhibit 6-F**. Croda Europe Ltd. and Croda Inc. are affiliated entities, namely "[r]elated undertakings" of Croda International Plc. **Exhibit 6-E-i**.

150. Croda's Promotional Materials identify "Incromega" as the name for a number of fish oils, including fish oil concentrates that are produced using PureMax™ technology. **Exhibit 6-A-i**. Incromega products include a number of E-OM3 products and concentrated OM3 products in triglyceride form. **Exhibit 6-A-ii**. Upon information and belief, these E-OM3 products and concentrated OM3 products in triglyceride form are among the Incromega products imported into the United States.

151. Croda violates Section 337 of the Tariff Act, because it violates certain standards in the FDCA. Specifically, the E-OM3 oil sold by Croda cannot meet the definition of "dietary supplement" because it is not a "dietary ingredient," 21 U.S.C. § 321(ff)(1), as explained in paragraphs 61-71, and it is excluded from the definition of "dietary supplement" by the exclusionary clause, *id.* § 321(ff)(3), as explained in paragraphs 71-83. In addition, as explained

in paragraph 95, it is a "drug" because, upon information and belief, it is a drug recognized in the USP/NF. **Exhibit 64**. It is also a drug because it is intended to affect the structure/function of the body and to affect disease, as evidenced by, among other things, structure/function and disease promotional claims made by Croda. For example, structure/function claims include "Croda's Incromega™ range offers many possibilities for consumer health trends having clear benefits in numerous condition specific areas such as heart health, joint health, cognitive function, and eye health." **Exhibit 6-C-i**; **Table 2**. In addition, disease claims include "EPA can be beneficial for • Depression, • Inflammatory and autoimmune conditions," "Studies reveal that essential Omega 3 fats help reduce the brain inflammation associated with cognitive decline, which can harm brain cells," "Accumulating evidence suggests that diets that include Omega 3 fatty acids, specifically . . . [EPA and DHA] also protect against the development of dementia and Alzheimer's." **Exhibits 6-D-i and 6-D-iii; Table 2**. As explained in paragraphs 100-101, this product is also an unapproved "new drug" under the FDCA. *Id.* §§ 321(g), (p), 355(a).

152. Similarly, the rTG-OM3 oil sold by Croda cannot meet the definition of "dietary supplement" because it is not a "dietary ingredient," 21 U.S.C. § 321(ff)(1), as explained in paragraphs 61-71. Rather, it is a drug because it is intended to affect the structure/function of the body and to affect disease, as evidenced by, among other things, the same promotional claims cited above. As explained in paragraphs 100-101, this product is also an unapproved "new drug" under the FDCA. *Id.* §§ 321(g), (p), 355(a).

153. In addition, Croda's E-OM3 oil and its rTG-OM3 oil are (1) falsely promoted for use in "dietary supplements" when they cannot legally be used for that purpose and they are actually unapproved "new drugs," in violation of the standards set forth in Section 502(n) of the

FDCA, *id.* § 352(n), **Exhibits 6-B-i – 6-B-iv**; (2) upon information and belief, as explained in paragraph 110, misbranded drugs under Section 502(o) of the FDCA, *id.* § 352(o), because they were manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under Section 510 of the FDCA, *id.* § 360; and/or not included in a list as required by Section 510(j) of the FDCA, *id.* § 360(j); and (3) upon information and belief, as explained in paragraph 111, adulterated drugs because they were not manufactured in compliance with current good manufacturing practices for drugs, in violation of the standards set forth in Section 501(a)(2)(B) of the FDCA, 21 U.S.C. § 351(a)(2)(B).).

154. Croda also violates the standard set forth in Section 301 of the FDCA. Section 301 of the FDCA prohibits the introduction, or delivery for introduction, into interstate commerce of any unapproved "new drug" that violates Section 505(a) of the FDCA, and/or any adulterated or misbranded drug that violates Sections 501 and/or 502 of the FDCA. *Id.* § 331(a), (d).

155. In addition, Croda violates Section 337 of the Tariff Act, because it violates the provisions of the Lanham Act. Specifically, Croda is falsely stating that its E-OM3 oil and its rTG-OM3 oil can be used in "dietary supplements," **Exhibits 6-B-i – 6-B-iv**, when these products are actually unapproved "new drugs"; these literally false statements have the capacity to deceive consumers and are likely to influence purchasing decisions; Croda caused these false statements to enter interstate commerce; and as discussed in paragraphs 217-238, Amarin is likely to be injured as a result.

TASA

156. Proposed Respondent Tecnologica de Alimentos S.A. ("TASA") is a manufacturer of Synthetically Produced Omega-3 Products. Complainants have obtained data from Datamyne, Inc. showing that TASA shipped to the United States 16.61 metric tons of oil, including "Concentrate Omega 3 EE 33/22" on or about July 17, 2017; 32.37 metric tons of oil, including "Omega 3 Fish Oil EE 33-22," on or about July 6, 2017; 17.10 metric tons of oil, including "Omega 3 Fish Oil EE 33-22" on or about June 7, 2017; 16.23 metric tons of oil, including "Fish Oil EE 33-22" on or about May 15, 2017; and 80 drums of "Peruvian Refined Anchovy Omega 3 Fish Oil EE 33-22" in March 2017. **Exhibits 7-F-i**.

157. According to Promotional Materials on TASA's website, TASA "offer[s] . . . Omega-3 concentrates according to the needs of our customers with different concentration levels of EE and TG." **Exhibits 7-A-i**. "EE" stands for "ethyl esters," or E-OM3, **Exhibit 7-A-i**, and, upon information and belief "TG" stands for rTG-OM3. *See id.*

158. TASA violates Section 337 of the Tariff Act, because it violates certain standards in the FDCA. Specifically, the E-OM3 oil sold by TASA cannot meet the definition of "dietary supplement" because it is not a "dietary ingredient," 21 U.S.C. § 321(ff)(1), as explained in paragraphs 61-71, and it is excluded from the definition of "dietary supplement" by the exclusionary clause, *id.* § 321(ff)(3), as explained in paragraphs 71-83. In addition, as explained in paragraph 95, it is a "drug" because, upon information and belief, it is a drug recognized in the USP/NF. **Exhibit 64**. It is also a drug because it is intended to affect the structure/function of the body and to affect disease, as evidenced by, among other things, structure/function and disease promotional claims made by TASA. For example, TASA's structure/function claims

include the following: "HIGH Omega levels are related to speed improvements IN TEENS . . . . The study indicates that the 1% increase in the Omega-3 Index I related to an increase of 1.23 in the substitution test (LDST)." **Exhibit 7-C**; **Table 2**. In addition, TASA's disease claims include:

> Low Omega-3 consumption CONTRIBUTES to increased death rate . . . . The risk-of-morbidity study (GBD 2013), which quantifies threats to the health of the population and opportunities for prevention, concludes that low levels of omega-3 intake may increase the risk of disease . . .

Exhibit 7-D-i; **Table 2**. As explained in paragraphs 100-101, this product is also an unapproved "new drug" under the FDCA. *Id.* §§ 321(g), (p), 355(a).

159. Similarly, rTG-OM3 oil sold by TASA cannot meet the definition of "dietary supplement" because it is not a "dietary ingredient," 21 U.S.C. § 321(ff)(1), as explained in paragraphs 61-71. Rather, it is a drug because it is intended to affect the structure/function of the body and to affect disease, as evidenced by, among other things, the same structure/function and disease promotional claims made by TASA cited above. As explained in paragraphs 100-101, this product is also an unapproved "new drug" under the FDCA. *Id.* §§ 321(g), (p), 355(a).

160. In addition, TASA's E-OM3 oil and its rTG-OM3 oil are (1) falsely promoted for use in "dietary supplements," by TASA, when they cannot legally be used for that purpose and they are actually unapproved "new drugs," in violation of the standards set forth in Section 502(n) of the FDCA, *id.* § 352(n), **Exhibits 7-B-i – 7-B-ii**; (2) upon information and belief, as explained in paragraph 110, misbranded drugs under Section 502(o) of the FDCA, *id.* § 352(o), because they were manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under Section 510 of the FDCA, *id.* § 360; and/or not included

in a list as required by Section 510(j) of the FDCA, *id.* § 360(j); and (3) upon information and belief, as explained in paragraph 110, adulterated drugs because they were nor manufactured in compliance with current good manufacturing practices for drugs, in violation of the standards set forth in Section 501(a)(2)(B) of the FDCA, 21 U.S.C. § 351(a)(2)(B).).

161. TASA also violates the standard set forth in Section 301 of the FDCA. Section 301 of the FDCA prohibits the introduction, or delivery for introduction, into interstate commerce of any unapproved "new drug" that violates Section 505(a) of the FDCA, and/or any adulterated or misbranded drug that violates Sections 501 and/or 502 of the FDCA. *Id.* § 331(a), (d).

162. In addition, TASA violates Section 337 of the Tariff Act, because it violates the provisions of the Lanham Act. Specifically, TASA is falsely stating that its E-OM3 oil and its rTG-OM3 oil can be used in "dietary supplements," **Exhibits 7-B-i – 7-B-ii**, when these products are actually unapproved "new drugs;" these literally false statements have the capacity to deceive consumers and are likely to influence purchasing decisions; TASA caused these false statements to enter interstate commerce; and as discussed in paragraphs 217-238, Amarin is likely to be injured as a result.

B. Distributor Respondents

Nature's Bounty

163. Proposed Respondent The Nature's Bounty Company ("Nature's Bounty") is a U.S. importer and distributor of Synthetically Produced Omega-3 Products under brand names Nature's Bounty®, Puritan's Pride®, Solgar®, and Sundown Naturals®. Nature's Bounty was the

consignee on the import shipments from its affiliate, Ultimate, described in paragraph 122 above. **Exhibit 2-F**.

164. Nature's Bounty sells the following E-OM3 products comprised predominantly of E-EPA in the United States under the brand name Nature's Bounty: Fish Oil 1400 mg (E-OM3), **Exhibit 8-A**, and Mini-Fish Oil 1290 mg (E-OM3), **Exhibit 8-B**. The Promotional Materials accompanying Mini-Fish Oil 1290 mg state that Nature's Bounty sources its fish oil "directly from Peru." **Exhibit 8-B-vi-b**. Although the Fish Oil 1400 mg product does not contain country of origin markings visible on the Nature's Bounty website, there are no known commercial-grade fish oil concentration production facilities in the United States. **Confidential Exhibit 70.** In addition, at least one unit of Nature's Bounty Fish Oil 1400 mg has been sold in the United States. **Confidential Exhibit 70.** Accordingly, the Fish Oil 1400 mg product containing concentrated fish oil is imported.

165. The following Nature's Bounty E-OM3 products comprised predominantly of E-EPA and rTG-OM3 products comprised predominantly of rTG-EPA are offered for sale in the United States under the brand name Puritan's Pride®: Double Strength Omega-3 Fish Oil 1200 mg (E-OM3), **Exhibit 8-C**; Omega-3 Fish Oil 645 mg Mini Gels (upon information and belief, rTG-OM3), **Exhibit 8-D**; Krill Oil + High Omega-3 Concentrate 1085 mg (E-OM3), **Exhibit 8-E**; Lutigold™ Nutra-Vision with Lutein, Zeaxanthin & Omega-3 (E-OM3), **Exhibit 8-F**; One Per Day Omega-3 Fish Oil 1360 mg (upon information and belief, rTG-OM3), **Exhibit 8-G**; Specific Care™ Vision (E-OM3), **Exhibit 8-H**; Triple Strength Omega-3 Fish Oil 1360 mg (E-OM3), **Exhibit 8-I**; Ubiquinol 100 mg & Omega Fish Oil 400 mg (E-OM3), **Exhibit 8-J**. Upon information and belief, the Puritan's Pride® Synthetically Produced Omega-3 Products are

imported into the United States. Although the Puritan's Pride® Synthetically Produced Omega-3 Products do not contain country of origin markings visible on the Puritan's Pride® website, there are no known commercial-grade fish oil concentration production facilities in the United States. **Confidential Exhibit 70**. In addition, at least one unit of Puritan's Pride® Omega-3 Fish Oil 645 mg Mini Gels has been sold in the United States. **Confidential Exhibit 70.** Accordingly, the Puritan's Pride® Synthetically Produced Omega-3 Products containing concentrated fish oil are imported.

166. The following Nature's Bounty E-OM3 Products comprised predominantly of E-EPA are sold in the United States under the brand name Solgar®: Triple Strength Omega 3 950 MG (E-OM3), **Exhibit 8-K**; Double-Strength Omega-3 700 MG (E-OM3), **Exhibit 8-L**; and EFA 1300 MG Omega 3-6-9 (E-OM3), **Exhibit 8-M**. Upon information and belief, the Solgar® Synthetically Produced Omega-3 Products are imported into the United States. Although the Solgar® Synthetically Produced Omega-3 Products do not contain country of origin markings visible on the Solgar® website, there are no known commercial-grade fish oil concentration production facilities in the United States. **Confidential Exhibit 70**. In addition, at least one unit each of Solgar's Triple Strength Omega 3 950 MG and Double-Strength Omega-3 700 MG has been sold in the United States. **Confidential Exhibit 70.** Accordingly, the Solgar® Synthetically Produced Omega-3 Products containing concentrated fish oil are imported.

167. The following Nature's Bounty E-OM3 Product comprised predominantly of E-EPA is sold in the United States under the brand name Sundown Naturals®: Odorless Fish Oil 1290mg/900mg (E-OM3), **Exhibit 8-N**. The Promotional Materials accompanying the Sundown Naturals® Odorless Fish Oil 1290mg/900mg product state that Sundown Naturals®, "fish oil is

sourced in Peru." **Exhibit 8-N-vi-b**. In addition, at least one unit of Sundown Naturals® Fish Oil Omega 3-1290 MG has been sold in the United States. **Confidential Exhibit 70.** Accordingly, the Sundown Naturals® Synthetically Produced Omega-3 Products containing concentrated fish oil are imported.

168. Nature's Bounty violates Section 337 of the Tariff Act, because it violates standards established in the FDCA. Specifically, the E-OM3 capsules sold by Nature's Bounty cannot meet the definition of "dietary supplement" because E-OM3 is not a "dietary ingredient," 21 U.S.C. § 321(ff)(1), as explained in paragraphs 61-71, and it is excluded from the definition of "dietary supplement" by the exclusionary clause, *id.* § 321(ff)(3), as explained in paragraphs 71-83. In addition, as explained in paragraph 92, the capsules are "drugs" because, upon information and belief, they are recognized in the USP/NF. **Exhibit 62**. The capsules are also "drugs" because they are intended to affect the structure/function of the body and to affect disease, as evidenced by, among other things, structure/function and disease promotional claims made by Nature's Bounty (**Table 1** (listing structure/function claims and disease claims for all of Distributors' products)).

169. Similarly, the rTG-OM3 capsules sold by Nature's Bounty cannot meet the definition of "dietary supplement" because rTG-OM3 is not a "dietary ingredient," 21 U.S.C. § 321(ff)(1), as explained in paragraphs 61-71. The capsules are also "drugs" because they are intended to affect the structure/function of the body and to affect disease, as evidenced by, among other things, structure/function and disease promotional claims made by Nature's Bounty for those products (**Table 1** (listing structure/function claims and disease claims for all of Distributors' products)).

170. For example, Nature's Bounty's website provides the following structure/function claim, which applies to all of the Nature's Bounty brand products: "Nature's Bounty® Fish Oil contains Omega-3 fatty acids including EPA and DHA which help support and maintain the health of your cardiovascular and circulatory system." **Exhibits 8-A-iii-b, 8-B-iii-b**. The Puritan's Pride® website contains many structure/function claims, including "Omega-3 fatty acids are important for heart health," "Omega-3 fatty acids are important for the body's immune system," and "Omega-3's can support bone health." **Exhibits 8-C-iii-b – 8-J-iii-b**. The same website also contains disease claims, including "Omega 3 fatty acids are important for heart health . . . Cardiovascular disease is the number one cause of death in the United States [implied claim for the prevention or treatment of cardiovascular disease and for the prevention of death]," and "In a study of women over 65 with osteoporosis, those who took EPA and GLA supplements saw a reduced rate of bone loss. In fact, many of the women experienced an increase in bone density [implied prevention/treatment of osteoporosis claim]." **Exhibits 8-C-iv-b, 8-D-iv – 8-I-iv, 8-J-iv-b**. Further, a Solgar brochure for all of its essential fatty acid products contains structure/function claims, such as "EPA and DHA leapfrog several metabolic steps, so they quickly yield health benefits.* EPA forms the hormone-like prostaglandin 3 series of compounds, which have circulatory and other heart-healthy benefits." **Exhibits -K-iii-b - 8-M-iii-b**. In addition, Sundown Naturals®' Odorless Fish Oil 1290mg/900mg is marketed with a number of structure/function claims, including "Sundown Naturals® Odor-less Fish Oil 1290 mg supplies omegas that are important for your heart health.* Omega-3s are 'good fats' that support cardiovascular health, and cellular/joint/skin health.*" **Exhibit 8-N-iii**. Other structure/function and disease claims for these products are listed in **Table 2**.

171. In addition, Nature's Bounty's E-OM3 and rTG-OM3 products are (1) falsely labeled as "dietary supplements," in violation of the standards set forth in Section 502(a) and/or (n) of the FDCA, 21 U.S.C. § 352(a), (n), when they cannot legally be used for that purpose and they are actually unapproved "new drugs," **Exhibits 8-A-ii – 8-N-ii**; (2) misbranded as a matter of law, in violation of the standards set forth in Section 502(f), as explained in paragraph 109, because they are "prescription drugs" that have not been approved by FDA, and therefore, the labeling fails to contain adequate directions for use, 21 U.S.C. § 352(f)(1), 353(b)(2); (3) upon information and belief, as explained in paragraph 110, misbranded drugs under Section 502(o) of the FDCA, *id.* § 352(o), because they were manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under Section 510 of the FDCA, *id.* § 360; and/or not included in a list as required by Section 510(j) of the FDCA, *id.* § 360(j); and (4) upon information and belief, as explained in paragraph 111, adulterated drugs because they were not manufactured in compliance with current good manufacturing practices for drugs, in violation of the standards set forth in Section 501(a)(2)(B) of the FDCA, 21 U.S.C. § 351(a)(2)(B).

172. The introduction, or delivery for introduction, into interstate commerce of any unapproved "new drug" that violates Section 505(a) of the FDCA, and/or any adulterated or misbranded drug that violates Sections 501 and/or 502 of the FDCA, is prohibited by Section 301(d) and (a) of the FDCA. *Id.* § 331(a), (d).

173. Nature's Bounty also violates Section 337 of the Tariff Act, because it violates the provisions of the Lanham Act. Specifically, Nature's Bounty is falsely stating on the product labels for all of its E-OM3 and rTG-OM3 products that they are "dietary supplements," **Exhibits 8-A-ii – 8-N-ii**, when these products are actually unapproved "new drugs;" these literally false

statements have the capacity to deceive consumers and are likely to influence purchasing decisions; Nature's Bounty caused these false statements to enter interstate commerce, **Exhibits 8-A-ii – 8-N-ii**; and as discussed in paragraphs 216-237, Amarin is likely to be injured as a result.

Nordic Naturals

174. Proposed Respondent Nordic Naturals is a U.S. distributor of Synthetically Produced Omega-3 Products. As described in paragraph 143 above, Complainants have obtained data from Datamyne, Inc. that show that Respondent Nordic Pharma imported "Fish Oil TG90 4020 80 drums" and "Fish Oil TG90 3525 37 Drums into the United States in December 2016. **Exhibit 5-F.** Nordic Pharma is "exclusively dedicated to manufacturing Nordic Naturals omega oils" and is "privately owned by Nordic Naturals." **Exhibit 5-E.** Nordic Naturals' Promotional Materials state that 100% of Nordic Naturals fish oil is manufactured in Norway" and its "soft gel products are bottled and encapsulated at [its] plant in Southern California." **Exhibit 71.**

175. Nordic Naturals distributes the following Synthetically Produced Omega-3 Products for direct sale to consumers or health care professionals: Ultimate Omega-D3, **Exhibit 9-A**; Ultimate Omega Xtra (Soft Gel), **Exhibit 9-B**; Ultimate Omega Xtra (Liquid), **Exhibit 9-C**; Ultimate Omega Liquid 2840 mg, **Exhibit 9-D**; Ultimate Omega Junior, **Exhibit 9-E**; Ultimate Omega in Fish Gelatin 1280 mg, **Exhibit 9-F**; Ultimate Omega D3 Sport (Professional Product), **Exhibit 9-G**; Ultimate Omega D3 Sport (Liquid) (Professional Product, **Exhibit 9-H**; Ultimate Omega 1280 mg, **Exhibit 9-I**; Ultimate Omega 2X, **Exhibit 9-J**; Ultimate Omega 2X with Vitamin D3, **Exhibit 9-K**; Ultimate Omega 2X Mini, **Exhibit 9-L**; Ultimate Omega 2X Mini with Vitamin D3, **Exhibit 9-M**; Ultimate Omega + CoQ10, **Exhibit 9-N**; ProEPA, **Exhibit 9-O**;

Complete Omega + D3 Junior, **Exhibit 9-P**; Complete Omega Junior, **Exhibit 9-Q**; Complete Omega XTRA, **Exhibit 9-R**; Daily Omega Kids, **Exhibit 9-S**; EPA Xtra, **Exhibit 9-T**; Omega ONE, **Exhibit 9-U**; EPA, **Exhibit 9-V**; Omega LDL, **Exhibit 9-W**; Omega Joint XTRA, **Exhibit 9-X**; Omega Curcumin, **Exhibit 9-Y**; Omega Blood Sugar, **Exhibit 9-Z**; ProOmega 2000 (Professional Product), **Exhibit 9-AA**; ProOmega (Professional Product), **Exhibit 9-BB**; ProOmega in Fish Gelatin (Professional Product), **Exhibit 9-CC**; Pro-Omega Liquid (Professional Product), **Exhibit 9-DD**; ProOmega-D (Professional Product), **Exhibit 9-EE**; ProOmega-D Xtra (Professional Product), **Exhibit 9-FF**; ProOmega-D Xtra Liquid (Professional Product), **Exhibit 9-GG**; ProOmega 2000-D (Professional Product), **Exhibit 9-HH**; Nordic Omega-3 Gummy Fish (Professional Product), **Exhibit 9-II**; Omega Boost Junior (Professional Product), **Exhibit 9-JJ**; Omega-3 Fishies (Professional Product), **Exhibit 9-KK**; Nordic Omega-3 Gummy Worms (Professional Product), **Exhibit 9-LL**; Nordic Omega-3 Gummies (Professional Product), **Exhibit 9-MM**; ProOmega 2000 Jr. (Professional Product), **Exhibit 9-NN**; ProOmega Junior (Professional Product), **Exhibit 9-OO**; ProOmega 3-6-9 (Professional Product), **Exhibit 9-PP**; ProOmega CRP (Professional Product), **Exhibit 9-QQ**; ProOmega Blood Sugar (Professional Product), **Exhibit 9-RR**; ProOmega LDL (Professional Product), **Exhibit 9-SS**; ProOmega Joint Xtra (Professional Product), **Exhibit 9-TT**; ProOmega CoQ10 (Professional Product), **Exhibit 9-UU**. In addition, at least one unit each of Nordic Naturals Complete Omega XTRA and Nordic Naturals ProOmega Blood Sugar has been sold in the United States. **Confidential Exhibit 70.** Accordingly, the Nordic Naturals Synthetically Produced Omega-3 Products containing concentrated fish oil are imported.

176. Notably, many of these products (*i.e.*, those designated as "Professional Product") are marketed directly to health care professionals (*see, e.g.*, **Exhibits 9-AA-i-a, 9-UU-i-a**). But, at least as a general matter, the purported "Professional Products" also are available to the general public on Amazon.com, *see, e.g.*, **Exhibits, 9-O-vi, 9-II-vi-a, 9-AA-vi-a, 9-GG-vi-a**.

177. The Nordic Naturals website states that "all Nordic Naturals formulas are produced in true triglyceride form," **Exhibit 72**. Upon information and belief, given that all of the products listed above contain EPA in concentrations above, or in ratios different from, common fish oil, *see id.*, all of these products contain rTG-OM3.

178. Nordic Naturals violates Section 337 of the Tariff Act, because it violates the standards established in the FDCA. Specifically, the products containing rTG-OM3 sold by Nordic Naturals cannot meet the definition of "dietary supplement" because rTG-OM3 is not a "dietary ingredient," 21 U.S.C. § 321(ff)(1), as explained in paragraphs 61-71. These products are also "drugs" because they are intended to affect the structure/function of the body and to affect disease, as evidenced by, among other things, structure/function and disease promotional claims made by Nordic Naturals for those products. For example, the Nordic Naturals website contains structure/function claims that apply to all of the products, such as "Extensive research has documented the health benefits of EPA and DHA, which include not only a healthy heart, but brain and cognitive function, joint mobility, eye health, pregnancy and lactation, healthy skin and hair, and a normally functioning immune response." **Exhibits 9-A-iii, 9-B-iii-b – 9-DD-iii-b, 9-EE-iii, 9-FF-iii-b – 9-HH-iii-b, 9-II-iii, 9-JJ-iii-b - 9-KK-iii-b, 9-LL-iii – 9-MM-iii, 9-NN-iii-b - 9-QQ-iii-b, 9-RR-iii, 9-SS-iii-b - 9-UU-iii-b.** Similarly, the website contains disease claims that apply to all of the products such as "Protects against age-related oxidative damage," "Can

help alleviate [eye] dryness and redness," "May help slow the progression of age-related memory loss," "Supports internal repair systems that operate in response to physical stress," "Omega-3 consumption may reduce the risk of allergies in children," and "Omega-3 consumption may reduce the risk of colds in infants." **Exhibits 9-A-iv – 9-U-iv, 9-V-iv-b - 9-W-iv, 9-X-iv-b - 9-Y-iv-b, 9-Z-iv - 9-QQ-iv, 9-RR-iv-b, 9-SS-iv, 9-TT-iv-b – 9-UU-iv-b**. Other structure/function and disease claims for these products are listed in **Table 1**.

179. In addition, the Nordic Naturals rTG-OM3 products are (1) falsely labeled as "dietary supplements," in violation of the standards set forth in Section 502(a) and/or (n) of the FDCA, 21 U.S.C. § 352(a), (n), when they cannot legally be used for that purpose and they are actually unapproved "new drugs," **Exhibit 9-A-ii – 9-UU-ii**; (2) misbranded as a matter of law, in violation of Section 502(f), as explained in paragraph 109, because they are "prescription drugs" that have not been approved by FDA, and therefore, the labeling fails to contain adequate directions for use, 21 U.S.C. § 352(f)(1), 353(b)(2); (3) upon information and belief, misbranded drugs under Section 502(o) of the FDCA, *id.* § 352(o), because they were manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under Section 510 of the FDCA, *id.* § 360; and/or not included in a list as required by Section 510(j) of the FDCA, *id.* § 360(j); and (4) upon information and belief, adulterated drugs because they were not manufactured in compliance with current good manufacturing practices for drugs, in violation of the standards set forth in Section 501(a)(2)(B) of the FDCA, 21 U.S.C. § 351(a)(2)(B).

180. The introduction, or delivery for introduction, into interstate commerce of any unapproved "new drug" that violates Section 505(a) of the FDCA, and/or any adulterated or

misbranded drug that violates Sections 501 and/or 502 of the FDCA, is prohibited by Section 301(d) and (a) of the FDCA. *Id.* § 331(a), (d).

181. Nordic Naturals also violates Section 337 of the Tariff Act, because it violates the provisions of the Lanham Act. Specifically, Nordic Naturals is falsely stating on the product labels for all of its products that they are "dietary supplements," **Exhibits 9-A-ii – 9-UU-ii**, when these products are actually unapproved "new drugs;" these literally false statements have the capacity to deceive consumers and are likely to influence purchasing decisions; Nordic Naturals caused these false statements to enter interstate commerce, **Exhibits 9-A-ii – 9-UU-ii**; and as discussed in paragraphs 217-238, Amarin is likely to be injured as a result.

Pharmavite LLC/Nature Made

182. Proposed Respondent Pharmavite LLC is a U.S. distributor of Nature Made-branded imported Synthetically Produced Omega-3 Products. In particular, Pharmavite sells at least the following Synthetically Produced Omega-3 Products in the United States under the Nature Made brand: Fish-Oil One Per Day Burpless (E-OM3), **Exhibit 10-A**; Fish Oil One Per Day (E-OM3), **Exhibit 10-B**; Fish Oil Pearls (E-OM3), **Exhibit 10-C**; Full Strength Mini Omega-3 (E-OM3), **Exhibit 10-D**; Omega-3 with Xtra Absorb (E-OM3), **Exhibit 10-E**; Triple Omega (E-OM3), **Exhibit 10-F**; and Ultra Omega-3 (E-OM3), **Exhibit 10-G**.

183. According to the applicable country of origin markings on the Nature Made Synthetically Produced Omega-3 Products, Norway is the country of origin of the fish oil used in Full Strength Mini Omega-3 product, **Exhibit 10-D-vi-b**, and the Omega-3 with Xtra Absorb product, **Exhibit 10-E-vi-b**. Colombia is the country of origin of the fish oil used in the Fish Oil Pearls product, **Exhibit 10-C-vi-b**. Canada is the country of origin of the fish oil used in the

Fish Oil One Per Day, Burpless product, **Exhibit 10-A-vi-b** and the Fish Oil One Per Day product, **Exhibit 10-B-vi-b**. The Triple Omega product also is imported into the United States. Although the Triple Omega product does not contain country of origin markings visible on the Nature Made website, there are no known commercial-grade fish oil concentration production facilities in the United States. **Confidential Exhibit 70**. In addition, at least one unit of Nature Made Fish Oil Pearls has been sold in the United States. **Confidential Exhibit 70.** Accordingly, the Nature Made Synthetically Produced Omega-3 Products are imported.

184. Pharmavite violates Section 337 of the Tariff Act, because it violates the standards established in the FDCA. Specifically, the E-OM3 capsules sold by Pharmavite cannot meet the definition of "dietary supplement" because E-OM3 is not a "dietary ingredient," 21 U.S.C. § 321(ff)(1), as explained in paragraphs 61-71, and it is excluded from the definition of "dietary supplement" by the exclusionary clause, *id.* § 321(ff)(3), as explained in paragraphs 71-83.. In addition, as explained in paragraph 92, the capsules are "drugs" because, upon information and belief, they are recognized in the USP/NF. **Exhibit 62.** The capsules are also "drugs" because they are intended to affect the structure/function of the body and to affect disease, as evidenced by, among other things, the structure/function and disease promotional claims made by Pharmavite. *See* **Table 1** (listing structure/function claims and disease claims for all of Distributors' products).

185. For example, structure/function claims on Pharmavite's website for Nature Made's fish oil products include the following: "A regular intake of EPA and DHA can play a positive role in your health. When made available to the body, EPA and DHA are incorporated into cell membranes (such as heart cells) and help support flexible cell membranes," and "EPA

and DHA . . . help support a healthy heart." **Exhibits 10-A-iii-b – 10-G-iii-b**; **Table 1**. Pharmavite's website for all of Nature Made's fish oil products also includes, for example, the disease claim, "Supportive but not conclusive research shows that consumption of EPA and DHA omega-3 fatty acids may reduce the risk of coronary heart disease." **Exhibits 10-A-iv-b – 10-G-iv-b**; **Table 1**. Notably, FDA has exercised enforcement discretion over this claim when it is used to promote dietary supplements and conventional foods. **Exhibit 73**. As explained in paragraph 184, however, Pharmavite's E-OM3 products are not "dietary supplements," and clearly, they are not conventional foods. Accordingly, they are not subject to FDA's enforcement discretion policy for this claim. Other structure/function and disease claims for these products are listed in **Table 1**.

186. In addition, Pharmavite's E-OM3 products are (1) falsely labeled as "dietary supplements," in violation of the standards set forth in Section 502(a) and/or (n) of the FDCA, 21 U.S.C. § 352(a), (n), when they cannot legally be used for that purpose and they are actually unapproved "new drugs," **Exhibits 10-A-ii – 10-G-ii**; (2) misbranded as a matter of law, in violation of the standards set forth in Section 502(f), as explained in paragraph 109, because they are "prescription drugs" that have not been approved by FDA, and therefore, the labeling fails to contain adequate directions for use, 21 U.S.C. § 352(f)(1), 353(b)(2); (3) upon information and belief, misbranded drugs under Section 502(o) of the FDCA, *id.* § 352(o), because they were manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under Section 510 of the FDCA, *id.* § 360; and/or not included in a list as required by Section 510(j) of the FDCA, *id.* § 360(j); and (4) upon information and belief, adulterated drugs because they were not manufactured in compliance with current good manufacturing practices

for drugs, in violation of the standards set forth in Section 501(a)(2)(B) of the FDCA, 21 U.S.C. § 351(a)(2)(B).

187. The introduction, or delivery for introduction, into interstate commerce of any unapproved "new drug" that violates Section 505(a) of the FDCA, and/or any adulterated or misbranded drug that violates Sections 501 and/or 502 of the FDCA, is prohibited by Section 301(d) and (a) of the FDCA. *Id.* § 331(a), (d).

188. Pharmavite violates Section 337 of the Tariff Act, because it violates the Lanham Act. Specifically, Pharmavite is falsely stating on the product labels for all of its E-OM3 products that they are "dietary supplements," **Exhibits 10-A-ii – 10-G-ii**, when these products are actually unapproved "new drugs;" these literally false statements have the capacity to deceive consumers and are likely to influence purchasing decisions; Pharmavite caused these false statements to enter interstate commerce, **Exhibits 10-A-ii – 10-G-ii**; and as discussed in paragraphs 217-238, Amarin is likely to be injured as a result.

Innovix Pharma Inc./OmegaVia

189. Proposed Respondent Innovix Pharma Inc. ("Innovix Pharma") is a U.S. distributor of OmegaVia-branded imported Synthetically Produced Omega-3 Products. In particular, Innovix Pharma sells at least the following Synthetically Produced Omega-3 Products in the United States: OmegaVia EPA 500 (rTG-EPA), **Exhibit 11-A**, and OmegaVia Fish Oil (rTG-OM3), **Exhibit 11-B**. Both of these products contain omega-3 in the rTG form. **Exhibits 11-A-i and 11-B-i.**

190. According to the OmegaVia Promotional Materials, the concentrated fish oil used in the OmegaVia Synthetically Produced Omega-3 Products is sourced from Peru, Chile and the

United States, and is concentrated in Europe before being imported into the United States for encapsulation. **Exhibits 11-A-vi – 11-B-vi**. The labels for OmegaVia EPA 500 and for OmegaVia Fish Oil state that the "source" of the fish oil is Peru and Chile, and the product is "[c]oncentrated and purified in Europe." *See id.* In addition, at least one unit of OmegaVia's EPA 500 has been sold in the United States. **Confidential Exhibit 70.** Accordingly, the OmegaVia Synthetically Produced Omega-3 Products are imported.

191. Innovix Pharma violates Section 337 of the Tariff Act, because it violates certain standards established in the FDCA. Specifically, the rTG-OM3 and rTG-EPA products sold by Innovix Pharma cannot meet the definition of "dietary supplement" because rTG-OM3 and rTG-EPA are not "dietary ingredients," 21 U.S.C. § 321(ff)(1), as explained in paragraphs 61-71. These products are also "drugs" because they are intended to affect the structure/function of the body and to affect disease, as evidenced by, among other things, structure/function and disease promotional claims made by Innovix Pharma for those products. For example, the Innovix Pharma website contains structure/function claims that apply to all of the products, such as: "Comfort your joints," "Keep Your Mind Sharp," and "maintaining mood health." **Exhibits 11-A-iii-c and 11-B-iii-c**. Similarly, the website contains disease claims that apply to all of the products such as: "Reduces enzymes that destroy cartilage," "reduces joint discomfort," "Moderate growth of atherosclerosis plaque," "EPA has been found to be as effective as prescription anti-depressants," "Manage age-related brain decline," "bring your triglyceride levels down naturally," "moderate blood pressure," "reducing redness and scaling," "That's 20% More Omega-3 Than Prescription Lovaza" (comparison claims to drugs are disease claims, 21 C.F.R. § 101.93(g)((vi)), "Clinically effective dose for triglycerides," "Pharmaceutical Grade,"

"EPA is more effective than DHA at lowering triglycerides," "improve mood and depression," "powerful anti-inflammatory for soothing arthritis." **Exhibits 11-A-iv-b – 11-A-iv-c, 11-B-iv-b – 11-B-iv-c**. Other structure/function and disease claims for these products are listed in **Table 1**.

192. In addition, Innovix Pharma's rTG-OM3 and rTG-EPA products are (1) falsely labeled as "dietary supplements," in violation of the standards set forth in Section 502(a) and/or (n) of the FDCA, 21 U.S.C. § 352(a), (n), when they cannot legally be used for that purpose and they are actually unapproved "new drugs," **Exhibit 11-A-ii – 11-B-ii**; (2) misbranded as a matter of law, in violation of the standards set forth in Section 502(f), as explained in paragraph 109, because they are "prescription drugs" that have not been approved by FDA, and therefore, the labeling fails to contain adequate directions for use, 21 U.S.C. § 352(f)(1), 353(b)(2); (3) upon information and belief, misbranded drugs under Section 502(o) of the FDCA, *id.* § 352(o), because they were manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under Section 510 of the FDCA, *id.* § 360; and/or not included in a list as required by Section 510(j) of the FDCA, *id.* § 360(j); and (4) upon information and belief, adulterated drugs because they were not manufactured in compliance with current good manufacturing practices for drugs, in violation of the standards set forth in Section 501(a)(2)(B) of the FDCA, 21 U.S.C. § 351(a)(2)(B).

193. The introduction, or delivery for introduction, into interstate commerce of any unapproved "new drug" that violates Section 505(a) of the FDCA, and/or any adulterated or misbranded drug that violates Sections 501 and/or 502 of the FDCA, is prohibited by Section 301(d) and (a) of the FDCA. *Id.* § 331(a), (d).

194. Innovix Pharma also violates Section 337 of the Tariff Act, because it violates the Lanham Act. Specifically, Innovix Pharma is falsely stating on the product labels for all of its rTG-OM3 and rTG-EPA products that they are "dietary supplements," **Exhibits 11-A-ii – 11-B-ii**, when these products are actually unapproved "new drugs;" these literally false statements have the capacity to deceive consumers and are likely to influence purchasing decisions; Innovix Pharma caused these false statements to enter interstate commerce, **Exhibits 11-A-ii – 11-B-ii**; and as discussed in paragraphs 217-238, Amarin is likely to be injured as a result.

Carlson

195. Proposed Respondent J.R. Carlson Laboratories, Inc. ("Carlson") is a U.S. distributor of imported Synthetically Produced Omega-3 Products. In particular, Carlson sells at least the following Synthetically Produced Omega-3 Products in the United States: Women's Omega Multi (upon information and belief, rTG-OM3), **Exhibit 12-A**; Very Finest Fish Oil Liquid (upon information and belief, rTG-OM3), **Exhibit 12-B**; Super Omega-3 Gems (E-OM3), **Exhibit 12-C**; Elite EPA Gems (E-EPA), **Exhibit 12-D**; Elite Omega-3 Gems (E-OM3), **Exhibit 12-E**; Fish Oil Q 100 mg (E-OM3), **Exhibit 12-F**; Inflammation Balance (upon information and belief, rTG-OM3), **Exhibit 12-G**; Maximum Omega 2000 (upon information and belief, rTG-OM3), **Exhibit 12-H**; MCT & Omega-3 (upon information and belief, rTG-OM3), **Exhibit 12-I**; Men's Omega Multi (E-OM3), **Exhibit 12-J**; Super Omega-3 Gems, Fish Gelatin (E-OM3), **Exhibit 12-K**; Omega 3-6-9 (upon information and belief, rTG-OM3), **Exhibit 12-L**; Super 2 Daily (upon information and belief, rTG-OM3), **Exhibit 12-M**. Notably, Carlson's omega-3 product brochure expressly states that its omega-3 products are comprised of (1) non-concentrated 100% natural triglycerides, (2) concentrated ethyl esters, (3) concentrated re-

esterified triglycerides (rTG), and (4) a mixture of both the natural triglyceride form and the more potent ethyl ester form. **Exhibits 12-A-i-c, 12-B-i-c, 12-G-i-c, 12-H-i-c, 12-I-i-c, 12-L-i-c, 12-M-i-c**.

196. According to the Carlson Promotional Materials, the concentrated fish oil used in the Carlson Omega-3 Products is sourced from Norway. **Exhibits 12-A-vi – 12-M-vi**. In addition, at least one unit each of Carlson's Elite EPA Gems and Elite Omega-3 Gems has been sold in the United States. **Confidential Exhibit 70.** Accordingly, the Carlson Synthetically Produced Omega-3 Products are imported.

197. Carlson violates Section 337 of the Tariff Act, because it violates certain standards established by the FDCA. Specifically, the E-OM3 capsules and oils sold by Carlson cannot meet the definition of "dietary supplement" because E-OM3 is not a "dietary ingredient," 21 U.S.C. § 321(ff)(1), as explained in paragraphs 61-71, and it is excluded from the definition of "dietary supplement" by the exclusionary clause, *id.* § 321(ff)(3), as explained in paragraphs 71-83. In addition, as explained in paragraphs 92 and 95, the E-OM3 capsules and the oil are "drugs" because, upon information and belief, they are recognized in the USP/NF. **Exhibits 62 and 64**. The E-OM3 products are also "drugs" because they are intended to affect the structure/function of the body and to affect disease, as evidenced by, among other things, structure/function and disease promotional claims made by Carlson. *See* **Table 1** (listing structure/function claims and disease claims for all of Distributors' products).

198. Similarly, the rTG-OM3 products sold by Carlson cannot meet the definition of "dietary supplement" because rTG-OM3 is not a "dietary ingredient," 21 U.S.C. § 321(ff)(1), as explained in paragraphs 61-71. The products are also "drugs" because they are intended to affect

the structure/function of the body and to affect disease, as evidenced by, among other things, structure/function promotional claims made by Carlson for those products. *See* **Table 1** (listing structure/function claims and disease claims for all of Distributors' products).

199. For example, a Carlson brochure accessible from Carlson's website provides the following structure/function claims, which apply to all of the Carlson Synthetically Produced Omega-3 Products: "EPA and DHA are required by our bodies and aid in our well-being by promoting and supporting:* Cardiovascular health . . . Brain and nerve health . . . Vision heath . . . Immune system health . . . Joint health . . . Skin health." **Exhibits 12-A-iii-c – 12-B-iii-c, 12-C-iii-b, 12-D-iii-c – 12-M-iii-c**. Other structure/function claims for these products are listed in **Table 1**.

200. In addition, Carlson's products are (1) falsely labeled as "dietary supplements," in violation of the standards set forth in Section 502(a) and/or (n) of the FDCA, 21 U.S.C. § 352(a), (n), when they cannot legally be used for that purpose and they are actually unapproved "new drugs," **Exhibits 12-A-ii – 12-M-ii**; (2) misbranded as a matter of law, in violation of the standards set forth in Section 502(f), as explained in paragraph 109, because they are "prescription drugs" that have not been approved by FDA, and therefore, the labeling fails to contain adequate directions for use, 21 U.S.C. § 352(f)(1), 353(b)(2); (3) upon information and belief, misbranded drugs under Section 502(o) of the FDCA, *id.* § 352(o), because they were manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under Section 510 of the FDCA, *id.* § 360; and/or not included in a list as required by Section 510(j) of the FDCA, *id.* § 360(j); and (4) upon information and belief, adulterated drugs because they were not manufactured in compliance with current good manufacturing practices

for drugs, in violation of the standards set forth in Section 501(a)(2)(B) of the FDCA, 21 U.S.C. § 351(a)(2)(B).

201. The introduction, or delivery for introduction, into interstate commerce of any unapproved "new drug" that violates Section 505(a) of the FDCA, and/or any adulterated or misbranded drug that violates Sections 501 and/or 502 of the FDCA, is prohibited by Section 301(d) and (a) of the FDCA. *Id.* § 331(a), (d).

202. Carlson also violates Section 337 of the Tariff Act, because it violates the Lanham Act. Specifically, Carlson is falsely stating on the product labels for all of its Synthetically Produced Omega-3 Products that they are "dietary supplements," **Exhibits 12-A-ii – 12-M-ii**, when these products are actually unapproved "new drugs;" these literally false statements have the capacity to deceive consumers and are likely to influence purchasing decisions; Carlson caused these false statements to enter interstate commerce, **Exhibits 12-A-ii – 12-M-ii**; and as discussed in paragraphs 217-238, Amarin is likely to be injured as a result.

VIII. CLASSIFICATION OF THE RESPONDENTS' PRODUCTS UNDER THE HARMONIZED TARIFF SCHEDULE

203. The Proposed Respondents' products are imported under the following HTS classifications: HTS Nos. 0306.19.0030; 1504.20.6040; 1517.90.2080; 1605.40.1090; 2106.90.99; 106.90.9998; 2916.19.5000; 3003.90.0000; 3004.90.9120; 3504.00.5000; 3824.90.4020; and 3824.90.4090.

IX. RELATED LITIGATION

204. Complainants are not aware of any related litigation.

X. DOMESTIC INDUSTRY

205. Amarin Corporation plc is a biopharmaceutical company focused on the commercialization and development of therapeutics to improve cardiovascular health. Two of Amarin Corporation's wholly owned subsidiaries are Complainants in this action: Amarin Pharma and Amarin Ireland. Amarin Pharma is a Delaware corporation and is located in Bedminster, New Jersey. Amarin Ireland is organized under the laws of the Republic of Ireland and is headquartered in Dublin, Ireland. Amarin has made significant expenditures in the United States. The details of these expenditures are set forth below and in the Confidential Declaration of Michael W. Kalb, Senior Vice President and Chief Financial Officer of Amarin Pharma, attached as **Confidential Exhibit 23**.

206. Amarin Pharma has full time employees and leases property located at 1430 Route 206, Bedminster, New Jersey. Amarin's administrative, commercial, research and development, supply chain, and regulatory activities, among other business services, take place in its Bedminster, NJ location. The details of Amarin's U.S.-based employment and physical facilities at its Bedminster, NJ location are contained in **Confidential Exhibit 23, at ¶ 4.**

207. Amarin has entered into agreements with three commercial API encapsulators for the encapsulation of Vascepa®. These companies have qualified and validated their manufacturing processes and are capable of manufacturing Vascepa® in each case consistent with the stringent requirements applicable to manufacturing of drugs sold in the United States. The details of Amarin's U.S.-based encapsulation expenditures in 2016 and the first and second quarters of 2017 are contained in **Confidential Exhibit 23, at ¶ 5.**

208. Amarin also has entered into packaging arrangements with two commercial API packagers for the packaging of Vascepa®. These companies have qualified and validated their manufacturing processes and are capable of packaging Vascepa® in each case consistent with the stringent requirements applicable to manufacturing of drugs sold in the United States. The details of Amarin's U.S.-based portion of these packaging expenditures in 2016 and the first and second quarters of 2017 are contained in **Confidential Exhibit 23, at ¶ 6**.

209. Amarin also has entered into a Logistics Service Agreement with a U.S.-based company. This agreement provides for inbound receipt of product, warehousing, order acceptance, order fulfillment and shipment of orders, among other services. The details of the U.S.-based portion of Amarin's logistics expenditures in 2016 and the first quarter 2017 are contained in **Confidential Exhibit 23, at ¶ 7.**

210. Amarin markets Vascepa® in the United States through its direct sales force of approximately 150 sales professionals, including sales representatives and their managers. Amarin also employs various marketing and medical affairs personnel to support Amarin's commercialization of Vascepa®. In addition to Vascepa® promotion by Amarin sales representatives, Amarin has a co-promotion agreement with Kowa Pharmaceuticals America, Inc. ("Kowa") that provides for no fewer than 250 sales representatives to promote Vascepa® in the United States. Total sales and marketing expenses for Vascepa, including the Kowa co-promotion fee, are contained in **Confidential Exhibit 23, at ¶ 8**.

211. To comply with the stringent regulatory requirements for the sale of a drug in the United States, Amarin undertook substantial risk and has made substantial investments in labor dedicated to research and develop Vascepa® to its current state. Amarin's program for

developing Vascepa has lasted over a decade, and the details of the total U.S.-based labor expenses dedicated to research and development during 2016 and the first and second quarters of 2017 are contained in **Confidential Exhibit 23 at ¶¶ 9-11.**

212. Significantly, the Vascepa® development programs include three key human clinical trials entitled MARINE, ANCHOR, and REDUCE-IT. Each clinical trial was undertaken under a special protocol assessment ("SPA") agreement with FDA involving years of costly regulatory interactions and SPA amendments. Such agreements reflect FDA's concurrence on the vigorous testing the company had to successfully complete even to be considered for FDA approval of Vascepa®.

213. The MARINE clinical trial demonstrated that Vascepa® was safe and effective for use as an adjunct to diet to reduce triglyceride levels in adult patients with severe (TGs ≥500 mg/dL) hypertriglyceridemia, commonly known as very triglyceride levels, and it supported FDA's July 26, 2012 approval of the drug for that indication.

214. Likewise, the ANCHOR clinical trial demonstrated that the product was safe and effective for use as an adjunct to diet to reduce triglyceride levels in adult patients with persistent high (TGs 200-499 mg/dL) triglyceride levels in addition to statin therapy.

215. The REDUCE-IT cardiovascular outcomes trial is an 8,175-patient clinical trial evaluating whether treatment with Vascepa® will reduce major cardiovascular events in patients who, despite stabilized statin therapy, have elevated triglyceride levels and other cardiovascular risk factors. The results of this important trial could help healthcare professionals save millions of lives and lead to improved medical care for tens of millions of patients. If successful, the REDUCE-IT study has the potential to significantly change the treatment paradigm for

cardiovascular risk reduction, the leading cause of death in the United States. In a 2014 letter to Amarin, John Jenkins, M.D., then FDA's Director, Office of New Drugs, Center for Drug Evaluation and Research (now retired) stated that completed REDUCE-IT study "data would be of significant public health value." Dr. Jenkins went on to state, "I strongly urge Amarin to complete the trial and I know [FDA's clinical data review division for cardiovascular-focused drugs], is ready and willing to work with Amarin to address any issues that may arise as you work to that end." *See* FDA Letter to Amarin Pharma, dated September 11, 2014. **Exhibit 74.**

216. Amarin manages the REDUCE-IT study through a Contract Research Organization with the exception of costs for clinical trials management and costs for internal management. Amarin expects to report results from the REDUCE IT study in the second or third quarter of 2018. Amarin's total historical and expected costs of conducting the REDUCE-IT study are more than $200 million, most of it in the United States, and are set forth in **Confidential Exhibit 23 at ¶¶ 9-11.** Amarin's total R&D expenses since 2007, including expenses for all three studies, are contained in **Confidential Exhibit 23 at ¶¶ 9-11.**

XI. SUBSTANTIAL INJURY

217. The Proposed Respondents have engaged in unfair acts and unfair methods of competition, the threat or effect of which is to substantially injure Amarin's domestic industry in manufacturing, selling, and distributing its Vascepa® capsules. The importation and sale of Proposed Respondents' Synthetic Omega-3 Products by means of their unfair acts and unfair methods of competition have injured Amarin's domestic industry or threatened it with injury by (i) damaging the Vascepa® brand by exploiting Vascepa®'s status as an FDA-approved drug, (ii)

causing lost sales and market share to Vascepa®, and (iii) diminishing Amarin's profitability and Vascepa®'s eroding prices.

A. Damage To The Vascepa® Brand

218. Amarin has spent considerable time, money, effort, and resources developing the Vascepa® brand. As described in paragraphs 205-216 above, it developed Vascepa® in compliance with the FDCA and obtained FDA approval of its drug. It conducted the successful ANCHOR and MARINE trials, and is conducting REDUCE-IT trial as part of its development of Vascepa®. To expand marketing claims for its drug by demonstrating its effect on cardiovascular risk reduction, Amarin has invested and expects to invest more than $200 million since 2011 on its REDUCE-IT study alone. **Confidential Exhibit 23 at ¶¶ 9-11.** Through this substantial pharmacological development risk, effort and investment, Amarin has built and is continuing to build a successful, branded FDA-approved pharmaceutical product that helps patients who have been diagnosed with persistent high or very high triglyceride levels.

219. By contrast, Proposed Respondents market their Synthetic Omega-3 Products as non-prescription "dietary supplements," which exploits the Vascepa® brand and creates non-prescription competition and product substitution by the Synthetically Produced Omega-3 Products marketed illegally as "dietary supplements." These products are largely untested and much less stringently regulated, despite the fact that they are accompanied by claims by the Proposed Respondents that such products reduce triglyceride levels. By labeling and promoting Synthetically Produced Omega-3 Products as "dietary supplements" when, in fact, they are unapproved "new drugs," Proposed Respondents are diluting the Vascepa® brand and its status and notoriety as an FDA-approved drug and profiting from Amarin's substantial efforts and

investments – all without using their own resources, investing their own time or money, or exerting similar efforts of their own.

220. For example, a 2015 article on the NutraceuticalsWorld website entitled *Omega-3s: Turning the Tide & Watching the Current*, explained how Omega-3 manufacturers exploit the presence of Vascepa® and other prescription drugs in the market at the expense of Amarin and the Vascepa® brand. The article explains that "[t]he presence in the market of prescriptions forms of omega-3 esters such as Lovaza, Vascepa and Epanova gives an extra level of confidence even in the absence of [a Reference Daily Intake] or unqualified health claim." **Exhibit 75.**

221. In another article entitled *Lovaza: A Wolf in Sheep's Clothing*, a Nordic Naturals sales manager was quoted as saying that the presence of FDA-approved pharmaceuticals in the market is "very positive" because "it validates the use of omega 3s in a clinical application." **Exhibit 76.** Another market participant agreed, noting that if pharmaceutical companies "want[] to spend millions of dollars advertising the health benefits of fish oil on TV, it can do nothing but benefit all of us. I'm in." **Exhibit 76.**

222. The Proposed Respondents' conflation of Amarin's FDA-approved Vascepa® product with their Synthetically Produced Omega-3 Products has caused confusion in the marketplace about the distinction between "drugs" and "dietary supplements" to the detriment of the Vascepa® brand. A survey conducted by Fairleigh Dickenson University's Public Mind Poll entitled, "*What's In Your Supplements? Even The Experts Are Stumped*," reported that "[a]mong those physicians and pharmacists who had recommended a non-prescription omega-3 product to patients, more than four in five (85%) believed incorrectly that they had recommended an FDA-

approved OTC product . . . ." **Exhibit 77.** Notably, there are no legally marketed OTC drugs containing omega-3 fatty acids.

223. Companies like Proposed Respondent Innovix Pharma intentionally add to the confusion by promoting their products with claims that make direct comparisons to FDA-approved drugs (*e.g.,* "Most fish oils are not the same as Lovaza. But some Are! A few over-the counter pharmaceutical grade fish oils [sic] are just as potent, pure and effective at reducing triglycerides as Lovaza," *see* OmegaVia Website, **Exhibit 44**; *see also* OmegaVia Website 2, **Exhibit 45** (making implicit comparisons of OmegaVia's so-called "pharmaceutical grade fish oil" products to both Vascepa® and Lovaza®)).

224. These and other statements made by the Proposed Respondents in conjunction with the importation and sale of the Synthetically Produced Omega-3 Products have damaged or diluted the Vascepa® brand causing injury and threatened injury to Amarin.

B. Lost Sales And Market Share

225. Amarin has lost sales and market share as a result of Proposed Respondents' unfair acts and unfair methods of competition in multiple channels of distribution. The Synthetically Produced Omega-3 Products can be purchased off the shelf at retail establishments, such as grocery stores, pharmacies, big box stores, and over the Internet, without restriction. In addition, the Synthetically Produced Omega-3 Products can be purchased through doctor prescriptions. By contrast, Vascepa® can only be distributed pursuant to a prescription.

226. The ubiquitous presence of the Proposed Respondents' products in retail and consumer distribution channels has injured or threatened Amarin with injury. For example, in 2012, Amarin commissioned Hall & Partners, a New York City-based market research firm to

conduct a consumer direct-to-consumer market research program for Vascepa®. The sample included a total of 810 individuals with high triglycerides (200-499 mg/dL) and very high triglycerides (500+ mg/dL). When asked "[w]hich of the following medications are you currently taking to treat high triglycerides, whether treated alone or with another condition?," 41% responded that they took a prescription omega-3 product and 54% responded that they took a fish oil dietary supplement. **Confidential Exhibit 78.**

227. Proposed Respondents' unfair acts and unfair methods of competition also have resulted in lost sales and lost market share for Amarin's Vascepa® product in the physician prescription channel of distribution. In particular, a TVG Marketing Research & Consulting Study conducted in late 2015 indicates that physicians are more than three times more likely (28 percent to 8 percent) to recommend "Omega-3 Fish Oil Dietary Supplements" instead of prescribing Vascepa® when treating patients with elevated triglycerides. **Confidential Exhibit 79.** Moreover, certain Distributors, like Nordic Naturals, have an entire line of purported "Professional Products," that are specifically marketed to healthcare professionals. **Exhibits 80.** Proposed Respondents have induced doctors to recommend and patients to purchase Respondents' products in the mistaken belief that they are equivalent to FDA-approved products, with the threat or effect of lost sales and lost market share to Vascepa®.

228. Proposed Respondents' sales of Synthetically Produced Omega-3 Products resulting from unfair acts and unfair methods of competition have injured or threatened Amarin with injury. In the absence of Proposed Respondents' unfair acts and unfair methods of competition, sales of Vascepa® would displace a significant percentage of Proposed Respondents' sales of Synthetically Produced Omega-3 Products in the direct-to-consumer

channel of distribution, as consumers would seek prescriptions for Vascepa and other FDA-approved triglyceride-lowering drugs. And in the absence of Proposed Respondents' unfair acts and unfair methods of competition, sales of Vascepa® or other FDA-approved prescription triglyceride-lowering drugs would displace all of Proposed Respondents' sales of Synthetically Produced Omega-3 Products in the physician prescription channel of distribution.

229. Amarin has the capacity and/or inventory to supply the entire U.S. market demand for the Synthetically Produced Omega-3 Products (and similarly situated products), and Proposed Respondents' unfair acts prevent Amarin from making these sales. **Confidential Exhibit 70 at ¶ 23.**

C. Lost Profits And Price Erosion

230. Proposed Respondents' unfair acts and unfair methods of competition have contributed to Amarin's lost profits and to the price erosion of Vascepa®. FDA regulates "drugs" more stringently than "dietary supplements": drugs are subject to FDA approval, 21 U.S.C. § 505; and drug approval triggers the need for complying with the FDCA's drug registration and listing requirements, 21 U.S.C. § 360, the FDCA's drug manufacturing requirements, 21 U.S.C. § 351, and certain user fees. 21 U.S.C. § 379h. Moreover, FDA regulates drug labeling, promotional materials, and advertising stringently. FDA reviews drug labeling and approves claims that can be made regarding the product's use and conditions of use. 21 U.S.C. §§ 321(p), 505; 21 C.F.R. § 314.81. And promotional materials and advertising are submitted to FDA at the time of dissemination. Further, prescription drugs, such as Vascepa® can only be distributed pursuant to a prescription. 21 U.S.C. § 353(b).

231. By illegally importing and selling Synthetically Produced Omega-3 Products, the Proposed Respondents are able to avoid the substantial costs of obtaining FDA approval, maintaining FDA approval (*i.e.*, certain user fees), and complying with FDA's drug registration, listing, labeling/advertising, and manufacturing requirements. By contrast, Amarin has had to incur substantial costs in obtaining and maintaining FDA approval for Vascepa®, and for complying with FDA's various requirements.

232. All of Amarin's product revenue is derived from product sales of 1-gram and 0.5-gram size capsules of Vascepa®, net of allowances, discounts, incentives, rebates, chargebacks and returns. Amarin sells product to a limited number of major wholesalers and selected regional wholesalers and specialty pharmacy providers (collectively "Vascepa® Distributors") who resell the product to retail pharmacies for purposes of their reselling the product to fill patient prescriptions that are issued by authorized medical professionals. The commercial launch of 1-gram size Vascepa® capsules in the United States occurred in January 2013 and a smaller 0.5-gram size capsule was introduced in October 2016. Since 2014, Amarin has recognized revenue based on sales to its Vascepa® Distributors. Net product revenues based on sales of Vascepa® to distributors totaled $79.3 million and $58.1 million during the six months ended June 30, 2017 and 2016, respectively. Amarin's revenues would have been higher but for the Proposed Respondents' unfair acts and unfair methods of competition.

233. Amarin has not yet reached profitability on sales of Vascepa®, and anticipates incurring losses for an indefinite period of time. For the fiscal years ended December 31, 2016, 2015, and 2014, Amarin reported losses of approximately $86.4 million, $49.1 million, and $56.4 million, respectively, and the company has an accumulated deficit as of December 31,

2016 of $1.2 billion. For the three months ended March 31, 2017 and 2016, Amarin reported losses of approximately $20.9 million and $29.8 million, respectively.

234. This cumulated deficit in operating losses is typical of pharmaceutical companies that introduce a new drug into the market. They reflect the fact that to legally enter the pharmaceutical market with a drug like Vascepa® involves years of development, hundreds of millions of dollars in research and development costs, and several years of operating losses, as well as the risk of development failure. Pharmaceutical companies like Amarin typically recover their development costs over time through increasing volumes of sales. Amarin's losses, however, are exacerbated by Proposed Respondents' conduct. Put differently, Amarin's operating losses would have been smaller, or Amarin would have become profitable more quickly, but for the Proposed Respondents' unfair acts or unfair methods of competition.

235. The details of Amarin's production volumes and inventories of Vascepa® are contained in **Confidential Exhibit 70**, at **¶¶ 21-23**. Amarin has entered into long-term supply agreements with multiple FDA-approved API suppliers and encapsulators, which include the potential for capacity expansion aimed at creating sufficient volumes to meet future demand for Vascepa®. Amarin's ability to meet those growth projections (and to achieve profitability) is inhibited by Proposed Respondents' unfair acts and unfair methods of competition.

236. Proposed Respondents' sales of the Synthetically Produced Omega-3 Products resulting from unfair acts and unfair methods of competition also have had a substantial adverse impact on Vascepa® pricing. While Vascepa® pricing may be affected by insurance coverage and offered discounts, the fact that Vascepa® and Proposed Respondents' products are sold in the

same or similar channels of distribution also has adverse impacts on Vascepa® pricing. Amarin Corporation plc 2016 10K Statement at 41, attached as **Exhibit 81.**

237. The adverse price effects of the Synthetically Produced Omega-3 Products also is evident from Amarin's coupon discount sales program. According to that program, a consumer with commercial insurance can pay as little as $9.00 for a 90-day supply prescription of Vascepa®. **Exhibit 25.** The percentage of Vascepa® prescriptions covered by Amarin's coupon program is set forth in the attached **Confidential Exhibit 23.** Amarin's coupon program was designed to make Vascepa price competitive with Synthetically Produced Omega-3 Products and to discourage physicians and pharmacists from directing consumers to purchase Synthetically Produced Omega-3 Products based on price. As a result, Amarin has suffered price erosion from the unfairly traded Synthetically Produced Omega-3 Products with respect to at least the sales covered by Amarin's coupon program.

238. In sum, the Proposed Respondents' importation and sale of Synthetically Produced Omega-3 Products has injured and/or threatened Amarin with substantial injury by (i) damaging the Vascepa® brand by exploiting Vascepa®'s status as an FDA-approved drug, (ii) causing lost sales and market share to Vascepa, and (iii) diminishing Amarin's profitability and eroding Vascepa®'s prices.

XII. RELIEF

WHEREFORE, by reason of the foregoing, Complainants request that the Commission:

A. Institute an immediate investigation pursuant to Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, with respect to the Proposed Respondents' violations of

Section 337 based on the importation and sale in the United States of the Synthetically Produced Omega-3 Products;

B. Schedule and conduct a hearing on permanent relief pursuant to 19 U.S.C. § 1337(d) and (f) of the Tariff Act of 1930, as amended;

C. Find that Synthetically Produced Omega-3 Products are violating Section 337 of the Tariff Act because they violate the Lanham Act and the standards set forth in the FDCA in that they are sold as "dietary supplements" in the United States, without meeting the definition of "dietary supplement" in the FDCA. Further find that the Synthetically Produced Omega-3 Products are violating Section 337 of the Tariff Act because they meet the definition of "drugs," under the FDCA, by virtue of the fact that they are articles: (i) recognized in the USP/NF, (ii) intended to affect disease (*e.g.,* they are marketed with drug comparison claims, as well as other "disease" claims), *see* **Tables 1 and 2,** (iii) intended to affect the structure or function of the body (*e.g.*, they are marketed with claims that they support healthy heart, brain, and joint function, among other structure/function claims), *see* **Tables 1 and 2,** and/or (D) intended for use as a component of any articles specified in clauses (i)-(iii). 21 U.S.C. § 321(g)(1).

D. Issue a permanent General Exclusion Order excluding from entry into the United States all Synthetically Produced Omega-3 Products pursuant to 19 U.S.C. § 1337(d);

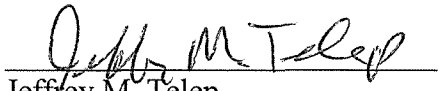
E. Issue a permanent Limited Exclusion Order specifically directed to each named Proposed Respondent and its subsidiaries and affiliates, pursuant to 19 U.S.C. § 1337(d), excluding from entry into the United States the Synthetically Produced Omega-3 Products through direct or indirect means;

F. Issue a permanent cease-and-desist order pursuant to 19 U.S.C. § 1337(f), prohibiting each Proposed Respondent and its subsidiaries and affiliates from directly or indirectly engaging in the importation, the use, the offering for sale, the sale after importation, or otherwise transferring within the United States, the Synthetically Produced Omega-3 Products;

G. Require Respondents to post a bond to secure Complainants' interests during any Presidential review of a Commission exclusion order; and

H. Issue such other and further relief as the Commission deems just and proper under the law, based upon the facts determined by the investigation and the authority of the Commission.

Respectfully submitted,



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Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Ltd.

Date: August 30, 2017

UNITED STATES INTERNATIONAL TRADE COMMISSION

In the Matter of **Certain Synthetically Produced, Predominantly EPA Omega-3 Products In Ethyl Ester Or Re-esterified Triglyceride Form**	)	**Investigation No. 337-TA- ___**

VERIFICATION OF COMPLAINT

I, Steven Ketchum, am Senior Vice President, President of Research and Development, and Chief Scientific Officer for Amarin Pharma, Inc., and am authorized to execute this verification on behalf of Complainants, Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Ltd. I have read the Complaint and am aware of its contents. To the best of my knowledge, information, and belief and based upon reasonable inquiry under the circumstances, I hereby certify that

1. The allegations contained in the Complaint are well grounded in fact and have evidentiary support, or are likely to have evidentiary support after a reasonable opportunity for further investigation or discovery;

2. The claims and other legal contentions set forth in the Complaint are warranted by existing laws or by a good faith, non-frivolous argument for extension, modification, or reversal of existing law, or by the establishment of new law; and

3. The Complaint is not being filed for any improper purpose, such as to harass or to cause unnecessary delay or needless increase in the cost of litigation.

Dated: August 25, 2017

Steven Ketchum

Steven Ketchum, Ph.D.
Senior Vice President, President of Research and Development, and Chief Scientific Officer
Amarin Pharma, Inc.

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EXHIBIT 29

Supplements and Safety: Transcript
PRODUCED BY

Neil Docherty

Anita Elash

Lisa Ellenwood

CORRESPONDENT

Gillian Findlay

DIRECTED BY

Neil Docherty

TRADE SHOW SALESMAN:
This is a product that was formulated for people who are severely—

TRADE SHOW SALESMAN:
It would be great for older individuals that are concerned about—

TRADE SHOW SALESMAN:
—joint supplement—

GILLIAN FINDLAY, Correspondent:
[voice-over] It's estimated that half of all Americans take a health supplement every day.

TRADE SHOW SALESMAN:
That one is going to be amazing for supporting—

TRADE SHOW SALESMAN:
—encapsulates the nutrients in a non-GMO soy—

GILLIAN FINDLAY:
It's a $30-plus billion industry.

TRADE SHOW SALESMAN:
I will guarantee you that this will change your reality within three to five days.

GILLIAN FINDLAY:
Companies range from big pharma to mom and pop.

Twitter #supplements

CANDICE TRIPP, Owner, Purity First:

I started in my kitchen making them by hand back in the '80s. I would order the ingredients, I would order the capsules, and with a plate of 100 capsules, I would weigh it out and fill them up, and you have a bottle of 100 capsules of any particular vitamin you wanted.

GILLIAN FINDLAY:
[on camera] Do you have background in pharmacology or medicine or any expertise in this area?

CANDICE TRIPP:
I did some college, but most of my time was spent in the medical libraries at Stonybrook.

GILLIAN FINDLAY:
So you sort of were self-taught, then, were you?

CANDICE TRIPP:
Self-taught, correct. Yes.

GILLIAN FINDLAY:
[voice-over] Candice Tripp called her company Purity First. She says she was helped by her then husband, Terence Dulin, a chiropractor.

[on camera] And what was his academic background or expertise in this area?

CANDICE TRIPP:
He was a chemist. He was a chemist in college, and then he went on to chiropractic school.

GILLIAN FINDLAY:
[voice-over] From modest beginnings, she grew the business into a half-a-million-dollar-a-year enterprise, selling on the Web, in stores and through local alternative health care providers.

VINCENT GROSSO, Purity First Customer:
Purity First is a great name, and I said,"Gee, how can you go wrong?" It's what you would imagine that you would want in every single vitamin, that it's absolutely pure.

GILLIAN FINDLAY:
Vinnie Grosso was an early Purity First customer. The vitamins became part of his daily quest for better health.

VINCENT GROSSO:
I felt fine. And of course, you know, I'm running every day. I'm feeling great up until the October, November, December timeframe of 2012, where I had some very unusual symptoms.

GILLIAN FINDLAY:
It started with unexplained back pain that soon became debilitating. He then started hearing from other Purity First customers with troubling symptoms of their own.

VINCENT GROSSO:
I'm hearing stories— "My daughter is an honor student and she's on the swim team, but she's been thrown out of school for being overly aggressive." I'm talking to a woman who had lost her position in a

choir because her voice had changed. I'm talking to another woman, who said, "I've got these incredible bleeding scales on my head, and I can't go to work."

GILLIAN FINDLAY:
They were all taking the same vitamins, recommended, they say, by Terence Dulin, the chiropractor, now a naturopath. Dulin declined to be interviewed and denies any responsibility.

CANDICE TRIPP:
Terry had come to me in January and asked me if I thought anything was wrong because he said there was some blood tests coming back that were funky. At that point, we had just had Hurricane Sandy come through, and a lot of people were getting sick after they were in their basements cleaning up water. And that's why he had recommended people go see this other doctor. And they started going to see Dr. Spaeth.

VINCENT GROSSO:
We had an examination, and he said to me, "What is it that all of you who have come to me in the past month and a half have one commonality. You've all taken Purity First B-50 vitamins."

GILLIAN FINDLAY:
It's estimated there are 85,000 dietary supplements for sale in the United States today.

TRADE SHOW SALESMAN:
Right here, I have our liposomal D—

TRADE SHOW SALESMAN:
So this is our bacopa. This is an herb that would be great for older individuals that are—

TRADE SHOW SALESMAN:
The essential nutrients, like chromium—

GILLIAN FINDLAY:
With so many pitches and promises, you might assume that some government agency has approved them before allowing them onto the market.

STEPHEN OSTROFF, M.D., Acting Commissioner, FDA:
The FDA does not do any review of dietary supplements before they come onto the market, and I think that all consumers need to understand this.

GILLIAN FINDLAY:
No testing, no obligation to provide any evidence a product is effective, or even safe. The one thing manufacturers do have to show is that they follow good manufacturing practices. The FDA conducts inspections for that, but it'and by information.

Dr. STEPHEN OSTROFF:
We actually don't know the total number of manufacturers that we need to be able to inspect because there is no formal registration system that is required of manufacturers that make dietary supplements, and so we do inspections of the ones that we know about.

GILLIAN FINDLAY:
The FDA did know about a supplement manufacturer that used to operate here. In 2012 and again in the spring of 2013, MIRA Health Products was cited by FDA inspectors for violating manufacturing codes. Among the products MIRA produced, Candice Tripp's Purity First vitamins.

CANDICE TRIPP:
I had a lot of faith in MIRA because he was more of a smaller-scale manufacturer. He wasn't one of these big pharmaceutical companies that just didn't really make you warm and fuzzy.

GILLIAN FINDLAY:
[on camera] Well, what did you do to try to verify that this was a reputable company that would make the product that you wanted?

CANDICE TRIPP:
They're supposed to test the product and give you an analysis at the end that what is in the capsule is what they've tested, and the certificate is supposed to be certified and this is what your product is.

GILLIAN FINDLAY:
And did they give you those certificates?

CANDICE TRIPP:
I believe— yes, they did. They gave us those, and there didn't seem to be a problem.

GILLIAN FINDLAY:
[voice-over] But by 2013, there was a problem. Dr. Kenneth Spaeth, who specializes in environmental health, is a man those Purity First customers turned to to investigate their symptoms. He arranged for the B-50 vitamins to be tested, and the results were a shock. The capsules were laced with two anabolic steroids.

Joe Kueler, Candice Tripp's current husband, took it up with MIRA's owner.

JOE KUELER, Purity First:
I called Mike and said pretty much, "What could have happened?" And you know, he was making the male enhancement pills, and he said, "Joe," he said "if they found any type of steroids in there, the only thing I could possibly think is maybe the mixer was not cleaned enough."

GILLIAN FINDLAY:
By now, Purity First customers had started hiring lawyers and sharing their stories.

CHRIS MEAGHER, Plaintiffs' Attorney, Meagher & Meagher, White Plains, NY:
A change in the voice, change in the sexual organs, hair growth on a young lady was one of our clients, basically developing moustache, beard, the female sexual organs taking on a male configuration. For the men who ingested these things, they developed what's called gynecomastia. You end up with male breasts.

GILLIAN FINDLAY:

It would take the FDA nearly six months to get the Purity First vitamins off the market, a response Dr. Spaeth called "glacial." He declined to be interviewed on camera, but he shared email exchanges with us detailing his efforts to get the FDA to act.

Spaeth says he suspected contamination, but his first inquiry went unanswered. When he emailed again, asking if the lack of response was a lack of interest, he was referred to the FDA's hotline for adverse reactions, called Medwatch. Spaeth had tried the line, been transferred and put on hold before being disconnected twice.

Five weeks later, he was still frustrated. "Will you tell me what your plans are?" he wrote. "I have 20 very worried patients and little to offer them."

Among the officials Spaeth was writing to was Daniel Fabricant, then head of the FDA's Division of Dietary Supplements.

DANIEL FABRICANT, Ph.D., Div. of Dietary Supplements, FDA, 2011-14:
We took that information. While it was helpful, it didn't make the whole case. We had to make the case at FDA, and we did, and removed the product successfully.

GILLIAN FINDLAY:
[on camera] One of his biggest complaints is the amount of time it took just to get somebody to call him back. He says that one of the operators— "She acted as if I was telling her that aliens put messages in my Cheerios."

Now, that doesn't suggest that you've got a particularly robust system in place to allow people to report problems when they happen, right?

DANIEL FABRICANT:
Well, I can assure you the government worked very quickly. The agency is acting to remove the product across the board, across the country. So it's a bit more of a heavier scientific lift than just a doctor having an intuition or a feeling about something. They have to build evidence, court-ready evidence, to take away somebody's product, somebody's manufacturing operation.

And that's exactly what we did. And doing that in six months, the team at the FDA worked diligently and worked quickly to do that, which was quite a successful accomplishment.

CANDICE TRIPP:
Two women from the FDA came in and were speaking with us about how there seems to be a problem with one of our products. When we asked which product, they said, Oh, that didn't matter yet. OK. "Do you want us to stop selling the product?" "No, you don't have to stop selling the product. Nobody died," they said.

GILLIAN FINDLAY:
[on camera] "Nobody died"— those were their words.

CANDICE TRIPP:
Their words were, "Nobody died. You don't have to pull the product."

GILLIAN FINDLAY:
If there was any concern at all, why didn't you just pull it from the market? I mean, why did you not do it yourself?

JOE KUELER:
Great question. Their response to me was, "People call the FDA all the time to report minor things, so don't worry about it."

GILLIAN FINDLAY:
[voice-over] The FDA strongly denies those things were said.

NEWSCASTER:
So vitamins manufactured here on Long Island are triggering—

NEWSCASTER:
The FDA recently issued a recall—

NEWSCASTER:
The FDA wants—

GILLIAN FINDLAY:
In the end, Purity First withdrew the vitamins under pressure. MIRA was forced out of business by the FDA. Nobody from the company would speak to us. Thirty-six people are now suing the companies, and no one knows how many people in total may have been harmed.

For Vinnie Grosso and his lawyer, it was a sobering look into a troubled world.

VINCENT GROSSO:
I was very concerned, and then I realized that this whole industry needs change and how much danger we're all in not just from Purity First, likely, but from others that can put anything into these little bottles and put a seal and a label on it.

GILLIAN FINDLAY:
In 2013, the Children's Hospital of Philadelphia had had enough. Worried about the number and quality of the supplements their patients were arriving with, hospital pharmacists decided to challenge manufacturers.

SARAH ERUSH, Pharm.D., Pharmacy Clinical Manager:
Families are showing up literally with shopping bags full of dietary supplements. The regulatory issues in the United States are that you have to— if a patient brings a medication into a hospital, we have to, as pharmacists, verify that this is a quality product, it is what it says it is, it's labeled appropriately, it's being dosed appropriately, and so on.

PAUL OFFIT, M.D., The Children's Hospital of Philadelphia:
We got fed up. We took a step back and we said, "OK, we're going to ask these companies to at least meet a labeling standard." They have to send us something called a certificate of analysis, which means they've had their product analyzed by an independent party that says that what's on the label is what's in the bottle.

Ninety percent of the companies never responded. And of the 10 percent that responded— of that 10 percent, often they would send us certificates of analysis where was what on the label wasn't even close to what was in the bottle. And these were the ones who responded to us, which made us fearful of an industry that we couldn't trust.

SARAH ERUSH:
For example, this is an aqueous Vitamin D drop. So we use Vitamin D in premature infants. It says it should have 400 International Units per one ml of solution. However, it tells us that the results are that it's 213 percent of the legal value. So it's more than double what it says that it is.

So if we're dosing premature infants who need very tiny doses if this drug, we're now potentially giving them double what they should get, and could really put them at risk for toxicity.

GILLIAN FINDLAY:
In the end, only 35 supplements met the hospital's standards.

SARAH ERUSH:
I come away very worried and dismayed, worried mostly about what the American public is being exposed to because it's essentially a complete unknown. When you're buying a dietary supplement, unless you have some proof of what's in that product, it could be anything.

GILLIAN FINDLAY:
At the New York Botanical Gardens, you can find many of the herbs we buy in bottles in their natural state. This is black cohosh, commonly recommended to women to treat symptoms of menopause. In 2010, gynecologist David Baker decided to check out what so many of his patients were taking. He bought dozens of brands of black cohosh supplements and starting testing the DNA.

Prof. DAVID BAKER, M.D., Stony Brook Univ. School of Medicine:
Thirty percent had no black cohosh. And in the samples that we found, we could identify the other plants, as well, and they were from ornamental plants from China.

GILLIAN FINDLAY:
Baker and his colleagues published the result in an academic journal, but they didn't get much attention, so they kept on testing. Other supplements produced results that were no less disturbing.

Dr. DAVID BAKER:
Upwards of 15 percent of supplements like saw palmetto are not saw palmetto. Supplements like devil's claw— 100 percent are not devil's claw or contaminated with some other problem.

What I see in this is that there are those who take the easy way out, the fraudulent way, and want to put something in the bottle that's cheap and readily available. And buyer beware.

GILLIAN FINDLAY:
With billions of dollars at stake, it's no surprise that the supplement industry is a powerful force in Washington. There are four separate lobby groups, the largest the Natural Products Association, headed by Daniel Fabricant.

DANIEL FABRICANT:
You know, a lot of the products now, you'll see private label. A lot of the contract manufacturers that make the private label are our members, as well.

GILLIAN FINDLAY:
It's the same Daniel Fabricant who until 2014 was in charge of regulating dietary supplements at the FDA. He defends what critics have called a disturbing revolving door.

DANIEL FABRICANT:
Folks who understand an industry make for very effective regulators. I think it certainly worked to the consumers' benefit, which at the end of the day, I think FDA and the industry are in the same business, is to make sure consumers have access to safe, healthy products.

GILLIAN FINDLAY:
[on camera] Do you accept that there is a problem with adulteration, though, in the natural health food industry?

DANIEL FABRICANT:
There may be some supply chain issues we need to be mindful of. But again, I think that there are federal authorities that cover that, that ensure the products are made to— you know, made to certain quality parameters. It's defined by law. And if firms don't, there are clear consequences.

So I think that that's the important thing, is Americans have a high degree of confidence in the products because of that.

GILLIAN FINDLAY:
[voice-over] But just months after leaving the FDA, Fabricant didn't sound so confident himself. In a presentation to a trade association conference, he shared some of the results of FDA inspections.

[on camera] You talked about some of the findings, the companies that were doing no testing, have no idea of what they're buying or selling, companies that have no standards—

DANIEL FABRICANT:
Sure.

GILLIAN FINDLAY:
—inadequate records being kept, no specifications set. And this is a quotation. "The extreme of this observation is more common than expected," which I read to be, "This is worse than we thought."

DANIEL FABRICANT:
The extreme, those are the companies we took action against. Those are the companies that we drove out of business. I'm speaking from my experience when I was a regulator, when we saw those problems and they were extreme, we threw the book at people. And so I think that that's— you know, that's good news for consumers.

GILLIAN FINDLAY:
How many companies did you throw out of business?

DANIEL FABRICANT:
Quite a number. I think we processed over 25 injunctions during my time at the agency, so—

GILLIAN FINDLAY:
In an industry that has 4,000 or more manufacturers, is that significant?

DANIEL FABRICANT:
I got my 25. You get yours.

GILLIAN FINDLAY:
[laughter] I'm not a regulator. I don't think that's going to happen!

DANIEL FABRICANT:
It is significant. It's very significant.

GILLIAN FINDLAY:
[voice-over] The FDA division in charge of the supplement industry is tiny, just 25 employees. They target companies they consider the most risky, but agree the problem remains much bigger than that.

Dr. STEPHEN OSTROFF:
Because of the targeting and because of, traditionally, the way this industry has developed over time, we do see a higher proportion of inspections that we do with dietary supplements, a higher proportion of them that have substantial problems than in other categories that we regulate.

GILLIAN FINDLAY:
[on camera] How much does that worry you?

Dr. STEPHEN OSTROFF:
Of course it's a concern because, ultimately, this isn't about us and it isn't about the companies, it's about the consumers.

GILLIAN FINDLAY:
[voice-over] To many, supplements may look like prescription drugs, but there is a big difference. Drug makers have to prove their products are safe and effective before putting them on the market. Those who make supplements don't, not unless they're introducing a new ingredient that's never been marketed before.

PIETER COHEN, M.D., Asst. Professor, Harvard Medical School:
It's an absurd system. In the future many years, we'll look back and we'll say, "How could we have possibly done this?"

It took a hundred years of thoughtful regulatory advances to ensure that drugs — now we're talking about prescription drugs — are both safe and effective. How could it be that the clock turned back to the world of the 1920s, 1930s, when you can sell something without any evidence that it's safe or effective?

DAVID KESSLER, M.D., Commissioner, FDA, 1990-97:

We are back at the turn of the century when snake oil salesmen could hawk their potions with promises that couldn't be kept.

GILLIAN FINDLAY:
In the early 1990s, the head of the FDA was David Kessler. He'd arrived in office promising tougher regulations for supplements, in particular demanding health claims be backed by scientific evidence.

Dr. DAVID KESSLER:
The industry went bonkers. Everything exploded. I mean, I've taken on some of the hardest regulatory issues. You know, I did tobacco. Tobacco looked easy compared to dietary supplements.

What happened was the dietary supplement industry recognized that the standard that we set — significant scientific agreement — would require it, before it could make a claim, to have a scientific basis. And they just couldn't make any claim. And they saw, literally, billions of dollars at stake, and they unleashed a lobbying campaign that was second to none.

GILLIAN FINDLAY:
The campaign was as dramatic as it was effective..

TELEVISION COMMERCIAL ACTORS:
Freeze! Hey guys, guys, it's only vitamins…

GILLIAN FINDLAY:
…complete with Hollywood stars.

TELEVISION COMMERCIAL ACTOR:
Vitamin C, you know, like in oranges—

DAN HURLEY, Author, Natural Causes:
Congress received more letters regarding this than they ever received regarding the Vietnam war.

GILLIAN FINDLAY:
Dan Hurley has written what many consider the definitive account of the industry's battle with the regulator.

Dr. DAVID KESSLER:
…we hear people claiming that FDA…

GILLIAN FINDLAY:
While David Kessler tried to convince Congress, behind the scenes another Kessler was at work.

DAN HURLEY:
Jerry Kessler ran a large dietary supplement company. He was a very strong-willed character.

JERRY KESSLER:
The FDA is going to limit potencies of vitamins, which is what they've said. The FDA is going to take herbs and make them drugs. The FDA—

DAN HURLEY:
And he called together every leading manufacturer to come out to his ranch in California, which used to belong to Ray Kroc of McDonald's, OK? So Jerry basically stands up before the group and says, "This is either the end of our industry or a new beginning. And we have to defend our interests."

GILLIAN FINDLAY:
Jerry Kessler would turn out to be a very effective lobbyist, joining forces with powerful political friends—

Sen. ORRIN HATCH (R), Utah:
—because today, we honor the wishes of 100 million people, consumers of dietary supplements—

GILLIAN FINDLAY:
—friends like Senator Orrin Hatch of Utah. The senator declined to be interviewed. His state is seen as the global center for dietary supplement manufacturing. His son has lobbied for the industry, and Hatch himself has owned shares in at least one supplement company. He's never hidden the fact he's a believer.

Sen. ORRIN HATCH:
We know that the American people are not a bunch of kooks or a bunch of dummies! And what the people want is the right to use products which have helped them for centuries!

GILLIAN FINDLAY:
The campaign worked.

DAN HURLEY:
Jerry Kessler said, "Forget this law that's going to actually regulate. We need a law that says you can't regulate these products." And he named it The Dietary Supplement Health and Education Act. He came up with the name of it, Jerry Kessler did, a manufacturer.

GILLIAN FINDLAY:
The one concession the FDA did get was an agreement that manufacturers would not make unproven health claims. And so, for example, they can't say their products "cure" arthritis or "prevent" heart disease. But they can say they "support" things like bone density, "promote" cardiovascular health.

Dr. DAVID KESSLER:
What Congress did is basically said, "Industry, you go make the claims, and if FDA has a problem with it, FDA has to prove it's false or misleading." So the horse is out of the barn. FDA then has to go seize the product, go into court, and it has the burden.

VOICE ON FLOOR OF CONGRESS:
…784, a bill to amend the Food, Drug and Cosmetic Act to establish standards with respect to dietary supplements…

GILLIAN FINDLAY:
Problems with the legislation would become apparent even before it passed. The FDA was getting complaints about popular new weight loss supplements containing an ingredient called ephedra. Manufacturers fought the FDA for more than a decade.

NEWSCASTER:
Yesterday, 23-year-old Steve Bechler became the first baseball player ever to die—

GILLIAN FINDLAY:
It wasn't until a young major league pitcher died after taking ephedra that sales were halted.

NEWSCASTER:
—a new stimulant called ephedra—

GILLIAN FINDLAY:
By then, more than 160 deaths had been linked to the supplement.

HERBERT BONKOVSKY, M.D., Wake Forest Baptist Medical Center:
It almost takes a sacrificial lamb to die of liver injury or some other injury before the Food and Drug Administration can take any action.

GILLIAN FINDLAY:
Dr. Herbert Bonkovsky is an investigator with a liver injury network funded by the National Institutes of Health. He's concerned about the harm supplements are causing.

Dr. HERBERT BONKOVSKY:
This has been sort of the fastest growing kind of liver injury that we're observing in the drug-induced liver injury network. The frequency with which we see this has roughly tripled in the last 10 years. About 7 percent of all the cases that we've enrolled into this network over the years were due to these. In the last couple of years, it's been around 20 percent.

PIETER COHEN, M.D., Asst. Professor, Harvard Medical School:
It's incredibly hard to quantify the current problem, how much harm are supplements are doing. Just yesterday, I was talking to a patient who suffered a bleeding stroke into his brain after taking just one workout supplement. And the reason why we don't know is that there's no effective system to detect harm from supplements.

GILLIAN FINDLAY:
Take what happened in Hawaii in the summer of 2013. There was an outbreak of liver problems health officials would link to a diet and workout supplement.

LINDA WONG, M.D., Transplant surgeon, Univ. of Hawaii:
We didn't know if it was something in the Hawaiian population or some sort of contaminant, or what exactly the problem was.

GILLIAN FINDLAY:
The state's only transplant center was overrun. An initial cluster of seven patients grew to more than two dozen, two of them sick enough to need new livers.

Dr. LINDA WONG:

It was difficult. It was stressful because people were calling up and they were continually referring new patients, and I don't have enough organs to give. I don't know how I could put all these patients on a transplant list and possibly save all of them.

NEWSCASTER:
Sad news tonight from the family of a Maui woman. The mother of seven, who fell ill after taking diet pills, has died.

NEWSCASTER:
The Department of Health reports 32 cases of liver damage—

NEWSCASTER:
The product is OxyElite Pro, and health officials want to know—

NEWSCASTER:
—dietary supplement OxyElite Pro—

GILLIAN FINDLAY:
Just two months before the outbreak, the makers of OxyElite Pro had been pressured to pull an earlier formulation from the market following years of complaints. The new version included a compound called aegeline.

Dr. HERBERT BONKOVSKY:
Now, aegeline is a normal component of the bael tree, and it's been used as a natural product by naturopathic healers for centuries, usually fairly safely.

But they didn't use bael tree extract. They bought aegeline from a Chinese drug company that made aegeline — at least, the company claimed it was aegeline — and within a few months, they began to observe patients with liver failure, mostly in Hawaii but not entirely.

GILLIAN FINDLAY:
Cynthia Novida is a chief petty officer with the U.S. Navy based in San Diego. She turned to OxyElite Pro to help pass fitness tests.

CYNTHIA NOVIDA:
It helped keep my weight down. It helped, you know, just give me that extra push during a workout, and I was liking it and I would take it.

GILLIAN FINDLAY:
But only half-way through the first bottle, Cynthia's eyes started turning yellow. Her doctor had bad news.

CYNTHIA NOVIDA:
That's when he told me that "Your liver is shot pretty much. You'll possibly need a liver transplant."

GILLIAN FINDLAY:
She would get a transplant.

The FDA has linked OxyElite to more than 70 cases of liver damage. The company declined to be interviewed and denies any responsibility.

Doctors in Hawaii still remember how slow the FDA was to act. They say they followed all the directions on the agency's Medwatch Web site. They phoned several times. But it wasn't until they approached the state health authorities that the FDA finally called them back.

Dr. LINDA WONG:
They told one of our liver doctors that, you know, they thought she was a prankster because she had sent in her, you know, private email address, and you know, kept bugging them, and you know, they didn't think we were real.

GILLIAN FINDLAY:
[on camera] They weren't taking you seriously.

Dr. LINDA WONG:
No. It would be nice if there was a system that, you know, we could use and get some consistent results.

GILLIAN FINDLAY:
But the FDA says they do have a system. That's what Medwatch is.

Dr. LINDA WONG:
Right. But I don't know if they're overwhelmed, but the way it stands is there's— you know, we're not getting a response as quick as we probably should be.

GILLIAN FINDLAY:
In Hawaii, there were reports of a cluster of people who developed severe liver problems. The doctor in the case we have spoken with raises troubling questions. Repeatedly, she says, she and her colleagues tried to contact Medwatch, tried to report and tried to get advice from the FDA as to what to do. And repeatedly, she says, they heard nothing back.

Had you heard this before?

DANIEL FABRICANT, Ph.D., Div. of Dietary Supplements, FDA 2011-14:
No. I can't deal with hearsay and speculation, and I'm not going to speculate. What I can tell you is when the documents did come in the FDA, that alerted us to the problem in Hawaii, we were able to remove the product within a month.

GILLIAN FINDLAY:
By that point, there were 56 cases of liver damage that had been reported, and this was for a company that only had six months earlier had had another formulation removed.

DANIEL FABRICANT:
There weren't 56 cases reported until sometime after we had the product removed. We had the product removed with effectively about 20 cases.

GILLIAN FINDLAY:

[voice-over] Cynthia Novida is one of more than 100 people who are now suing the makers of OxyElite Pro. A 23-year veteran with the Navy, she had hoped to get her 25-year service pin. That's not likely to happen now.

CYNTHIA NOVIDA:
You know, I have to be able to travel and can't do that now, can't go on a ship because they don't carry the meds that I need continuously.

GILLIAN FINDLAY:
Her doctors tell her the price of that one pill is that she'll have to take 19 pills every day for the rest of her life. The makers of OxyElite deny all claims against them.

JUSTICE DEPT. OFFICIAL:
The allegations against USP Labs and its operators—

GILLIAN FINDLAY:
But in November 2015, the Justice Department launched a criminal case against the company and arrested four of its executives on fraud charges.

JUSTICE DEPT. OFFICIAL:
—vigilant when it comes to the health and safety of the American public.

TELEVISION COMMERCIAL:
Omega 3 is essential for good health.

GILLIAN FINDLAY:
The promises are endless.

TELEVISION COMMERCIAL:
The minerals your kids need and—

GILLIAN FINDLAY:
But even if what you buy in those bottles is real, critics contend there's a bigger problem. Many supplements simply don't work. What's worse, they could be doing you harm.

OZ SHOW GUEST:
Now, supplements. I get this question all the time. I only take four pills—
GILLIAN FINDLAY:
Our screens blare advice on how to get health from a pill.

TV HOST:
Today, I'd like to talk to you a little bit about supplementation.

GILLIAN FINDLAY:
Reputations have been built on dispensing that advice.

ANDREW WEIL, M.D.:
—that everyone should be taking a multi-vitamin, multi-mineral product as insurance against—

GILLIAN FINDLAY:
But amid all the hype, what's often lost is the science.

PAUL OFFIT, M.D., The Children's Hospital of Philadelphia:
When people walk into the dietary supplement or vitamin store, they think that everything is just perfectly safe.

GILLIAN FINDLAY:
In addition to being a pediatrician, Paul Offit is a best-selling author whose book "Do You Believe in Magic?" questions our supplement habit.

Dr. PAUL OFFIT:
So I've got vitamins for children and vitamins for adults. The problem is, is when you look on the back, you find that a number of these vitamins are contained in amounts that are much greater than the recommended daily allowance.

GILLIAN FINDLAY:
Offit believes we simply take too many.

Dr. PAUL OFFIT:
I think multi-vitamins don't hurt, which is to say vitamins at or around the daily recommended daily allowance for each of those vitamins.

But you need vitamins to live. The question is, do you get enough in food? And I think the answer to that question is yes. But now there are studies done showing if you use— take a mega-vitamin, you actually can hurt yourself. You actually can increase your risk of cancer, increase your risk of heart disease. I think few people know the risks they're taking.

GILLIAN FINDLAY:
[on camera] And how do you know what's too much?

Dr. PAUL OFFIT:
Here's how you know what's too much. You shouldn't bypass the satiety level. Your stomach is only so big for a reason.

GILLIAN FINDLAY:
[voice-over] He illustrates the point with 1,000 milligrams of Vitamin C. That's one of these pills. To get the same amount of the vitamin from a food source, you'd have to eat between seven and eight entire cantaloupes.

Dr. PAUL OFFIT:
You know, you're not meant to eat eight cantaloupes. It's a dangerous thing to do, to go against what nature intends.

GILLIAN FINDLAY:

It's even worse with Vitamin E, he says. This capsule has 1,000 International Units. You can also find Vitamin E in almonds, but to get the same 1,000 units, you'd have to eat a lot of almonds— 1,670, to be precise. Scientific studies have shown that that much Vitamin E can be dangerous.

Dr. PAUL OFFIT:
If you take large quantities of Vitamin E as a supplement, you clearly and definitively increase your risk of prostate cancer. And in a better world, in a regulated world, were Vitamin E a regulated product, it should have a black-box warning on it that says just that.

GILLIAN FINDLAY:
Vitamins E and C are antioxidants, and for years we've been told to take them because antioxidants are the mortal enemy of "free radicals," cells linked to cancer and other diseases.

Dr. PAUL OFFIT:
I mean, if you look at people, for example, who eat diets rich in fruits, rich in vegetables that contain antioxidants, they do seem to live longer and have lesser rates of cancer and heart disease.

So the thinking was, "Great. OK, now we've figured out a way to make ourselves healthier. Now let's double down and take even larger quantities of antioxidants." And that's where we cross the line. And now study after study shows that in fact it's true. You can take too much in the way of anti-oxidants.

GILLIAN FINDLAY:
In response to the studies, in 2013, one of the world's most important scientific journals published an editorial. "Enough Is Enough" argued, "The case is closed. Supplementing the diet of well-nourished adults with most supplements has no clear benefit and might even be harmful."

Dr. Eliseo Guallar was the lead author.

ELISEO GUALLAR, M.D., Johns Hopkins:
These might be the some of the best well-studied compounds in the history of mankind in terms of clinical trials. There are well over a couple hundred thousand people that have participated in clinical trials. So the conclusions that we have for anti-oxidant vitamins I think are very strong.

GILLIAN FINDLAY:
Vitamin D is not an anti-oxidant, but it is one of the top-selling vitamins in America, pushed with information that's often confusing.

TV HOST DR. OZ:
Vitamin D - if I had to pick one vitamin to push to everybody to think about again in their lives, it's Vitamin D.

GILLIAN FINDLAY:
It's true we do all need some Vitamin D. The Institute of Medicine recommends adults get 600 International Units a day. But look at the doses some others are suggesting.

TV HOST:
—recommended 5,000 IUs daily, and if—

GILLIAN FINDLAY:
On one Web site, I answered just three questions — my age, my height and my weight — and was told I needed 10,000 International Units a day, 16 times the IOM's recommendation.

JoANN MANSON, M.D., Brigham and Women's Hospital:
When I hear that various groups are recommending 10,000 IUs a day, or even 5,000 IUs a day routinely, I really want to say,"Show me the data. Show me the evidence."

GILLIAN FINDLAY:
Evidence is what Dr. JoAnn Manson is accumulating here. She's collected blood samples from over 25,000 people.

Dr. JoANN MANSON:
The vital trial is, to our knowledge, the largest randomized clinical trial of Vitamin D supplementation in the world.

GILLIAN FINDLAY:
Manson is comparing disease rates between those who take Vitamin D supplements and those who don't. Final results won't be known until 2017, but already she has concerns.

Dr. JoANN MANSON:
Many people are taking too much vitamin D. The Institute of Medicine also recommended avoiding getting above 4,000 IUs daily because that could be associated with adverse events— calcium in the urine, which can be associated with kidney stones, high blood calcium, calcium in the arteries, vascular calcification, as well as soft tissue calcification.

And there are now studies that show a U-shaped curve that those who have high as well as low blood levels of Vitamin D have higher risk of cardiovascular disease, as well as all-cause mortality. So we can't assume that more is necessarily better.

GILLIAN FINDLAY:
The third most widely used supplement in America is fish oil. The Omega 3s contained in the oil are believed by many to be essential for good health.

ADAM ISMAIL, GOED fish oil trade association:
DHA, Omega 3 in particular, is— is extremely important—

GILLIAN FINDLAY:
It also helps prevent disease, according to the man who heads one of the largest fish oil trade associations.

ADAM ISMAIL:
There's certainly ample evidence that it helps things like reducing blood pressure, reducing your risk of coronary death.

GILLIAN FINDLAY:
But the science behind fish oil is a little more complicated than that.

PRESTON MASON, Ph.D., Harvard Medical School:
So these are two capsules. This is an FDA-approved product—

GILLIAN FINDLAY:
Dr. Preston Mason is a Harvard University researcher. Here he's comparing prescription-quality fish oil to the oil found in over-the-counter supplements.

PRESTON MASON:
And give it a smell.

GILLIAN FINDLAY:
[on camera] Smells a little bit fishy but not— not bad.

PRESTON MASON:
Right. Smells— you're going to have always some smell.

GILLIAN FINDLAY:
[voice-over] One of the issues with fish oil is it's delicate. It's extracted as a byproduct from oily fish like anchovies. As the fish get crushed, the oil is exposed to oxygen. And it doesn't take much oxygen to turn the oil rancid.

PRESTON MASON:
This is a common supplement for fish oil. See what that smells like.

GILLIAN FINDLAY:
[on camera] Oh!

PRESTON MASON:
What?

GILLIAN FINDLAY:
That doesn't smell good. That's— that smells like it's going bad.

PRESTON MASON:
Yeah. Right. Yeah. It's a very strong, fishy smell.

GILLIAN FINDLAY:
[voice-over] If it was simply an odor issue, that would be one thing. But oxidized oil contains oxidized lipids, one of the building blocks of cells. We've long known that lipids, when oxidized, can be harmful.

PRESTON MASON:
So oxidized lipid triggers inflammatory responses within our body, particularly in our cells. And if we ingest oxidized lipid, we can trigger these inflammatory changes that can lead to things like cardiovascular disease.

GILLIAN FINDLAY:

Recently, Mason published his own study of fish oil supplements. The results were consistent with other studies showing high levels of oxidation. One in New Zealand found 83 percent of fish oils tested failed to meet the industry's own standard.

ADAM ISMAIL, GOED fish oil trade association:
It was shocking to see such a high proportion of products that had high oxidation levels. And so we went and actually bought 47 products from the New Zealand market and had them tested at multiple labs, and we did not see that same effect.

GILLIAN FINDLAY:
[on camera] Well, what was the percentage you that you discovered that were not in compliance with your standards?

ADAM ISMAIL:
It was around 20 percent.

GILLIAN FINDLAY:
Would you agree that 20 percent is still problematic—

ADAM ISMAIL:
Well—

GILLIAN FINDLAY:
—from the consumer's point of view? I mean—

ADAM ISMAIL:
If it's truly 20 percent, then yeah, we would like to see those 20 percent improved.

GILLIAN FINDLAY:
[voice-over] But improving the quality won't address the other issue with fish oil, the growing questions about whether it prevents disease. Two years ago, epidemiologist Dr. Andrew Grey compiled all the best studies on fish oil as reported in the world's most prestigious scientific journals.

ANDREW GREY, M.D., University of Auckland:
I think for cardiovascular disease, one has to say there is no compelling evidence that taking fish oils protects against the first heart attack, or a second heart attack. And so people who are advised to do that, or are doing it, are wasting their time and their money.

GILLIAN FINDLAY:
But the fish oil industry continues to insist there is a benefit, particularly for preventing heart attacks. We asked their spokesman to send us his best evidence, which included some of the same studies Grey had cited, and didn't seem to support his case.

[on camera] This one says it doesn't appear to reduce sudden cardiac death. The next one, insufficient evidence. "JAMA" 2012, overall, Omega-3 supplementation was not associated with a lower risk of all cause mortality.

Another journal— "The evidence is not clear-cut, and any benefits are almost certainly not as great as previously believed."

So it doesn't seem to be suggesting that there's an overwhelming amount of evidence.

ADAM ISMAIL:
Yeah, well, I think what you're looking at are the abstracts.

GILLIAN FINDLAY:
But the conclusions are the conclusions.

ADAM ISMAIL:
Well, but again, those papers are looking at very large areas of cardiovascular disease, and you know, I think it's hard to argue that Omega-3s aren't important for how your heart functions.

GILLIAN FINDLAY:
[voice-over] Many researchers agree, if you get them from eating actual fish. The problem is science still hasn't proven it's true for supplements.

PRESTON MASON, Ph.D., Harvard Medical School:
Well, we would think that something that's natural, that's essential to normal cell function and body function would have clinical benefits. It just has to be proven.

But in the meantime, there's certainly been a lot of promotion suggesting a benefit in everything from Alzheimer's disease to cardiovascular disease. But we still need the strong clinical trials to validate those hypotheses.

GILLIAN FINDLAY:
The same can be said about virtually every product the supplement industry sells. We wanted to discuss the issues with some of the industry's most prominent advocates. Dr. Mehmet Oz, Dr. Joseph Mercola and Dr. Andrew Weil all declined to be interviewed.

While the debate continues over whether supplements actually work, in rural Guelph, Ontario, there is a botanist who may have found an answer to that other troublesome question, what's actually in the pills and potions that we take.

Dr. Steven Newmaster is part of a worldwide effort to collect and catalogue nature's wide array of DNA. He believes in the power of nature to heal.

STEVEN NEWMASTER, Ph.D., University of Guelph, Canada:
I buy and use natural health products. I believe in them. I've used them all my life. I've used them with my family. We have that anecdotal evidence that you have some ailment, and you take a— whatever the remedy is, and it's dealt with.

GILLIAN FINDLAY:
So it's an irony that Guelph University was responsible for one of the latest studies documenting problems with supplement quality. In 2012, Newmaster and his team randomly selected 44 herbal

products off the shelves in Canada and the U.S. and started comparing them to the plant DNA in their databank.

STEVEN NEWMASTER:
And we looked at the results. I was fairly astounded. It's, like, "Wow."

GILLIAN FINDLAY:
Sixty percent of the products contained ingredients not listed on their labels. Even more astonishingly, one in three proved to be outright fakes.

STEVEN NEWMASTER:
If I put my consumer hat on, that pissed me off because I go in to buy a product that I believe in, that I care about and I pay a lot of money for, and it's not even in the bottle? Are you kidding me?

GILLIAN FINDLAY:
Unlike similar studies in the past, this one got noticed, front page of the Health section in The New York Times, an article that was read by, among others, New York's attorney general.

ERIC SCHNEIDERMAN, Attorney General, New York:
Last December, my office purchased a variety of store brand herbal supplements from stores in different parts of New York state—

GILLIAN FINDLAY:
Eric Schneiderman ordered up his own tests of herbal supplements, which produced even worse results.

ERIC SCHNEIDERMAN:
—and found only 21 percent of products we tested, in fact, had DNA evidence that they contained the product listed on the label.

We found the results to be shocking. We purchased products from four major chains— Walmart, Walgreens, Target and GNC. We found asparagus DNA, houseplant DNA, rice and other things, but not the product that was on the labels. And it seemed that there was just a massive fraud going on.

GILLIAN FINDLAY:
The attorney general demanded the companies stop selling the products. At first, the industry questioned the methodology. But then GNC, the largest of the supplement retailers, agreed to use DNA barcoding to authenticate its products. The industry spokesman, however, still isn't convinced— Daniel Fabricant.

DANIEL FABRICANT:
We're working the attorney general's office so they understand more about the industry and we understand more of their concerns. I think that that's important that we work together.

GILLIAN FINDLAY:
[on camera] Do you accept the findings that they've published?

DANIEL FABRICANT:

Well, I haven't been able to review the findings because—

GILLIAN FINDLAY:
No, because— they say, because it's an active investigation. But what they have told you— do you accept them?

DANIEL FABRICANT:
Without seeing the science — I'm a scientist first and foremost — I can't really comment on data I haven't seen.

GILLIAN FINDLAY:
So is that a yes or a no?

DANIEL FABRICANT:
That's a no.

GILLIAN FINDLAY:
You haven't seen the actual study from the attorney general so you can't actually comment, but you have seen the study from Guelph University that was published in.

DANIEL FABRICANT:
I've seen that, and you know—

GILLIAN FINDLAY:
And what— what do you make of that? I mean—

DANIEL FABRICANT:
Well, there's some—

GILLIAN FINDLAY:
—they're fairly similar findings.

DANIEL FABRICANT:
Well, I think some— their same challenges, though, is the accreditation of the lab. There's no mention of reference materials. Reference materials are critical when you're doing DNA analysis. You know, not knowing how you establish the baseline, what are you comparing?

GILLIAN FINDLAY:
[voice-over] Newmaster's comparison was to that library of DNA he and international scientists have been collecting.

STEVEN NEWMASTER:
We've done this now thousands, actually tens of thousands of times for products, and the process works and it works really well.

GILLIAN FINDLAY:
Today, 14 states' attorneys general have come together to demand change not only from the industry but from the FDA and lawmakers.

ERIC SCHNEIDERMAN, Attorney General, New York:
We think that there's responsibility in Congress and there's responsibility at the agency level. And we're just going to keep pressing until we can get them to take action.

GILLIAN FINDLAY:
Since that interview, federal prosecutors and regulators announced they've taken action against over 100 companies.

HOWARD SKLAMBERG, Deputy Commissioner, FDA:
We see a number of serious issues with dietary supplements and products falsely marketed as dietary supplements.

GILLIAN FINDLAY:
There are now signs that at least some in the industry are adopting new technology to ensure accurate labeling.

TRAVIS BORCHARDT, V.P., Nature's Way:
We have implemented the use of the DNA barcode technology here in our products. I think it is a game changer, right? It's new, and with newness comes, you know, first some early adopters—

GILLIAN FINDLAY:
Nature's Way is among those leading the way. The manufacturer is one of several which have now partnered with the Canadian scientists in a renewed effort to put quality first.

TRAVIS BORCHARDT:
We made contact with him and started a relationship, which included testing many of our herbal dietary ingredients for identity. Right now, testing is done off site at the University of Guelph, and Dr. Newmaster is working on some technology that could possibly be implemented, you know, in a commercial manner.

STEVEN NEWMASTER:
Take some of the sample and simply put it into the—

GILLIAN FINDLAY:
Newmaster believes the partnership is just the beginning.

STEVEN NEWMASTER:
And load it into the machine, press go.

GILLIAN FINDLAY:
He's refined his barcoding technology further, making it cheaper and easier to use.

STEVEN NEWMASTER:
You can start testing further back in the supply chain. What about that batch that came in and it's a huge vat and it's powder? The DNA is excellent in that. It's easy. It's cheap. It could be tested at where it's being transported, and the supplier's doing trading and buying. It could be tested at the producer,

the farmer. It could be tested all the way along. And I think that's an appropriate way to solve the problem.

GILLIAN FINDLAY:
But that still leaves the question of what, if any, of this stuff actually works.

TRADE SHOW SALESMAN:
We're using the herb combined with a standardized extract—

GILLIAN FINDLAY:
The industry is quick to criticize studies that challenge their products, but it hasn't produced large, peer-reviewed studies of its own with clinical trials where supplements are tested against placebos.

DAN HURLEY, Author, Natural Causes:
The crazy thing about the dietary supplement world is there are none of those studies, and the studies that are done say the stuff doesn't work!

DANIEL FABRICANT:
There's new science out there all the time. Consumers are going to continue to take supplements because they derive a benefit. Over half the country every day takes a supplement safely and effectively.

PAUL OFFIT, M.D., The Children's Hospital of Philadelphia:
We love the notion of a magic pill. It's something that makes it all better. It's just too seductive. But it is a pill just like any other pill. The only difference is it's an unregulated pill, and you don't know what's in it.

EXHIBIT 33

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date: May 1, 2014

From: Fred Hines, Consumer Safety Officer, New Dietary Ingredient Review Team, Division of Dietary Supplement Programs , Office of Nutrition, Labeling and Dietary Supplements, HFS-810

Subject: 75-Day Premarket Notification of New Dietary Ingredients

To: Dockets Management Branch, HFA-305

Subject of the Notification: Fatty acid esters derived from anchovy or menhaden oil (trade name: Provenal)

Firm: Tersus Pharmaceuticals, LLC

Date Received by FDA: January 24, 2014

90-Day Date: April 24, 2014

In accordance with the requirements of section 413(a) of the Federal Food, Drug, and Cosmetic Act, the attached 75-day premarket notification and related correspondence for the aforementioned substance should be placed on public display in FDA dockets (www.regulations.gov) reserved for NDI notifications as soon as possible since the 90-day date is April 24, 2014. Thank you for your assistance.

Fred A. Hines, DVM, CSO

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
5100 Paint Branch Parkway
College Park, Maryland 20740

MAR 1 9 2014

John R. Endres
Chief Scientific Officer,
AIBMR Life Sciences, Inc.,
4117 S. Meridian; Puyallup, WA 98373

Dear Mr. Endres:

This is to inform you that the notification, dated January 13, 2014, which you submitted pursuant to 21 United States Code (U.S.C.) § 350b(a)(2) (section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act (the Act)) was received and filed by the Food and Drug Administration (FDA) on January 24, 2014. Your notification concerns the new dietary ingredient product called "Provinal™" which is said to be "a blend of fatty acid esters, derived from anchovy or menhaden oil." The notifier intends to market the NDI in a dietary supplement product called "Provinal.™"

According to your notification, the daily serving is 1 to 4 capsules per day providing a daily intake of "Provinal™" in the range of 420 to 2000 mg per day. The conditions of use are as follows: "There is no specific target population for Provinal™, but excluded populations would include those with seafood allergy.

Under 21 U.S.C. 350b(a), the manufacturer or distributor of a dietary supplement containing a new dietary ingredient that has not been present in the food supply as an article used for food in a form in which the food has not been chemically altered must submit to FDA, at least 75 days before the dietary ingredient is introduced or delivered for introduction into interstate commerce, information that is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such new dietary ingredient will reasonably be expected to be safe. FDA reviews this information to determine whether it provides an adequate basis for such a conclusion. Under 21 U.S.C. 350b(a)(2), there must be a history of use or other evidence of safety establishing that the new dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe. If this requirement is not met, the dietary supplement is considered to be adulterated under 21 U.S.C. 342(f)(1)(B) because there is inadequate information to provide reasonable assurance that the new dietary ingredient does not present a significant or unreasonable risk of illness or injury.

FDA has carefully considered the information in your submission and the agency has significant concerns about the evidence on which you rely to support your conclusion that the dietary supplement product containing "Provinal™" will reasonably be expected to be safe under the conditions of use described in your notification.

It is not readily apparent whether the substance that is the subject of your notification is a "dietary ingredient" within the meaning of 21 U.S.C. 321(ff)(1) that may be lawfully used in dietary supplements. The term "dietary supplement" is defined in 21 U.S.C. 321(ff). A dietary supplement means, among other things, a "product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients: (A) a vitamin; (B) a mineral; (C) an herb or other botanical; (D) an amino acid; (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or (F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E)."

Based on the information in your submission, it is unclear if "fatty acid esters, derived from anchovy or menhaden oil", which you intend to market under the trade name Provinal™ is a "dietary ingredient" within the meaning of 21 U.S.C. 321(ff)(1). For example, synthetic fish oil fatty acid ethyl esters do not fit within the statutory definition of "dietary ingredient" because they are not constituents of a dietary substance for use by man under section 201(ff)(1)(F). Therefore, FDA cannot determine, at this time, whether your product contains a dietary ingredient that may lawfully be marketed as a dietary supplement.

Nevertheless, FDA has carefully considered the information in your submission and the agency has significant concerns about the evidence on which you rely to support your conclusion that the dietary supplement product containing Provinal™ will reasonably be expected to be safe under the conditions of use described in your notification.

FDA was unable to establish the identity of your new dietary ingredient Provinal™ based on the evidence provided in your notification. For example, you did not provide information on the identity of the composition of 22.5% of your ingredient. In addition, your manufacture description consisted of a flow chart with little or no details. For example, you did not provide information on controls of undesirable by-products. Without such information, it is unclear how the product you intend to market is qualitatively and quantitatively similar to the substances described in the information that you rely on as evidence of safety or how that information forms the basis for a reasonable expectation of safety under the intended conditions of use.

FDA was unable to establish the safety of your new dietary ingredient, "Provinal™", based on the history of use provided in your notification. For example, your notification did not contain information that your ingredient, synthetically produced ethyl esters of fish oil fatty acids , has a history of use as food. In addition, the history of use information that you provided for the predominant free fatty acid components, palmitoleic acid and oleic acid, including the referenced GRAS notifications, is inadequate to address the safety of your ingredient under the proposed conditions of use. For example, you did not provide information that palmitoleic acid ethyl ester completely dissociates prior to absorption in the gastrointestinal tract. Without such information, it is unclear how your history of use information establishes the basis of safety of your ingredient under the proposed conditions of use.

In addition, FDA was unable to establish the safety of the new dietary ingredient, "Provinal™", based on the referenced toxicology studies provided in your notification. For example, the test articles used in the toxicological studies were not equivalent to "Provinal™". In addition, the subchronic toxicology study is inadequate to address the safety of your ingredient under the proposed conditions of use. For example, the study design had the following limitations: The study was conducted on male rats only; the study duration was only 6 weeks; the study dosage was one single dose, and the results were presented in the form of a summary report. Furthermore, your primary data on the four weeks oral mice study that was conducted using 300 mg/kg palmitoleic acid solution showed a marked increase ($P<0.05$) in pancreas weight. However, the results of an outside literature search conducted by the FDA suggested that this increase in pancreas weight may be an indication of pancreatic injury. For example, in the study by Werner et al. (1997), fatty acid ethyl esters at concentrations found in human plasma produced pancreatic injury in rats; [1] And, in the study by Criddle et al. (2004; 2006), the nonoxidative metabolite palmitoleic acid ethyl ester induced pancreatic calcium toxicity via elevations of calcium ion levels, that results in acinar cell necrosis. [2] In the absence of a chronic study on the product of commerce, it is unclear how your toxicology studies and other evidence of safety on which you rely forms a basis to conclude that your new dietary ingredient will reasonably be expected to be safe under the proposed conditions of use.

It is possible that a recently enacted law may affect the legal status of dietary supplements containing "Provinal™", Section 301(ll) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(ll)) prohibits the introduction or delivery for introduction into interstate commerce of any food (including a dietary supplement) that contains a drug approved under 21 U.S.C. 355, a biological product licensed under 42 U.S.C. 262, or a drug or a biological product for which substantial clinical investigations have been instituted and their existence made public, unless one of the exemptions in section 301(ll)(1)-(4) applies. In our review of your notification, FDA did not consider whether section 301(ll) or any of its exemptions apply to dietary supplements containing "Provinal™" Accordingly, this response should not be construed to be a statement that a dietary supplement containing "Provinal™" if introduced or delivered for introduction into interstate commerce, would not also violate section 301(ll).

For the reasons discussed above, the information in your submission does not provide an adequate basis to conclude that the dietary supplement containing "Provinal™", when used under the conditions recommended or suggested in the labeling of your product, will reasonably be expected to be safe. Therefore, your product may be adulterated under 21 U.S.C. 342(f)(1)(B) as a dietary supplement that contains a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury. Introduction of such a product into interstate commerce is prohibited under 21 U.S.C. 331(a) and (v).

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[1] Werner J, Laposata M, Fernandez-Del CC, Saghir M, Iozzo RV, Lewandrowski KB, and Warshaw AL. Pancreatic Injury in Rats Induced by Fatty aAid Ethyl Ester, A Nonoxidative Metabolite of Alcohol. Gastroenterology1997; 113: 286-294.

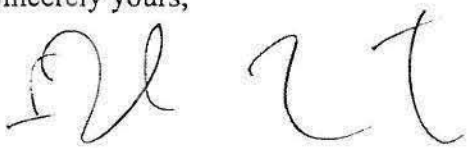
[2] a) Criddle DN, Raraty MG, Neoptolemos JP, Tepikin AV, Petersen OH, Sutton R. Ethanol toxicity in pancreatic acinar cells: mediation by nonoxidative fatty acid metabolites. Proc Natl Acad Sci U S A 2004; 101: 10738-10743.

b)Criddle, D.N, Murphy J, Fistetto G, Barrow S, Tepikin AV, Neoptolemos JP, Sutton R, and Petersen OH. Fatty Acid Ethyl Ester Cause Pancreatic Calcium Toxicity via Inositol Trisphosphate Receptors and Loss of ATP Synthesis. Gastroenterology 2006; 130:781-793.

Your notification will be kept confidential for 90 days after the filing date of January 24,2014. After the 90-day date, the notification will be placed on public display at FDA's Docket Management Branch in docket number FDA-1995-S-0039 (formerly docket number 95S-0316) as new dietary ingredient notification report number 819. Prior to that date, you may wish to identify in writing specifically what information you believe is proprietary, trade secret or otherwise confidential for FDA's consideration.

If you have any questions concerning this matter please contact Dr. Fred Hines, Consumer Safety Officer, New Dietary Ingredients Review Team, at (240) 402-1756.

Sincerely yours,



Daniel Fabricant, Ph.D., Director,
Division of Dietary Supplement Programs
Office of Nutrition, Labeling and Dietary Supplements
Center for Food Safety and Applied Nutrition

Materials Omitted; Will be Provided To the Court Upon Request

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

REQUEST FOR ACTION
NO 18-04
TO GC
OUII
Office of the Secretary

OCT 0 6 2017

Hon. Lisa R. Barton
Secretary
U.S. International Trade Commission
500 E Street, S.W.
Washington, DC 20436

Re: Certain Synthetically Produced, Predominantly EPA Omega-3 Products in Ethyl Ester or Re-esterified Triglyceride Form, Docket No. 3247

Dear Secretary Barton:

On behalf of the United States Food and Drug Administration ("FDA"), we write to express FDA's views to the Commission on the above-referenced Complaint.[1] FDA respectfully submits that the Commission should decline to initiate the requested investigation. As pled, Complainants' claims—unfair methods of competition under the Tariff Act based on false advertising under the Lanham Act and violations of the Federal Food, Drug, and Cosmetic Act ("FDCA")—can succeed only if the Commission finds that Respondents' products are unapproved "new drugs" rather than "dietary supplements" under the FDCA. The Complaint here is predicated on open questions of law and policy on which FDA has not reached final conclusions.[2] Any such findings by the Commission on those issues may conflict with later determinations by FDA. Further, through the Complaint, Complainants attempt an unlawful private FDCA enforcement action based on Complainants' allegations, not on FDA's findings. As detailed below, because Congress has authorized only FDA to initiate FDCA enforcement actions, the FDCA precludes claims that would require the adjudicator to interpret, apply, or enforce the FDCA. For Complainants to succeed on any of their claims, the Commission would have to do all three of those things.

A. FDA Has Not Determined Whether The Challenged Products Are Drugs Or Dietary Supplements.

The FDCA and its implementing regulations set forth the legal definitions of "drugs," "new drugs," and "dietary supplements," as well as legal requirements for, among other things, the distribution of such products in interstate commerce. *See*, *e.g.*, 21 U.S.C. §§ 321(g)(1), (p), 355, 21 C.F.R. Part 314 (drugs and new drugs); 21 U.S.C. §§ 321(ff), 350b, 21 C.F.R. Part 190 (dietary supplements). Congress has delegated to FDA the authority to determine whether products are "drugs," "new drugs," and/or "dietary supplements." *See*, *e.g.*, 21 U.S.C. §§ 355,

[1] The Office of Unfair Import Investigations ("OUII"), Complainants (Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Ltd.), and the Council for Responsible Nutrition, a trade association representing dietary supplement manufacturers, have sought FDA's views on this matter.

[2] As explained below, Complainants' suggestion that their arguments here "do not turn on open questions of law or policy" under the FDCA, *see* Amarin Juris. Br. at 24, is mistaken.

350b; *see generally Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 627 (1973) ("The heart of the new procedures designed by Congress [for determining whether a product is a 'new drug'] is the grant of primary jurisdiction to FDA."); *Hi-Tech Pharms, Inc. v. Hodges Consulting, Inc.*, 230 F. Supp. 3d 1323, 1331 (N.D. Ga. 2016) (the determination of whether a product marketed as a "dietary supplement" is instead a "new drug" is one that "Congress has delegated exclusively to the FDA").

The FDA statutory scheme is undeniably "complex."[3] For example, to be a dietary supplement, a product must, among other things, contain one or more "dietary ingredients." 21 U.S.C. § 321(ff)(1). "Dietary ingredients" include, among other things, "a dietary substance for use by man to supplement the diet by increasing the total dietary intake," or "a concentrate, metabolite, constituent, extract, or combination of any" other dietary ingredient or ingredients. 21 U.S.C. § 321(ff)(1)(E)&(F).[4] And a manufacturer wishing to market a dietary supplement which contains a "new dietary ingredient" ("NDI")—defined as a dietary ingredient that was not marketed in the United States before October 15, 1994—must submit a pre-market notification to FDA unless the NDI and any other dietary ingredients in the dietary supplement "have been present in the food supply as an article used for food in a form in which the food has not been chemically altered." 21 U.S.C. § 350b; *see also* 21 C.F.R. § 190.6.

Because of this complex statutory scheme, determinations of whether a product is a dietary supplement require case-specific analysis, as very small differences in factors such as an ingredient's chemical structure or history of presence in the food supply can mean the difference between dietary-ingredient status and non-dietary-ingredient status. In other words, the determination requires, among other things, a careful and thorough scientific review of the ingredients of the product at issue as well as review of the history of those ingredients. Any determination by the Commission on those issues in this case may conflict with later determinations by FDA on the same issues.

Moreover, FDA is in the process of developing a guidance document for industry on when a dietary supplement ingredient is an NDI, when the manufacturer of a dietary ingredient or supplement should submit an NDI notification, the evidence needed to document the safety of an NDI, appropriate methods for establishing the identity of an NDI, and related issues. FDA guidance documents "describe the agency's interpretation of or a policy on a regulatory issue," 21 C.F.R. § 10.115(b), and are one of the tools Congress gave to the agency for the administering the FDCA, *see* 21 U.S.C. § 371(h)(1)(A) (the "Secretary shall develop guidance documents with public participation," and those documents "present the views of the Secretary on matters under the jurisdiction of the Food and Drug Administration").

FDA initially published a draft guidance document on NDI issues for public comment in 2011. *See* 76 F.R. 39111, *Draft Guidance for Industry; Dietary Supplements: New Dietary*

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[3] *See, e.g., Boehringer Ingelheim Pharma GMBH & Co. v. FDA*, 195 F. Supp. 3d 366, 380 (D.D.C. 2016) (noting FDA's "long experience in administering this complex statute"); *Hi-Tech Pharms, Inc.*, 230 F. Supp. 3d 1323 at 1331; *see also Hynson, Westcott & Dunning, Inc.*, 412 U.S. at 627 (noting that Congress created an "expert agency"—FDA—to administer the FDCA).

[4] *See also* 21 U.S.C. § 321(ff)(1)(A)-(D)&(F) (addressing additional substances that qualify as "dietary ingredients").

Ingredient Notifications and Related Issues; Availability (Jul. 5, 2011). FDA received thousands of comments on the initial draft guidance, and issued a revised draft guidance in 2016. *See* 81 F.R. 53486, *Dietary Supplements; New Dietary Ingredient Notifications and Related Issues: Revised Draft Guidance for Industry; Availability* (Aug. 12, 2016).[5] To date, FDA has received over 300 comments on the revised draft guidance, some of which address issues raised in the Complaint. Accordingly, a Commission finding on issues raised in the Complaint could conflict with later-finalized FDA guidance.

In the revised draft guidance, FDA stated its willingness to compile an authoritative list of pre-October 15, 1994, dietary ingredients based on independent and verifiable data to be supplied by industry. Comments submitted regarding the revised draft guidance generally support the idea that FDA should develop a list of pre-October 15, 1994, dietary ingredients, but reflect varying opinions on the standard of evidence for demonstrating that an ingredient was marketed before October 15, 1994, and on the process by which ingredients should be added to the list. Because FDA believes that public discussion of these issues will be beneficial to the agency in developing the list, FDA held a public meeting on these issues on October 3, 2017. *See* 82 F.R. 42098, *Development of a List of Pre-Dietary Supplement Health and Education Act Dietary Ingredients; Public Meeting; Request for Comments* (Sept. 6, 2017). A Commission finding on issues raised in the Complaint here could conflict with any later FDA-finalized list of pre-October 15, 1994, dietary ingredients.

Furthermore, FDA is concerned that initiation of the investigation requested by Complainants could create an incentive for other parties to file similar complaints about other FDA-regulated products. FDA's regulatory authority is not limited to foods (which include dietary supplements) and drugs. Under complex statutory and regulatory regimes, FDA also regulates a broad range of other types of products, including biologics, blood products, cosmetics, medical devices, medical foods, radiation-emitting devices, tobacco products, vaccines, and animal drugs. Just like in this case, Commission investigations involving those types of products would present the possibility of the Commission reaching findings that conflict with FDA findings.

Accordingly, even if Complainants have pled a viable claim (which, as explained below, they have not), FDA believes that the Commission should decline to initiate an investigation under principles of comity to FDA—the federal agency that has the congressionally-delegated authority to determine the status of the products at issue. Complainants contend that the requested investigation will not intrude on FDA's jurisdiction because the Tariff Act provides that the Commission will "consult with, and seek advice from," relevant federal agencies, including FDA. *See* Amarin Juris. Br. at 18 (quoting 19 U.S.C. § 1337(b)(2)). But the Tariff Act also requires "expeditious adjudication" and conclusion of investigations "at the earliest practical time" after initiation of the investigation. *See* 19 U.S.C. § 1337(b)(1). FDA respectfully submits that consultation with FDA during such an expedited process is not an adequate substitute for FDA's normal regulatory process.

[5] The 2016 revised draft guidance is available on FDA's website at www.fda.gov/downloads/food/guidanceregulation/guidancedocumentsregulatoryinformation/ucm515733.pdf.

B. Private Parties Have No Private Right of Action Under The FDCA

Because FDA is the expert agency responsible for determining whether products comply with the FDCA, Congress gave FDA a number of enforcement tools to address the distribution of products in violation of the FDCA. For example, FDA may initiate a civil injunction action against a firm distributing such products. *See* 21 U.S.C. §§ 331(a)-(d), 332. In such an action, a district court can enjoin the firm from continuing to distribute the product at issue. *See, e.g., United States v. Lane Labs-USA, Inc.*, 324 F. Supp. 2d 547 (D.N.J. 2004). Other enforcement mechanisms include seizure of violative products, civil money penalties, and criminal prosecution of individuals and firms. 21 U.S.C. §§ 331, 333, 334; *see also, e.g., Heckler v. Chaney*, 470 U.S. 821, 835 (1985) (discussing enforcement mechanisms available to FDA); *United States v. Undetermined Quantities of Articles of Drug*, 145 F. Supp. 2d 692 (D. Md. 2001) (seizure of unapproved new drugs); *United States v. Kaminski*, 2008 WL 1886008 (S.D. Ohio Apr. 28, 2008) (criminal prosecution for distribution of unapproved new drugs).[6]

But while Congress gave *FDA* these and other tools to enforce the FDCA, Congress prohibited *private parties* from bringing actions to enforce the FDCA. *See* 21 U.S.C. § 337(a) ("all such proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States"); *see also, e.g., Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4 (2001) ("The FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the [FDCA.]"); *In re Darvocet, Darvon & Propoxyphene Prods. Liab. Litig.*, 756 F.3d 917, 936 (6th Cir. 2014) ("because the FDA has exclusive power to enforce the FDCA, there is no private right to enforce the statute").

The reason that the FDCA prohibits private enforcement actions—including unfair trade practice and false advertising actions that seek to enforce the FDCA—is straightforward. FDA cannot administer and enforce the FDCA effectively if core FDA issues—such as whether a product is a "new drug" or a "dietary supplement" under the FDCA—are decided in actions brought by private parties. After all, "Congress's decision to centralize authority to determine the legality of drug sales in the FDA was obviously intended to provide uniformity of administration" of the FDCA, *JHP Pharms., LLC v. Hospira, Inc.*, 52 F. Supp. 3d 992, 1005 (C.D. Cal. 2014) (quotation and citation omitted), and allowing private parties to bring enforcement actions—either in courts or in other federal agencies—threatens such uniformity of administration. *See also Hynson, Westcott & Dunning, Inc.*, 412 U.S. at 624 (noting FDA "cannot administer the Act intelligently and rationally unless it has authority to determine what drugs are 'new drugs' under [21 U.S.C. § 321(p)].").

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[6] FDA may take other steps short of enforcement action to address products that appear to be violative. For example, FDA may issue import alerts to detain violative products at the border. *See* 21 U.S.C. § 381(a). FDA may also issue a Warning Letter to the firm identifying violations of the FDCA and asking the firm to take voluntary corrective action. *See FDA Regulatory Procedures Manual*, p. 4-2 (Mar. 2017) (available at www.fda.gov). A Warning Letter is "informal and advisory," and "FDA does not consider Warning Letters to be final agency action." *Id.* at 4-3; *see also Holistic Candlers and Consumers Ass'n v. FDA*, 664 F.3d 940 (D.C. Cir. 2012) (finding that FDA Warning Letter was not final agency action).

Indeed, in keeping with these principles, less than a year ago (and more than two years after the Supreme Court's *POM Wonderful* decision) the Commission's Staff correctly recognized: "the Staff believes that a cause of action is likely not precluded by the FDCA *if* it does *not* require the Commission to directly apply, enforce, or interpret the FDCA." *See* Staff Response to Respondents' Motion for Summary Determination Dismissing Claims Precluded by the FDCA in *In the Matter of Certain Potassium Chloride Powder Prods.*, Inv. No. 337-TA-1013, EDIS Doc. I.D. 593245 at 4 n.2 (Oct. 21, 2016) (emphasis added). *A fortiori*, the FDCA *would* preclude such a claim if—as is the case here—it required the Commission to directly apply, enforce, or interpret the FDCA.

Similarly, even after *POM Wonderful*, courts continue to routinely recognize that because the FDCA prohibits private enforcement actions, the FDCA "preclude[s] Lanham Act claims" where, "in order to determine the falsity or misleading nature of the representation at issue, the court would be required to interpret and apply FDCA statutory [and] regulatory provisions." *Hi-Tech Pharms, Inc.*, 230 F. Supp. 3d at 1330 (quotation and citation omitted). *See also, e.g.*, *Intra-Lock Intern., Inc. v. Choukroun*, 2015 WL 11422285, *7 (S.D. Fla. May 4, 2015) ("because the FDCA forbids private rights of action under the statute, a private action brought under the Lanham Act may not be pursued when the claim would require litigation of the alleged underlying FDCA violation in circumstances where the FDA has not itself concluded there was such a violation") (quoting *PhotoMedex, Inc. v. Irwin*, 601 F.3d 919, 924 (9th Cir. 2010)); *Church & Dwight Co, Inc. v. SPD Swiss Precision Diagnostics*, 104 F. Supp. 3d 348, 361 (S.D.N.Y. 2015) ("*POM Wonderful* did not disturb the longstanding proposition that private parties may not use the Lanham Act as a vehicle to enforce the FDCA. That is, because the FDCA does not contain a private right of action, claims that require a court to interpret, apply, or enforce the FDCA remain precluded.");[7] *Catheter Connections, Inc. v. Ivera Med. Corp.*, 2014 WL 3536573, *4 (D. Utah. Jul. 17, 2014) ("because no private right of action exists under the FDCA, a plaintiff may not use the Lanham Act as an alternative vehicle by which to seek redress for an FDCA violation," and Lanham Act "claims that require direct interpretation and application of the FDCA are not properly recognized because such matters are more appropriately addressed by the FDA") (quoting *Cottrell, Ltd. v. Biotrol, Int'l*, 191 F.3d 1248, 1254-55 (10th Cir. 1999)).

The Complaint requires interpretation, application, and enforcement of the FDCA. Specifically, Complainants' claims—whether styled as a Tariff Act claim, a Lanham Act claim, or an FDCA claim—all depend on the allegation that the products at issue are falsely labeled as "dietary supplements" because they do not meet the FDCA definition of "dietary supplements" and instead meet the FDCA definition of "new drugs." *See, e.g.*, Complaint at ¶ 60 (alleging that labeling the products "as 'dietary supplements' is literally false because these products (i) cannot meet the definition of 'dietary supplement" in section 201(ff) of the FDCA, 21 U.S.C. § 321(ff)

[7] Although Complainants' "Jurisdictional Brief" relies heavily on *POM Wonderful LLC v. Coca-Cola Co.*, 134 S. Ct. 2228 (2014), that case is inapposite here. In *POM Wonderful*, the Court ruled that the FDCA did not preclude a private party from bringing a Lanham Act claim alleging that certain fruit juice labeling was misleading even though FDA regulates juice labels. Unlike this case, however, *POM Wonderful* did not require the tribunal to interpret, apply, or enforce the FDCA. And, as the above-cited cases demonstrate, even after *POM Wonderful*, courts have adhered to the principle that the FDCA precludes Lanham Act claims when those claims amount to attempts to interpret, apply, or enforce the FDCA.

and (ii) are being referred to as 'dietary supplements' to hide the fact that they are actually unapproved 'new drugs.'"); ¶ 120 (alleging that Tariff Act and Lanham Act claim is based on false statements that the products can be used in "'dietary supplements' when these products are actually unapproved 'new drugs.'").[8] In short, in order to resolve any of Complainants' claims, the Commission will necessarily have to step into the shoes of the FDA to interpret, apply, and enforce the FDCA. But the FDCA precludes such action.

Finally, we note that FDA has, in the past, addressed questions regarding the regulatory status of certain products through the agency's citizen petition process. *See* 21 C.F.R. §§ 10.25(a), 10.25(b) ("FDA has primary jurisdiction to make initial determinations on issues within in statutory mandate"); 10.30;[9] *see also, e.g.*, 70 F.R. 69976, *Request for Comment on Status of Pyridoxamine* (Nov. 18, 2005); FDA Response to Citizen Petition, Docket No. FDA-2005-P-0259 at p.3 (Jan. 12, 2005) ("FDA has concluded that a product containing pyridoxamine is not a dietary supplement under the Act because pyridoxamine is excluded from the dietary supplement definition under the prior market clause in 21 U.S.C. § 321(ff)(3)(B)(ii).").[10]

For these reasons, FDA respectfully requests that the Commission decline to initiate the requested investigation.

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[8] *See also, e.g.*, ¶¶ 58, 61-68, 70-71, 79, 82, 84-88, 92-93, 95-100, 102, 106-107, 109-111, 113, 116-120, 124-127, 131-134, 138-141, 144-146, 151-154, 158-161, 168-169, 171-172, 178-180, 184, 186-187, 191-193, 197-198, 200-202 (all citing the FDCA).

[9] Generally, FDA must respond to a citizen petition within 180 days, although that response may be a tentative response. *See* 21 C.F.R. § 10.30(e)(2)(iv).

[10] Available at https://www.regulations.gov/document?D=FDA-2005-P-0259-0004.

Sincerely,

Anna K. Abram
Deputy Commissioner for
Policy, Planning, Legislation, and Analysis
U.S. Food and Drug Administration

Rebecca K. Wood
Chief Counsel
U.S. Food and Drug Administration

CERTIFICATE OF SERVICE

I hereby certify that I have obtained the consent of Anna K. Abram to file the forgoing letter, and that the forgoing letter was served on the following parties on October 6, 2017, as indicated below:

Party	**Method of Service**
The Honorable Lisa K. Barton Secretary U.S. International Trade Commission 500 E Street, SW Washington, DC 20436	Via UPS Next-Business Day Delivery (8 copies) Via Electronic Filing
Cortney Hoecherly Office of Unfair Import Investigations U.S. International Trade Commission 500 E Street, SW Washington, DC 20436	Via First Class Mail Via Electronic Service (Cortney.Hoecherly@usitc.gov)
Jeffrey M. Telep Lisa M. Dwyer King & Spalding LLP 1700 Pennsylvania Ave., NW, Ste. 200 Washington, DC 20006 *Counsel for Complainants Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Ltd.*	Via First Class Mail Via Electronic Service (jtelep@kslaw.com) (ldwyer@kslaw.com)
Andrew F. Pratt Venable LLP 600 Massachusetts Ave., NW Washington, DC 20001 *Counsel for Proposed Respondents Nordic Naturals and Nordic Pharma, Inc.*	Via First Class Mail Via Electronic Service (afpratt@venable.com)
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Jay Sirois, Ph.D. Consumer Healthcare Products Association 1625 Eye Street, NW Suite 600 Washington, DC 20006	Via First Class Mail
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Marine Ingredients AS Strandgata 60 6270 Brattvag Norway *Proposed Respondent*	Via First Class Mail
Marine Ingredients LLC 794 Sunrise Blvd. Mt. Bethel, PA 18343 *Proposed Respondent*	Via First Class Mail
Golden Omega S.A. Av. Apoquindo Ote. 5550	Via First Class Mail

Party	**Method of Service**
Piso 8 Las Condes, Santiago, Chile *Proposed Respondent*	
Golden Omega USA LLC 65 Enterprise Aliso Viejo, CA 92656 *Proposed Respondent*	Via First Class Mail
Croda Europe Ltd. Cowick Hall Snaith Goole East Yorkshire DN14 9AA, United Kingdom *Proposed Respondent*	Via First Class Mail
Croda Inc. 300-A Columbus Circle Edison, NJ 08837 *Proposed Respondent*	Via First Class Mail
Technologica de Alimentos S.A Las Begonias 441 Of. 352 San Isidro, Lima 27, Peru *Proposed Respondent*	Via First Class Mail
Nature's Bounty 2100 Smithtown Avenue Ronkonkoma, NY 11779 *Proposed Respondent*	Via First Class Mail
Innovix Pharma Inc. 26500 Agoura Road Suite 102790 Calabasas, CA 91302	Via First Class Mail

Party	**Method of Service**
Proposed Respondent	
J.R. Carlson Laboratories, Inc. 600 W. University Dr. Arlington Heights, IL 60004 *Proposed Respondent*	First Class Mail

Rebecca K. Wood

In re Halliburton Co.

United States Court of Appeals for the Federal Circuit

March 11, 1993, Decided ; March 12, 1993, Filed

MISCELLANEOUS DOCKET NO. 371

Reporter
1993 U.S. App. LEXIS 14271 *

IN RE HALLIBURTON COMPANY, Petitioner.

Notice: [*1] RULE 47.8. OPINIONS AND ORDERS DESIGNATED AS UNPUBLISHED SHALL NOT BE EMPLOYED AS PRECEDENT BY THIS COURT, AND MAY NOT BE CITED BY COUNSEL, EXCEPT IN SUPPORT OF A CLAIM OF RES JUDICATA, COLLATERAL ESTOPPEL, OR LAW OF THE CASE. ANY PERSON MAY REQUEST THAT AN UNPUBLISHED OPINION OR ORDER BE REPREPARED AND REISSUED FOR PUBLICATION, CITING REASONS THEREFOR. SUCH REQUEST WILL BE GRANTED OR DENIED BY THE PANEL THAT RENDERED THE DECISION.

Disposition: Halliburton's petition is granted. The district court's order is vacated and the district court is directed to allow the filing of motions authorized by the Federal Rules of Civil Procedure.

Judges: Before ARCHER, Circuit Judge, BENNETT, Senior Circuit Judge, and MICHEL, Circuit Judge.

Opinion by: FOR THE COURT; PAUL R. MICHEL

Opinion

ON PETITION FOR WRIT OF MANDAMUS

ORDER

Halliburton Company petitions for a writ of mandamus directing the United States District Court for the Southern District of Texas to vacate its March 4, 1993 order. Louis J. Wardlaw, III and Joe A. Young oppose.

This matters stems from Wardlaw and Young's patent infringement suit against Halliburton. Following a jury trial, the jury returned a verdict that Wardlaw and Young's patent was not invalid, that Halliburton [*2] infringed certain claims of the patent, and that the infringement was willful. The court awarded treble damages and attorney fees and judgment was entered on February 26, 1993.

Halliburton filed a Fed. R. Civ. P. 59(e) motion to alter or amend the judgment. Halliburton states that it intended to file additional post-judgment motions also. The time limit for any party to file any post-judgment motions is March 15, 1993.

On March 4, 1993, the district court denied Halliburton's R. 59(e) motion and further ordered that:

> no party in this case file anything further before this Court. The Court will not grant, and is not interested in considering, motions to amend judgment, motions for judgment notwithstanding the verdict, motions for new trial, or any other sorts of motions. The Court is in complete agreement with the substance of the jury verdict, and has ruled regarding all remaining issues in the case. The cost issue has been resolved. This Court must now turn its attention to the some 550 other civil disputes, and more than 40 criminal cases, presently pending on one of the largest dockets in the Country. None of the foregoing filings are required for proper appellate [*3] scrutiny, and the filing of anything further in this Court, in the absence of the exhaustion of such appellate scrutiny, will constitute an act of contempt, for which appropriate sanctions will issue.

As Halliburton points out, the Federal Rules of Civil Procedure permit any party to file timely post-judgment motions. Further, this court has stated that the failure to file certain post-

judgment motions will result in limited appellate review. *Biodex Corp v. Loredan Biomedical, Inc.,* 946 F.2d 850, 862 (Fed. Cir. 1992) ("Biodex's failure to present the district court with a post-verdict motion precludes appellate review of sufficiency of the evidence.") Wardlaw and Young's argument that Halliburton filed a lengthy addendum to its proposed judgment does not negate Halliburton's right to file any post-judgment motions authorized by the rules.

Mandamus has traditionally been used to confine a trial court to a lawful exercise of its prescribed jurisdiction or to compel it to exercise its authority when it is its duty to do so. *Gulfstream Aerospace Corp. v. Mayacamas,* 485 U.S. 271, 289 (1988). For example, mandamus has been [*4] granted to compel a district court to accept the filing of a motion to extend the time to appeal, *Merritt v. Broglin,* 841 F.2d 184 (7th Cir. 1988), to compel a district court to consider a motion for leave to amend an answer to a complaint, *Richardson Greenshields Securities, Inc. v. Lau,* 825 F.2d 647 (2d Cir. 1987), and to vacate an order denying both sides right to employ preemptory challenges, *Maloney v. Plunkett,* 854 F.2d 152 (7th Cir. 1988).

In *Richardson,* the Second Circuit stated that absent extraordinary circumstances, "a [district] court has no power to prevent a party from filing pleadings, motions or appeals authorized by the Federal Rules of Civil Procedure." *Richardson,* 825 F.2d at 652. We are in agreement with this principle.

Accordingly,

IT IS ORDERED THAT:

Halliburton's petition is granted. The district court's order is vacated and the district court is directed to allow the filing of motions authorized by the Federal Rules of Civil Procedure.

FOR THE COURT

Paul R. Michel, Circuit Judge

11 [*5] Mar 93

Date

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ThermoLife Int'l, LLC v. Gaspari Nutrition Inc.

United States Court of Appeals for the Ninth Circuit

February 10, 2016, Argued and Submitted, San Francisco, California; April 14, 2016, Filed

No. 14-15180

Reporter
648 Fed. Appx. 609 *; 2016 U.S. App. LEXIS 6807 **; 2016-1 Trade Reg. Rep. (CCH) P79,637

THERMOLIFE INTERNATIONAL, LLC, Plaintiff-counter-defendant - Appellant, v. GASPARI NUTRITION INC., Defendant-counter-claimant - Appellee.

Notice: PLEASE REFER TO FEDERAL RULES OF APPELLATE PROCEDURE RULE 32.1 GOVERNING THE CITATION TO UNPUBLISHED OPINIONS.

Prior History: [**1] Appeal from the United States District Court for the District of Arizona. D.C. No. 2:11-cv-01056-NVW. Neil V. Wake, District Judge, Presiding.

Thermolife Int'l, LLC v. Gaspari Nutrition, Inc., 2014 U.S. Dist. LEXIS 3426 (D. Ariz., Jan. 10, 2014)

Disposition: AFFIRMED in part; VACATED and REMANDED in part.

Counsel: For THERMOLIFE INTERNATIONAL, LLC, an Arizona limited liability company Plaintiff-counter-defendant - Appellant: Gregory Blain Collins, Attorney, Geoffrey S. Kercsmar, Counsel, Esquire, Kercsmar - Feltus PLLC, Scottsdale, AZ; Raymond A. Cardozo, Reed Smith LLP, San Francisco, CA; Michael Hillel Sampson, Esquire, Attorney, Reed Smith LLP, Pittsburgh, PA.

For GASPARI NUTRITION INCORPORATED, a New Jersey Corporation, Defendant-counter-claimant - Appellee: Robert Itri, Millagan Lawless, P.C., Phoenix, AZ; Flynn P. Carey, Attorney, Mitchell Stein Carey, PC, Phoenix, AZ; Cober C. Plucker, Gallagher - Kennedy, P.A., Phoenix, AZ.

Judges: Before: SILVERMAN, FISHER and TALLMAN, Circuit Judges.

Opinion

[*611] MEMORANDUM*

ThermoLife International, LLC (ThermoLife) appeals from an adverse judgment in its suit against Gaspari Nutrition Inc. (GNI), a competitor in the dietary supplement market. As relevant here, ThermoLife sued GNI for six counts [**2] of false advertising under the Lanham Act, 15 U.S.C. § 1125(a)(1)(B), and unfair competition under Arizona common law. ThermoLife alleges that from 2005 to 2010 GNI falsely advertised its testosterone boosters as "safe," "natural," "legal" and compliant with the Food, Drug & Cosmetic Act, (FDCA), as amended by the Dietary Supplement Health Education Act (DSHEA). [*612] The district court excluded four of ThermoLife's experts as unreliable; granted summary judgment because the FDCA precluded or preempted all but one of ThermoLife's claims and ThermoLife could not establish the elements of falsity, materiality and injury; and denied ThermoLife's requests for discovery sanctions and Rule 59(e) relief.

We have jurisdiction under 28 U.S.C. § 1291, and we vacate the judgment and remand for further proceedings on all six of the Lanham Act claims and the unfair competition claim.

I. FDCA preclusion and preemption

We review de novo the district court's grant of summary judgment based on its interpretation of the FDCA, *see PhotoMedex, Inc. v. Irwin*, 601 F.3d 919, 923 (9th Cir. 2010), and hold the

* This disposition is not appropriate for publication and is not precedent except as provided by 9th Cir. R. 36-3.

FDCA neither precludes ThermoLife's Lanham Act claims nor preempts its unfair competition claim.

A. In deciding whether the FDCA precludes ThermoLife's claims, the district court did not have the benefit of *Pom Wonderful LLC v. Coca-Cola Co.*, 134 S. Ct. 2228, 189 L. Ed. 2d 141 (2014), which squarely [**3] controls the issue. *Pom Wonderful* established that the FDCA generally does not preclude Lanham Act claims for false labeling of food. *Id.* at 2241. Both of the Court's rationales applies to ThermoLife's claims: neither the FDCA nor the Lanham Act expressly bars ThermoLife's claims, *id.* at 2237; and whereas the FDCA protects public health by relying on the FDA's expertise, Lanham Act claims like ThermoLife's protect commercial interests by relying on the market expertise of competitors, *id.* at 2238-39. Indeed, *Pom Wonderful* expressly rejected most of GNI's arguments on preclusion.[1]

GNI contends *Pom Wonderful* is distinguishable because ThermoLife's claims "require litigation of the alleged underlying FDCA violation . . . where the FDA has not itself concluded that there was such a violation." *PhotoMedex*, 601 F.3d at 924. But ThermoLife's claims that GNI falsely advertised its products as "safe" and "natural" require no interpretation of the FDCA; and, as we explain below, ThermoLife [**4] need not demonstrate a FDCA violation to prevail on its claims that GNI falsely advertised its products as "legal" or "DSHEA-compliant." Whatever the precedential value of the *PhotoMedex* rule after *Pom Wonderful* — an issue we do not decide — that rule would not bar ThermoLife's claims. Accordingly, the FDCA does not preclude ThermoLife's Lanham Act claims.

B. The unfair competition claim also is not preempted. Although the FDCA expressly preempts state-law requirements that conflict with certain FDCA provisions, *see* 21 U.S.C. § 343-1, those provisions do not include § 343(a), which governs the misbranding of food through false or misleading labeling. Nor does the FDCA's bar against private enforcement impliedly preempt the unfair competition claim. There is a general "presumption against pre-emption," *Wyeth v. Levine*, 555 U.S. 555, 565 n.3, 129 S. Ct. 1187, 173 L. Ed. 2d 51 (2009), and the FDCA does not impliedly preempt claims where, as here, "the state-law duty 'parallels' the federal-law duty," *Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1231 (9th Cir. 2013) (en banc).

[*613] The district court's ruling that ThermoLife abandoned its unfair competition claim was clearly erroneous. At summary judgment, ThermoLife responded to each of GNI's arguments by contending the unfair competition claim was not preempted, the elements of that claim (and the false advertising [**5] claims) were established and the claim was timely.

II. Exclusion of Expert Opinion Evidence

Reviewing for an abuse of discretion, *see Lust ex rel. Lust v. Merrell Dow Pharm., Inc.*, 89 F.3d 594, 596-97 (9th Cir. 1996), we hold the district court improperly excluded Dr. Sox's and Berger's opinion evidence but properly excluded Hornbuckle's and Epperson's opinion evidence.

A. The district court erred in excluding Dr. Sox's opinion on the safety of GNI's products. Each of the district court's rationales essentially faulted Dr. Sox for not opining on whether GNI's products were, in fact, safe. But that reasoning "applied too high a relevancy bar." *Messick v. Novartis Pharms. Corp.*, 747 F.3d 1193, 1197 (9th Cir. 2014). Dr. Sox's opinion needed only to "logically advance[]" the issue, *id.* at 1196 (quoting *Daubert v. Merrell Dow Pharm., Inc.*, 43 F.3d 1311, 1315 (9th Cir. 1995)), which it did by opining the dietary supplement industry would not have deemed GNI's products "safe." Contrary to the district court's conclusions, moreover, Dr. Sox did provide a standard for determining what is "safe" — *i.e.*, the industry standard — and his presumption that GNI's ingredients were not safe was sufficiently valid in light of the industry's strict reliance on establishing safety through certain procedures GNI had not used.

B. The district court also erred in excluding

[1] *See Pom Wonderful*, 134 S. Ct. at 2239 (explaining that a Lanham Act plaintiff seeks to enforce unfair competition rules, not the FDCA); *id.* (explaining that the FDCA's exclusive federal enforcement authority "does not indicate that Congress intended to foreclose private enforcement of other federal statutes").

Berger's survey evidence on materiality. "[S]urvey evidence should be admitted [**6] 'as long as [it is] conducted according to accepted principles and [is] relevant." *Fortune Dynamic, Inc. v. Victoria's Secret Stores Brand Mgmt., Inc.*, 618 F.3d 1025, 1037 (9th Cir. 2010) (second and third alterations in original) (quoting *Wendt v. Host Int'l, Inc.*, 125 F.3d 806, 814 (9th Cir. 1997)). By asking consumers of testosterone boosters whether they would have continued using GNI's products (or switched to another testosterone booster) after learning GNI's advertisements were false, Berger's survey was "probative on whether the advertisements influenced consumers' purchasing decisions." *Southland Sod Farms v. Stover Seed Co.*, 108 F.3d 1134, 1143 (9th Cir. 1997). Although the district court faulted the survey's biased questions and unrepresentative sample, neither defect was so serious as to preclude the survey's admissibility. *See Fortune Dynamic*, 618 F.3d at 1037-38 (holding that a survey with "highly suggestive" questions was admissible); *Southland Sod Farms*, 108 F.3d at 1143 (holding that objections as to "leading questions" and an unrepresentative sample "go only to the weight, and not the admissibility, of the survey").

Scott Fetzer Co. v. House of Vacuums Inc., 381 F.3d 477 (5th Cir. 2004), is distinguishable. Berger's survey sample did not "severely limit[] the probative value of the survey's results" by omitting a "large proportion" of the class of potential consumers, but included both consumers of GNI's products and consumers of other testosterone boosters. *Id.* at 487-88. Nor was the survey unreliable simply because it was not validated. Berger reasonably [**7] explained why the survey could not be validated and concluded it was nevertheless a "good survey" based on respondents' "consistent, across-the-board answers." GNI also asserts Berger's conclusions were not based on sufficient facts or data, but none [*614] of his conclusions involved "too great an analytical gap between the data and the opinion proffered." *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146, 118 S. Ct. 512, 139 L. Ed. 2d 508 (1997). We therefore conclude the district court improperly excluded Berger's opinion and survey evidence.

C. The district court did not abuse its discretion in excluding Hornbuckle's opinion on injury as too subjective to be reliable. A trial court has broad discretion to decide "how to determine reliability." *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152, 119 S. Ct. 1167, 143 L. Ed. 2d 238 (1999). Although the reliability of a non-expert opinion can "depend[] heavily on the knowledge and experience of the expert," *United States v. Hankey*, 203 F.3d 1160, 1169 (9th Cir. 2000), the district court was not required to base Hornbuckle's reliability on his knowledge and experience. Because Hornbuckle used a novel and wholly subjective methodology, the district court could exercise its discretion to exclude his opinion evidence.

D. The district court did not err in excluding Epperson's opinion on damages. Epperson's model for calculating actual damages relied on Hornbuckle's report to establish [**8] the market share ThermoLife could have captured absent GNI's allegedly false advertising. Given the exclusion of that report, Epperson's model required a substitute estimate of ThermoLife's market share. Yet ThermoLife points to no evidence in the record from which a reasonable jury could conclude a specific percentage of customers would have purchased ThermoLife's testosterone boosters. Because a jury would be unable to supply this essential input, Epperson's model of actual damages was not "based on sufficient facts or data" and would not have been helpful to the jury. Fed. R. Evid. 702.

Epperson's disgorgement calculations likewise were unreliable because they included sales revenue for five years before the first allegedly false statement. Although Epperson could assume the issue of causation, his assumption still had to be "based on sufficient facts or data," *id.*, and there is no evidence that GNI profited from 2000 to 2004 from false advertising that commenced in 2005. Epperson's assumption, which was never explained, relied on "simply too great an analytical gap between the data and the opinion proffered" for the disgorgement calculations to be reliable. *Joiner*, 522 U.S. at 146.

III. Falsity, materiality and injury [**9] **elements of the Lanham Act claims**

We review de novo the district court's grant of

summary judgment on the Lanham Act claims — including the determination that ThermoLife failed to establish injury, *see Southland Sod Farms*, 108 F.3d at 1145-46 — and ask whether the evidence, when viewed in the light most favorable to ThermoLife, establishes a triable issue of material fact. *See id.* at 1138. We hold there is a triable issue of falsity, materiality and injury on all six Lanham Act claims.

A. The district court erroneously concluded there is no triable issue of falsity for each type of GNI's advertisements.

1. Counts 1, 2 and 5 involve advertisements that GNI's products were "legal" or "DSHEA-compliant." The district court was correct that such statements are generally inactionable opinion because they "purport to interpret the meaning of a statute or regulation." *Coastal Abstract Serv., Inc. v. First Am. Title Ins. Co.*, 173 F.3d 725, 731 (9th Cir. 1999). But there is a "well-established exception" that an opinion "by a speaker [*615] who lacks a good faith belief in the truth of the statement" is actionable. *PhotoMedex*, 601 F.3d at 931. Because every opinion "explicitly affirms . . . that the speaker actually holds the stated belief," a CEO's statement about legal compliance "would falsely describe her own state of mind if she thought her company was breaking the [**10] law." *Omnicare, Inc. v. Laborers Dist. Council Const. Indus.*, 135 S. Ct. 1318, 1326, 191 L. Ed. 2d 253 (2015). Here, ThermoLife points to numerous emails indicating GNI was aware its products were not DSHEA-compliant. Therefore there is a triable issue of falsity on Counts 1, 2 and 5.

2. There is also a triable issue of falsity on Counts 4 and 6, concerning GNI's statements that its products were "safe." Because those statements do not "purport to interpret the meaning of a statute or regulation," they are statements of fact, not opinion. *Coastal Abstract Serv.*, 173 F.3d at 731. GNI asserts its products were presumed safe until the FDA proved otherwise. But the statutory provision on which GNI relies, 21 U.S.C. § 342(f), neither mentions a presumption of safety nor establishes whether a dietary supplement is safe, but defines when a supplement is safe enough that it is not an "adulterated food." On the merits, a reasonable jury could find GNI's products were not safe based on the recall evidence and Dr. Sox's report.[2]

3. Finally, [**11] there is a triable issue of falsity on Count 3, concerning GNI's statements that Novedex is "natural" and its ingredients are "naturally occurring and are found in natural foodstuffs." These statements were not inactionable opinion. Because the statements were "capable of . . . being reasonably interpreted as a statement of objective fact" — namely, that the ingredients were taken from or could be found in nature — they were statements of fact, not opinion. *Coastal Abstract Serv.*, 173 F.3d at 731. Based on Dr. Sox's opinion evidence, a reasonable jury could conclude that the dietary ingredients in GNI's products were not natural or naturally occurring and hence GNI's statements in Count 3 were false.

B. The district court erred with respect to materiality, as well. A statement is material if it is "likely to influence the purchasing decision." *Cook, Perkiss & Liehe, Inc. v. N. Cal. Collection Serv. Inc.*, 911 F.2d 242, 244 (9th Cir. 1990). ThermoLife pointed to GNI's survey results, Berger's survey results and Internet message board posts, all of which indicated that the safety, legality and natural ingredients of GNI's products were — to varying degrees — important factors in consumer purchasing decisions. This evidence establishes a triable issue of materiality.[3]

C. There is a triable issue on injury. "We have generally presumed commercial injury when defendant and plaintiff are direct competitors and defendant's misrepresentation has a

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[2] We reject GNI's contention that the recall evidence is inadmissible. Unlike in *Toole v. McClintock*, 999 F.2d 1430, 1434-35 (11th Cir. 1993), the FDA's finding on the safety of aromatase inhibitors was neither "proposed" nor based on outside research. And unlike in *Werner v. Upjohn Co.*, 628 F.2d 848, 853 (4th Cir. 1980), ThermoLife seeks to introduce the recall evidence to prove the falsity of GNI's statements, not GNI's negligence.

[3] Because we conclude there is a triable issue on materiality, [**12] we do not reach ThermoLife's argument that GNI's statements were material as a matter of law.

tendency to mislead consumers." *TrafficSchool.com, Inc. v. Edriver Inc.*, 653 F.3d 820, 826 (9th Cir. 2011). This presumption is warranted even in false advertising cases because, when competitors [*616] vie for the same customers, "a misleading ad can upset their relative competitive positions" and thereby cause injury. *Id.* at 827.

GNI contends this presumption is inconsistent with our observation that "actual evidence of some injury *resulting from the deception* is an essential element of the plaintiff's case." *Harper House Inc. v. Thomas Nelson, Inc.*, 889 F.2d 197, 210 (9th Cir. 1989). But *Harper House* held only that a court cannot assume injury without any evidence of causality and consumer deception. *See id.* at 209-10. Consistent with that observation, TrafficSchool.com permits a jury to infer injury based on evidence of direct competition (which provides a causal link) and a likelihood of consumer deception. *See* 653 F.3d at 826.

GNI argues the presumption applies only in the context of standing, but the two standards — which are derived from the same statutory language — are one and the same. *See id.* ("The [**13] Lanham Act permits 'any person' to sue if he 'believes that he . . . is *likely* to be damaged.'" (alterations in original) (quoting 15 U.S.C. § 1125(a))); *Southland Sod Farms*, 108 F.3d at 1139 ("The elements of a Lanham Act § 43(a) false advertising claim are: . . . the plaintiff has been or is likely to be injured as a result of the false statement. . . ." (footnote omitted)).

A reasonable jury could infer ThermoLife has established a presumption of commercial injury. GNI does not dispute it directly competed with ThermoLife in the market for testosterone booster products; and GNI's literally false statements necessarily misled consumers. Because GNI has not attempted to rebut the presumption, ThermoLife has established a triable issue on injury. See TrafficSchool.com, 653 F.3d at 827.

D. The district court decided only the issue of injury ("actual harm"), but not damages ("amount of harm"). Thus we decline to decide whether ThermoLife has presented sufficient evidence to establish entitlement to damages.

IV. Discovery sanctions and Rule 59(e) relief

We review for an abuse of discretion the district court's denial of discovery sanctions, refusal to reopen discovery and denial of Rule 59(e) relief based on newly discovered evidence. *See Panatronic USA v. AT&T Corp.*, 287 F.3d 840, 846 (9th Cir. 2002) (request to reopen discovery); *Dixon v. Wallowa County*, 336 F.3d 1013, 1022 (9th Cir. 2003) (Rule 59(e) relief); *Fjelstad v. Am. Honda Motor Co.*, 762 F.2d 1334, 1337 (9th Cir. 1985) (discovery sanctions). [**14] We hold that the district court properly exercised its discretion on each ruling.

A. Case-dispositive sanctions for spoliation were not proper because the evidence was too speculative to make the requisite finding of willfulness, fault, or bad faith. *See Leon v. IDX Sys. Corp.*, 464 F.3d 951, 958 (9th Cir. 2006). Even ThermoLife's expert concluded intentional deletion was merely the "typical explanation" — but not the only explanation — for the number of deleted files found on the CEO's hard drive. The district court's finding of lack of willfulness was a "permissible view[] of the evidence." *Anderson v. City of Bessemer City, N.C.*, 470 U.S. 564, 574, 105 S. Ct. 1504, 84 L. Ed. 2d 518 (1985).

B. ThermoLife failed to "show how allowing additional discovery would have precluded summary judgment." *Panatronic USA*, 287 F.3d at 846 (quoting *Chance v. Pac-Tel Teletrac Inc.*, 242 F.3d 1151, 1161 n.6 (9th Cir. 2001)). The district court considered all of the evidence ThermoLife now points to — and in any [*617] case no additional discovery was needed to preclude summary judgment because ThermoLife raised a triable issue on each element of its claims.

C. ThermoLife was not entitled to Rule 59(e) relief based on newly discovered evidence. ThermoLife has not shown how "the outcome would likely have been different" had GNI disclosed the evidence sooner, *Dixon*, 336 F.3d at 1022, and the evidence was not "newly discovered" because it was "available before

disposition of the motion for summary judgment," [**15] *Frederick S. Wyle Prof'l Corp. v. Texaco, Inc.*, 764 F.2d 604, 609 (9th Cir. 1985).

V. Costs

Because we vacate the district court's grant of summary judgment to GNI, we also vacate the award of costs to GNI.

VI. Conclusion

In sum, the district court properly excluded the opinions of Hornbuckle and Epperson and properly denied discovery sanctions and Rule 59(e) relief. But the district court improperly excluded Dr. Sox's and Berger's opinion and erred in granting summary judgment on ThermoLife's six Lanham Act claims and unfair competition claim. Because the FDCA neither precludes nor preempts those claims and factual issues preclude summary judgment, we vacate the judgment and remand for further proceedings. Each party shall bear its own costs on appeal.

AFFIRMED in part; VACATED and REMANDED in part.

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UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES – GENERAL

Case No. SA CV 17-1551-DOC (JDEx) Date: November 14, 2017

Title: ALLERGAN USA INC. V. IMPRIMIS PHARMACEUTICALS, INC.

PRESENT:

THE HONORABLE DAVID O. CARTER, JUDGE

Deborah Lewman	Not Present
Courtroom Clerk	Court Reporter
ATTORNEYS PRESENT FOR PLAINTIFF: None Present	ATTORNEYS PRESENT FOR DEFENDANTS: None Present

PROCEEDINGS (IN CHAMBERS): ORDER DENYING DEFENDANT'S MOTION TO DISMISS [27]

Before the Court is Defendant Imprimis Pharmaceutical, Inc.'s ("Imprimis" or "Defendant") Motion to Dismiss ("Motion") and Request for Judicial Notice ("RJN") (Dkts. 27, 27-2). The Court finds this matter appropriate for resolution without oral argument. *See* Fed. R. Civ. P. 78; L.R. 7-15. Having reviewed the moving papers and considered the parties' arguments, the Court DENIES Imprimis's Motion.

I. Background

A. Facts

The Court adopts the facts set out in Plaintiff Allergan USA, Inc.'s ("Allergan" or "Plaintiff") Complaint ("Compl.") (Dkt. 1).

Allergan is a pharmaceutical company that manufactures, develops, and sells a wide range of ophthalmic drugs (drugs relating to the eye). *See* Compl. ¶¶ 29, 31. Allergan incurs significant time and financial costs to develop its drugs due to the drug

approval requirements imposed by the Food, Drug, and Cosmetics Act ("FDCA") and parallel state laws. *Id.* ¶ 9.

Imprimis is a pharmaceutical manufacturer that formulates, manufactures, and sells a wide range of drugs, including ophthalmic drugs. *Id.* ¶ 40. Although at the time of its founding in 2011 Imprimis was focused on producing its drugs through the FDCA Section 505(b)(2) pathway for generic drug products, Imprimis instead began "compounding" its drugs in 2013. *Id.* ¶¶ 43–45. Compounding is the practice of combining, mixing, or altering ingredients of an existing drug in order to create medication tailored to the needs of an individual patient. *Id.* ¶ 6. Imprimis compounds its products in facilities located in New Jersey and California, which operate under FDCA Section 503A or 503B. *Id.* ¶¶ 33–34.

Imprimis aims to market its compounded drug products nationwide and capture a significant market share. *Id.* ¶¶ 49, 50. The CEO of Imprimis has stated that its drugs have already captured over ten percent of the national cataract surgery market and could be used for all cataract surgeries performed in the United States. *Id.* ¶ 54. Specifically, Imprimis claims its ocular surgery treatments Dropless Therapy and LessDrops are used in about 10,000 ocular surgeries every week. *Id.* ¶¶ 52a–b, 55. Imprimis also claims its glaucoma eye drops, Simple Drops, have made a substantial impact and taken market share away from other pharmaceutical manufacturers. *Id.* ¶ 56. In March 2017, Imprimis announced development of a dry eye drop, Klarity, which aims to compete with Allergan's dry eye treatment, Restasis. *Id.* ¶ 57.

Allergan claims that Imprimis misleads consumers and doctors through four false statements. First, Imprimis claims on its website that it operates "under the regulatory framework of the Drug Quality & Security Act (2013) and state pharmacy laws." *Id.* ¶ 70. Second, Imprimis advertises LessDrops on its website, stating "ORDER NOW Order . . . LessDrops from 503B Outsourcing Facility today. No patient information required." *Id.* ¶ 75. Third, Imprimis promotes its Dropless Therapy treatment with a video that states "[t]he patient is protected from infection and inflammation even more effectively than can be achieved with expensive, inconvenient, and irritating topical medications." *Id.* ¶ 79. Finally, based on a 2014 survey of 21 cataract surgeons, Imprimis also claims that "95% of cataract surgeons surveyed would prefer Dropless Therapy." *Id.* ¶ 80.

B. Statutory and Regulatory Background

Generally, the FDCA and parallel state statutes require approval by the FDA and other state agencies before drugs can be sold. *See, e.g.*, 21 U.S.C. § 355; Cal. Health &

Safety Code § 111550(a), (b). Compounded drugs are exempted from these requirements, *inter alia*, under both federal and state laws when certain conditions are met. *See* 21 U.S.C. §§ 353a, 353b; 16 Cal. Code Regs. § 1735, *et seq*. In 2013, Congress passed the Drug Quality and Security Act ("DQSA"), amending FDCA Section 503A and adding Section 503B. *See* DQSA, 113 Pub. L. No. 54, 127 Stat. 587 (2013).

Section 503A of the FDCA, codified at 21 U.S.C. § 353a, regulates pharmacy compounding. Drug products compounded "for an identified individual patient . . . [that are] necessary for the identified patient" are exempted from normal drug-approval requirements under Section 503A when certain conditions are met. 21 U.S.C. § 353a(a). Section 503A allows pharmacy compounding in two scenarios: (1) drug compounding after the receipt of a prescription; and (2) drug compounding before the receipt of a prescription when the compounding is "based on a history [of] receiving valid prescription orders for the compounding of the drug product, which orders have been generated solely within an established relationship between" the compounding pharmacy and the patient or prescribing physician. *Id.*

In both scenarios, Section 503A also requires that the compounded drug is (1) compounded using approved drug products; (2) compounded using ingredients that comply with national standards; (3) not compounded "regularly or in inordinate amounts (as defined by the Secretary)" if the compounded drug is "essentially a copy of a commercially available product"; (4) not a drug product whose safety or effectiveness may be adversely effected by compounding; and (5) compounded in a state that has entered into a "Memorandum of Understanding" ("MOU") with the FDA or, if no such MOU exists for that state, compounded by a pharmacy or individual that distributes less than "5 percent of [its] total prescription orders" to out-of-state patients. 21 U.S.C. § 353a(b).

Section 503B of the FDCA, codified at 21 U.S.C. § 353b, regulates compounding by "outsourcing facilities." Outsourcing facilities that seek to compound drugs under this provision must comply with certain registration and reporting requirements. 21 U.S.C. §§ 353b(a)(1), 353b(b). Section 503B does not require a patient prescription for compounding, but instead specifically limits the types of drugs that can be compounded at outsourcing facilities registered under Section 503B ("503B facilities"). Such 503B facilities can only compound bulk drug substances that appear on (1) a list established by the FDA "identifying bulk drug substances for which there is a clinical need" ("503B bulks list"); or (2) a drug shortage list established by the FDA. 21 U.S.C. § 353b(a)(2)(A).

In addition to the limitation on the types of drugs that may be compounded, Section 503B also imposes a litany of other conditions including, *inter alia*: (1) the drug is not "essentially a copy of one or more approved drugs;" (2) the drug is not sold wholesale; and (3) the "drug is compounded in an outsourcing facility in which the compounding of drugs occurs only in accordance [with Section 503B]." 21 U.S.C. § 353b(a).

The FDA is authorized to create the rules and regulations necessary to implement both Sections 503A and 503B. *See* 21 U.S.C. §§ 353a(c), 353b(c). The FDA, however, has not produced any finalized rules or regulations for either Section. *See* 2017 Inactive Actions, RIN No. 0910-AH10, *Current Unified Agenda of Regulatory and Deregulatory Actions*, Office of Mgmt. & Budget, available at https://www.reginfo.gov/public/do/eAgendaMain. *But see* RJN, Ex. 11 (statement from FDA commissioner regarding rulemaking progress dated September 2017). For instance, the FDA has yet to produce a standard MOU for Section 503A. *See* RJN, Ex. 4 at 6. As a result, no state has entered into an MOU with the FDA under that Section. Similarly, the FDA has published an interim list of bulk drug substances ("503B interim bulks list") that it is considering for inclusion on the 503B bulks list, but no finalized list exists. *See* RJN, Ex. 9 at 6–8.

C. Procedural History

Allergan initiated this action on September 7, 2017 (Dkt. 1). The lawsuit concerns Imprimis's allegedly unlawful production of drug products under the guise of drug compounding, as well as statements Imprimis made to promote those products. Compl. ¶¶ 1, 6, 27. Allergan alleges two causes of action: (1) unfair competition and false advertising in violation of the Lanham Act, 15 U.S.C. § 1125(a); and (2) unlawful or unfair business practices in violation of California's Unfair Competition Law ("UCL"), Cal. Bus. & Prof. Code § 17200, *et seq.* Compl. ¶¶ 108–124.

On October 11, 2017, Imprimis filed the instant Motion to Dismiss for failure to state a claim as to each of Allergan's causes of action. Allergan opposed on October 23, 2017 ("Opp'n") (Dkt. 28). Imprimis replied on October 30, 2017 ("Reply") (Dkt. 29).

II. Request for Judicial Notice

Imprimis requests that the Court take judicial notice of fourteen documents. RJN at 1–3 (Dkt. 27-2). Eleven of those documents are available on the FDA's website. RJN, Exs. 1-9, 11, 12. One document is a proposed rule by the FDA published in the Federal

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES – GENERAL

Register. RJN, Ex. 10. Another document is a letter to the FDA from the Medical Director for Governmental Affairs at the American Academy of Ophthalmology. RJN, Ex. 13. The last document is a Congressional Record regarding the DQSA. RJN, Ex. 14. Allergan has not objected to the RJN and has relied upon some of the documents proffered by Imprimis.

Pursuant to Federal Rule of Evidence 201, "[a] court shall take judicial notice if requested by a party and supplied with the necessary information." Fed. R. Evid. 201(d). An adjudicative fact may be judicially noticed if it is "not subject to reasonable dispute in that it is either (1) generally known within the territorial jurisdiction of the trial court or (2) capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201(b). Thus, a court "may take judicial notice of matters of public record, including duly recorded documents, and court records available to the public through the Pacer system via the internet." *C.B. v. Sonora Sch. Dist.*, 691 F. Supp. 2d 1123, 1138 (E.D. Cal. 2009); *see also Holder v. Holder*, 305 F.3d 854, 866 (9th Cir. 2002). Congressional records are also subject to judicial notice. *Hadley v. Kellogg Sales Co.*, 243 F. Supp. 3d 1074, 1087 (N.D. Cal. 2017). The contents of the Federal Register are noticeable as a matter of law. *See* 44 U.S.C. § 1507 ("The contents of the Federal Register shall be judicially noticed . . . ."). The Court may also take judicial notice of documents available on a government agency's website. *Gustavson v. Wrigley Sales Co.*, 961 F. Supp. 2d 1100, 1113 n.1 (N.D. Cal. 2013).

Exhibit 13, a letter from the American Academy of Ophthalmology to the FDA, does not appear to be available on the FDA's website and Imprimis does not otherwise explain why this document is appropriate for judicial notice. The remaining documents, however, are appropriate subjects of judicial notice. Therefore, the Court takes judicial notice of the following documents, filed with the Court as Exhibits 1 through 12, and 14 to Imprimis's Request for Judicial Notice:

1. FDA website titled "Compounding and the FDA: Questions and Answers" (accessed on October 9, 2017);

2. FDA website titled "For Consumers: The Special Risk of Pharmacy Compounding" (accessed on October 9, 2017);

3. "Dear Colleague" letter from Margaret A. Hamburg, M.D., Commissioner of the FDA, dated January 8, 2014;

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES – GENERAL

4. FDA document titled "Pharmacy Compounding of Human Drug Products Under Section 305A of the Federal Food, Drug, And Cosmetic Act Guidance," dated June 2016;

5. FDA document titled "Prescription Requirement Under Section 305A of the Federal Food, Drug, and Cosmetic Act Guidance for Industry," dated December 2016;

6. The transcript of the September 26, 2017 remarks for the 50 State Intergovernmental Meeting to Discuss Pharmacy Compounding by Anna Abram, Deputy Commissioner for Policy, Planning, Legislation and Analysis for the FDA;

7. FDA document titled "Compounding Drug Products That Are Essentially Copies of Approved Drug Products Under Section 503B of the Federal Food, Drug, and Cosmetic Act Guidance for Industry," dated July 2016;

8. FDA document titled "Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act Guidance for Industry," dated January 2017;

9. FDA document titled "Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act Guidance for Industry," dated January 2017;

10. FDA's proposed rule on List of Bulk Drug Substances That Can Be Used To Compound Drug Products in Accordance With Section 503A of the Federal, Food, Drug, and Cosmetic Act, dated December 16, 2016, published in Volume 81, Number 242 of the *Federal Register*;

11. FDA statement titled "Statement from FDA Commissioner Scott Gottlieb, M.D., on new efforts to encourage compounding of better quality drugs under DQSA and help health care professionals access compounded medications needed for patient care from outsourcing facilities," dated September 26, 2017;

12. Excerpts from a FDA Excel document that lists drug manufactured by entities registered under Section 503B as of September 28, 2017; and

14. 159 Congressional Record H5946-02, Proceedings and Debates of the 113th Congress, First Session, Drug Quality and Security Act, September 28, 2013.

III. Legal Standard

Under Federal Rule of Civil Procedure 12(b)(6), a complaint must be dismissed when a plaintiff's allegations fail to set forth a set of facts that, if true, would entitle the complainant to relief. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007); *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009) (holding that a claim must be facially plausible in order to survive a motion to dismiss). The pleadings must raise the right to relief beyond the speculative level; a plaintiff must provide "more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Twombly*, 550 U.S. at 555 (citing *Papasan v. Allain*, 478 U.S. 265, 286 (1986)). On a motion to dismiss, a court accepts as true a plaintiff's well-pleaded factual allegations and construes all factual inferences in the light most favorable to the plaintiff. *See Manzarek v. St. Paul Fire & Marine Ins. Co.*, 519 F.3d 1025, 1031 (9th Cir. 2008). A court is not required to accept as true legal conclusions couched as factual allegations. *Iqbal*, 556 U.S. at 678.

In evaluating a Rule 12(b)(6) motion, review is ordinarily limited to the contents of the complaint and material properly submitted with the complaint. *Van Buskirk v. Cable News Network, Inc.*, 284 F.3d 977, 980 (9th Cir. 2002); *Hal Roach Studios, Inc. v. Richard Feiner & Co., Inc.*, 896 F.2d 1542, 1555 n.19 (9th Cir. 1990). Under the incorporation by reference doctrine, the court may also consider documents "whose contents are alleged in a complaint and whose authenticity no party questions, but which are not physically attached to the pleading." *Branch v. Tunnell*, 14 F.3d 449, 454 (9th Cir. 1994), *overruled on other grounds by* 307 F.3d 1119, 1121 (9th Cir. 2002). The court may treat such a document as "part of the complaint, and thus may assume that its contents are true for purposes of a motion to dismiss under Rule 12(b)(6)." *United States v. Ritchie*, 342 F.3d 903, 908 (9th Cir. 2003).

In addition, Federal Rule of Civil Procedure 9(b) states that an allegation of "fraud or mistake must state with particularity the circumstances constituting fraud." Fed. R. Civ. P. 9(b). The "circumstances" required by Rule 9(b) are the "who, what, when, where, and how" of the fraudulent activity. *Vess v. Ciba—Geigy Corp. USA*, 317 F.3d 1097, 1106 (9th Cir. 2003); *Neubronner v. Milken*, 6 F.3d 666, 672 (9th Cir.1993) ("[Rule 9(b) requires] the times, dates, places, benefits received, and other details of the alleged fraudulent activity."). In addition, the allegation "must set forth what is false or misleading about a statement, and why it is false." *Vess*, 317 F.3d at 1106 [*33] (quoting *In re Glenfed, Inc. Sec. Litig.*, 42 F.3d 1541, 1548 (9th Cir.1994)). Rule 9(b)'s heightened pleading standard applies not only to federal claims, but also to state law claims brought in federal court. *Vess*, 315 F.3d at 1103. This heightened pleading standard ensures that "allegations of fraud are specific enough to give defendants notice of the particular

misconduct which is alleged to constitute the fraud charged so that they can defend against the charge and not just deny that they have done anything wrong." *Semegen v. Weidner*, 780 F.2d 727, 731 (9th Cir.1985).

However, "intent, knowledge, and other conditions of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b); see also Neubronner, 6 F.3d at 672 (explaining that Rule 9(b)'s heightened pleading standard may be relaxed when the allegations of fraud relate to matters particularly within the opposing party's knowledge, such that a plaintiff cannot be expected to have personal knowledge).

IV. Discussion

Imprimis moves to dismiss all of Allergan's claims, which include a Lanham Act claim and a California UCL claim. The parties organize Allergan's Lanham Act claim into two overarching categories: false statements made by Imprimis about the lawfulness of its business and false statements about Dropless Therapy. The Court will address each category in turn before addressing Allergan's UCL claim.

A. Lanham Act False Advertising Claim

Allergan alleges that Imprimis violated the Lanham Act's prohibition against false advertising by making two false statements of fact about the lawfulness of its business and two false statements of fact about Dropless Therapy's comparative efficacy and superiority. Opp'n at 12; Compl. ¶¶ 70–80. Imprimis asserts that Allergan's false advertising claim should be dismissed for three reasons. First, Imprimis argues that Allergan failed to allege an injury sufficient to establish a right to sue under the Lanham Act. Mot. at 24. Second, Imprimis argues that Allergan's false advertising claim, to the extent it is premised on statements Imprimis made about the lawfulness of its business, fails because: (1) the claim is precluded under the FDCA; (2) the statements are not false because Imprimis's conduct does not violate the FDCA; and (3) the primary jurisdiction doctrine applies. *Id.* at 12, 16, 17. Finally, with respect to the two statements about Dropless Therapy, Imprimis argues that neither statements are actionable under the Lanham Act as a matter of law because they are generalized statements of opinions. *Id.* at 23.

To state a claim for false advertising in violation of the Lanham Act, a plaintiff must allege that: (1) the defendant made a false statement of fact in a commercial advertisement; (2) the statement actually deceives or has the tendency to deceive its audience; (3) the deception is material; (4) the defendant entered its false statement into

interstate commerce; and (5) the plaintiff has or is likely to be injured as a result. *Southland Sod Farms v. Stover Steed Co.*, 108 F.3d 1134, 1139 (9th Cir. 1997); *see also Newcal Indus., Inc. v. Ikon Office Solution*, 513 F.3d 1038, 1052 (9th Cir. 2008).

1. Lanham Act Injury

As a threshold matter, Imprimis argues that Allergan has failed to allege an injury sufficient to establish a right to sue under the Lanham Act. Mot. at 24.

In addition to the elements of a prima facie case, to state a Lanham Act false advertising claim a plaintiff must also "allege an injury to a commercial interest in reputation or sales" that is proximately caused by the defendant's violations of the statute. *Lexmark Int'l., Inc. v. Static Control Components, Inc.*, 134 S. Ct. 1377, 1390 (2014). However, the Ninth Circuit has stated that "a false advertising plaintiff need only believe that he is *likely* to be injured in order to bring a Lanham Act claim. *TrafficSchool.com, Inc. v. Edriver, Inc.*, 653 F.3d 820, 825 (9th Cir. 2011).

Here, Allergan has alleged that many of its drugs—particularly its dry-eye drugs—compete with Imprimis's products. Compl. ¶ 29. Imprimis's CEO has allegedly stated that Imprimis's products have "capture[d] market share from much larger pharmaceutical companies" and can "take market share away from many of the larger or incumbent players." *Id.* ¶¶ 55–56. Allergan is one of those companies. *Id.* ¶ 56. Allergan also claims that it has lost sales and had to engage in corrective advertising to counter Imprimis's allegedly unlawful claims. *Id.* ¶¶ 90, 112. These allegations are sufficient to show that Allergan suffered "an injury to a commercial interest in reputation or sales" necessary to state a claim under the Lanham Act. *Lexmark Int'l*, 134 S. Ct. at 1390.

2. Statements Regarding Lawfulness of Imprimis's Conduct

Next, Imprimis argues that the first category of allegedly false statements—those relating to the lawfulness of Imprimis's business operations—fail to support a Lanham Act false advertising claim. On its website, Imprimis states that it operates "under the regulatory framework of the Drug Quality & Security Act (2013) and state pharmacy laws." Compl. ¶ 70. Allergan alleges that the statement is false because Imprimis does not comply with all provisions of the FDCA—specifically, Allergan claims Imprimis violates FDCA Sections 503A and 503B. *Id.* Imprimis's website also promotes its LessDrop product with the statement "ORDER NOW Order . . . LessDrops from 503B Outsourcing Facility today. No patient information required." Allergan argues that statement is false, too, because it implies that Imprimis lawfully produces and sells

LessDrops from a 503B facility. Imprimis contends that neither of these statements are actionable because (1) the claims are precluded under the FDCA; (2) the statements are not false because Imprimis is not violating the FDCA; and (3) primary jurisdiction applies.

a. Preclusion of Lanham Act Claims under the FDCA

Imprimis argues that Allergan's Lanham Act claim relating to statements about Imprimis's legal compliance with the FDCA are precluded, because the FDA has the sole authority to enforce violations of the FDCA. Mot. at 12. Allergan argues that the FDCA does not preclude its Lanham Act claim because the claim does not depend on the interpretation of an FDA regulation. Opp'n at 15.

In *POM Wonderful v. Coca-Cola Co.*, 134 S. Ct. 2228, 2241 (2014), the Supreme Court held that "the FDCA and the Lanham Act complement each other" and that the FDCA does not categorically bar Lanham Act suits. While enforcement of the FDCA is almost exclusively committed to the FDA, the FDA "does not have the same perspective or expertise in assessing market dynamics that day-to-day competitors possess." *Id.* at 2238. Lawsuits regarding unfair competition practices are therefore outside the scope of the FDCA, and the Lanham Act allows private parties to sue on a case-by-case basis to "'provide incentives' for manufacturers to behave well." *Id.* at 2238–39; *see also Wyeth v. Levine*, 555 U.S. 555, 575 (2009) ("Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness.").

However, Lanham Act suits in "direct conflict[] with the agency's policy choice" may still be precluded post-*POM Wonderful*. 134 S. Ct. at 2241 (citing *Geier v. Am. Honda Motor Co.*, 529 U.S. 861 (2000)); *see, e.g., JHP Pharmaceuticals, LLC v. Hospira, Inc.*, 52 F. Supp. 3d 992, 999 (C.D. Cal. 2014) (finding that "*some* claims *may* require the expertise of the FDA to resolve"). For instance, claims that "directly implicate the FDA's rulemaking authority," are not "binary factual determinations," or involve an issue on which the FDA has taken "positive regulatory action" are all likely precluded by the FDCA. *Id.* at 1000 n.5, 1004. In short, the preclusion question turns on the specific nature of the claim in question—only claims where the law is unclear and the FDA's particular expertise or rulemaking authority is required are precluded by the FDCA.

Here, the false advertising claim in question is based on the allegation that Imprimis does not comply with Sections 503A and 503B of the FDCA. At first blush, this claim is similar to the precluded false advertising claim in *JHP Pharmaceuticals* that was based on a statement that a drug product "compl[ied] with all applicable laws." *JHP*

Pharms., 52 F. Supp. 3d at 1003. The court reasoned that exceptions to a "seemingly clear rule" prohibiting the sale of new drugs implicated "complex issues of history, public safety, and administrative priorities that Congress has delegated exclusively to the FDA." *Id.* at 1004. Specifically, the determination of whether a drug is "new" required the FDA's particular expertise since "not all drugs marketed are 'new,' and many older drugs, even when updated, are exempt from the strictures of § 355(a)." *Id.* As a result, the district court held that the question of a drug product's legality "directly implicate[d] the FDA's rulemaking authority." *Id.* In contrast, the court held that the question of whether the drugs were "FDA-approved" was a binary factual question that did not require a positive determination by the FDA and was therefore not precluded. *Id.* at 1001.

Although Allergan's claims in this case also address the general question of legality, Allergan's claims revolve around a different section of the FDCA—namely, the drug-compounding provisions of Section 503A and 503B. Here, Allergan's claims only require binary factual determinations similar to the FDA-approval claim in *JHP Pharmaceuticals*. Allergan's claims do not require the Court to resolve thorny questions that may require the FDA's expertise. For instance, the Court does not need to interpret what the FDCA means by "regularly in inordinate amounts" (21 U.S.C. § 353a(b)(1)(D)) or "essentially a copy" (§§ 353a(b)(2), 353b(a)(5)), nor does the Court need to create or interpret a standard MOU § 353a(b)(3)(B)) or determine whether a drug should be included on the 503B bulks list (§ 353b(a)).

According to Allergan's factual allegations, which must be taken as true for the purposes of this Motion, Imprimis's conduct ignores the plain statutory text of FDCA Sections 503A and 503B. *See, e.g.*, Compl. ¶¶ 44, 45, 50, 51, 54–58. Section 503A requires pharmacies to compound drugs "for an identified individual patient." 21 U.S.C. § 353a(a); *see also* RJN, Ex. 5 at 7–8 (FDA guidance discussing "identified individual patient"). Imprimis, however, is allegedly mass-manufacturing its products and claims that its products can be used for *all* cataract surgeries, not just "identified individual patients." Compl. ¶ 54. A drug that can be used for all cataract surgeries is clearly not compounded for an identified individual patient and therefore violates Section 503A.

Section 503A also limits distribution of compounded drugs to five percent of a pharmacy's interstate practice unless the drugs are compounded within a state that has entered into an MOU with the FDA. 21 U.S.C. § 353a(b)(3)(B). Because no such MOU exists for any state due to the FDA's failure to develop a standard MOU, Imprimis contends that the Court must effectively read out that portion of the statute. Mot. at 18. Imprimis, however, cites no authority to support its novel proposition. *Id.* The FDA cannot effectively rewrite the law through its inaction. Unlike *JHP Pharmaceuticals*,

where the issue of whether a particular drug was covered by Section 355(a) was an open ended question delegated exclusively to the FDA, Section 503A gives compounding pharmacies a clear, binary choice—compound in a state that has entered into an MOU or limit its interstate distributions. This statutory provision is not unclear, nor does its interpretation require the FDA's particular expertise or rulemaking authority. If there is no MOU, Imprimis must limit its interstate distributions. As alleged, Imprimis has failed to do so and is therefore in violation of Section 503A. *See* Compl. ¶¶ 51, 54.

Section 503B presents a similar binary determination. Under 503B, registered outsourcing facilities are only allowed to compound drugs on an FDA-created list of bulk drug substances "for which there is a clinical need." 21 U.S.C. § 353b(a)(2)(A). Otherwise, 503B facilities are limited to compounding drugs on the FDA's drug shortage list. *Id.* Like the lack of a standard MOU, the lack of a finalized 503B bulks list does not eliminate this 503B restriction. Moreover, the FDA has announced that it will not take action against a 503B facility for compounding a drug not on the 503B bulks list or the FDA's drug shortage list as long as, *inter alia*, the drug is listed as a Category 1 drug on the 503B interim bulks list. Imprimis allegedly compounds its LessDrop product at its 503B facility using bulk drug substances not listed as a Category 1 drug on the 503B interim bulks list. *Compare* Compl. ¶ 52b (alleged ingredients of Imprimis's LessDrops product) *with* "503B Category 1 Drugs" referenced by RJN, Ex. 9 at 8, available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/UCM467374.pdf. "[I]t takes no special expertise to [make] a simple factual determination," i.e., checking if Imprimis's compounded drugs appear on a list. *JHP Pharms.*, 52 F. Supp. 3d at 1001.

Finally, the FDA's decision to decline enforcement of certain Section 503A and 503B requirements does not help Imprimis. As an executive agency, the FDA has discretion to enforce the law, but the lack of enforcement does not make Imprimis's actions legal.

Because Imprimis's alleged conduct clearly violates the plain text of the statute, the question of legality in this case does not implicate the FDA's rulemaking authority. Therefore, Allergan's Lanham Act claims regarding Imprimis's statements that it operates "under the regulatory framework of [Section 503A and 503B]" and sells LessDrops from a "503B Outsourcing Facility" are not precluded by the FDCA.[1]

[1] Allergan also alleges that Imprimis violates Section 503A and 503B's "essentially a copy" rules. *See* Opp'n at 21–23. The "essentially a copy" rules place restrictions on pharmacies compounding drugs that are essentially copies of other drugs. *See* 21 U.S.C. § 353a(b)(1)(D) (prohibiting the compounding of "any drug products that are essentially

b. Falsity of Imprimis's Statements

Imprimis argues that the statements on its website claiming that it operates "under the regulatory framework of [the FDCA]" and lawfully sells LessDrops from a "503B Outsourcing Facility" are not false because it complies with Sections 503A and 503B. Mot. at 17; *see* Compl. ¶¶ 70, 75. As explained above, however, Allergan's factual allegations—which are to be taken as true for the purposes of this Motion—show that Imprimis is not complying with Sections 503A and 503B. Moreover, Allergan has made numerous factual allegations that support its claim that Imprimis's statements are false.

Specifically, as to Section 503A, Allergan alleges that Imprimis mass-manufactures its products and has quoted Imprimis's CEO as claiming that its products can be used for any patient who has had ocular surgery. Compl. ¶¶ 53–55. Allergan also alleges that Imprimis ships more than five percent of the products manufactured at Imprimis's Irvine, California facility interstate. *Id.* ¶¶ 50–51. Finally, Allergan alleges that Imprimis violates Section 503B by compounding drugs at its outsourcing facility that are not on the 503B bulks list or the 503B interim bulks list. *Id.* ¶ 78. Taken as true, these allegations demonstrate that Imprimis's statements about the legality of its business operations are false.

c. Primary Jurisdiction Doctrine

In the alternative, Imprimis contends that the Court should apply the primary jurisdiction doctrine and dismiss or stay Allergan's claims relating to Imprimis's statements about the legality of its business. Imprimis asserts that Congress has committed regulation of Sections 503A and 503B to the FDA, and that the FDA is engaged in rulemaking relating to these Sections. Mot. at 16. Allergan asserts that the doctrine is inapplicable because its claims do not turn on any technical or policy questions that need to be addressed by the FDA in the first instance. Opp'n at 18–19.

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copies of a commercially available drug product" "regularly or in inordinate amounts"); 21 U.S.C. § 353b(a)(5) (blanket prohibition on compounding drugs that are "essentially a copy of one or more approved drugs"). Imprimis's alleged violation of Section 503A and 503B's "essentially a copy" rule are precluded because the rule implicates various exceptions that "directly implicate the FDA's rulemaking authority." *JHP Pharms*, 52 F. Supp. 3d at 1004. For instance, Section 503A explicitly requires the FDA to define the phrase "regularly and in inordinate amounts." 21 U.S.C. § 353a(b)(1)(D). The fact that Section 503B defines the term "essentially a copy" does not change the analysis, because the statutory definition is rife with exceptions that the FDA must first determine. *See* 21 U.S.C. § 353b(d)(2) (failing to define "nearly identical to an approved drug" and "clinical difference"). The preclusion of these allegations is not fatal to Allergan's Lanham Act claims, however, because Imprimis's statements about the lawfulness of its business are broad and sweeping and fail on other grounds.

The primary jurisdiction doctrine is "a prudential doctrine under which courts may, under appropriate circumstances, determine that the initial decisionmaking responsibility should be performed by the relevant agency rather than the courts." *Syntek Semiconductor Co., Ltd. v. Microchip Tech. Inc.*, 307 F.3d 775, 780 (9th Cir. 2002). If a district court determines that primary jurisdiction is appropriate, it may stay proceedings or dismiss the case without prejudice in order to allow the relevant agency to address the issue first. *Astiana v. Hain Celestial Grp., Inc.*, 783 F.3d 753, 761 (9th Cir. 2015). This doctrine is reserved for a "limited set of circumstances" and is not intended to "secure expert advice from agencies every time a court is presented with an issue conceivably within the agency's ambit." *Clark v. Time Warner Cable*, 523 F.3d 1110, 1114 (9th Cir. 2008) (internal quotations omitted). Rather, a court should only invoke primary jurisdiction when an "otherwise cognizable claim implicates technical and policy questions that should be addressed in the first instance by the agency with regulatory authority over the relevant industry rather than by the judicial branch." *Id.*

Courts consider several factors when applying the primary jurisdiction doctrine, including whether the issue (1) is within the conventional experience of judges; (2) "involves technical or policy considerations within an agency's field of expertise"; (3) is "particularly within the agency's discretion"; or (4) "there exists a substantial danger of inconsistent rulings." *Maronyan v. Toyota Motor Sales, U.S.A., Inc.*, 658 F.3d 1038, 1049–50 (9th Cir. 2011) (internal quotations omitted). The Ninth Circuit has also held that primary jurisdiction is inappropriate "when a referral to the agency would significantly postpone a ruling that a court is otherwise competent to make." *Astiana*, 783 F.3d at 761. "The deciding factor should be efficiency." *Rhoades v. Avon Prods.*, 504 F.3d 1151, 1165 (9th Cir. 2007).

Here, primary jurisdiction is inappropriate for four reasons: (1) the FDA's particular expertise is not required; (2) Lanham Act claims are appropriately heard by the courts; (3) some risk of variation is acceptable; and (4) it is unclear when the FDA will complete its rulemaking process, if ever. First, although determining the legality of a drug manufacturer's business model generally requires the FDA to make technical and policy determinations in the first instance, it takes no special expertise to determine that question in this case. As explained above, Allergan has successfully pled violations of the plain statutory language of the FDCA Section 503A and 503B.

Second, claims of false or misleading statements are not "particularly within the [FDA's] discretion." *Maronyan*, 658 F.3d at 1049–50; *see also POM Wonderful*, 134 S. Ct. at 2238 (noting that the FDA "does not have the same perspective or expertise in assessing market dynamics"). Indeed, the Supreme Court made clear in *POM Wonderful*

that "the FDA does not have authority to enforce the Lanham Act." *POM Wonderful*, 134 S. Ct. at 2241. Claims under the Lanham Act, such as those at issue here, are appropriately decided by the courts.

Third, Imprimis's contention that "litigating myriad lawsuits brought by . . . Allergan" will "result in a patchwork of standards" is unavailing. Mot. at 16. In *POM Wonderful*, the Supreme Court stated that although "the application of . . . the Lanham Act . . . may give rise to some variation in outcome, this is the means Congress chose to enforce a national policy to ensure fair competition." *POM Wonderful*, 134 S. Ct. at 2239. Furthermore, Allergan's factual allegations paint a picture of blatant infringement of the plain statutory language of the FDCA. Taken as true, the factual allegations in this case do not occupy a gray area that may result in inconsistent rulings. *See JHP Pharms.*, 52 F. Supp. 3d at 1001.

Finally, Imprimis asserts that the FDA is in the process of rulemaking and that the Court should stay Allergan's claims until the FDA has issued its rules. Imprimis does not and likely cannot state with any certainty when the FDA will issue finalized rules. In fact, the Office of Management and Budget has placed the FDA's rulemaking with regards to Section 503A and 503B on an "Inactive Actions" list. *See* 2017 Inactive Actions, RIN No. 0910-AH10, *Current Unified Agenda of Regulatory and Deregulatory Actions*, Office of Mgmt. & Budget. In the interest of efficiency, the Court declines to indefinitely stay the case.

In sum, Allergan's Lanham Act claim relating to statements about the lawfulness of Imprimis's business is not precluded, those statements are false as alleged, and primary jurisdiction does not apply. Accordingly, the Court DENIES Imprimis's Motion to Dismiss as to Allergan's Lanham Act false advertising claim to the extent that claim is premised on Imprimis's statements that its business complies with Sections 503A and 503B.

3. Statement Regarding Relative Effectiveness

Next, Imprimis argues that its statement about the relative effectiveness of its Dropless Therapy treatment fails to support a Lanham Act false advertising claim. Imprimis claims in a video on its website that with its Dropless Therapy treatment, "[t]he patient is protected from infection and inflammation even more effectively than can be achieved with expensive, inconvenient, and irritating topical medications." Compl. ¶ 79. In its Complaint, Allergan asserts that this statement constitutes false advertising because Imprimis opted out of complying with drug-approval requirements and therefore has no

evidence to support its claims about Dropless Therapy's effectiveness. *Id.* Imprimis argues that this claim fails because the statement is not "specific and measurable" and it "likely falls within the primary jurisdiction of the FDA." Mot. at 23–24; Reply at 16. Allergan argues that the statement is capable of being proved false, in part because Imprimis has no basis to claim that its drugs are safe or effective. Opp'n at 13.

The Lanham Act requires that statements must be false or misleading representations of fact to constitute an actionable claim—mere puffery is not actionable. *See Newcal Indus. v. Ikon Office Solutions*, 513 F.3d 1038, 1053 (9th Cir. 2008). A statement that is quantifiable may be an actionable statement of fact, but a general, subjective claim is not actionable. *Id.* (citing *Cook, Perkiss, & Liehe v. N. Cal. Collection Serv., Inc.*, 911 F.2d 242 (9th Cir. 1990)). "[C]onsumer reliance will be induced by specific rather than general assertions." *Id.*

Imprimis's statement that its Dropless Therapy treatment is more effective than topical medications at protecting patients from infection and inflammation is actionable. Whether a drug is more effective than another drug is capable of measurement. *See Sterling Drug, Inc. v. FTC*, 741 F.2d 1146, 1151–53 (9th Cir. 1984) (statements that a brand is "consistently better" for "purity, stability, speed of disintegration" were "therapeutic claims" that could be measured). Even if Imprimis's statement was simply a subjective opinion, Allergan alleged that Imprimis had *no* basis to make its statement. A statement "by a speaker who lacks a good faith belief in the truth of the statement" is actionable. *ThermoLife Int'l, LLC v. Gaspari Nutrition Inc.*, 648 Fed. Appx. 609, 614–615 (9th Cir. 2016) (quoting *PhotoMedex, Inc. v. Irwin*, 601 F.3d 919, 931 (9th Cir. 2010)).

Next, Imprimis's reliance on *JHP Pharmaceuticals* for the proposition that effectiveness claims may fall within the primary jurisdiction of the FDA is unavailing. *See* Reply at 4–6. Claims that a drug is "effective" may certainly fall within the FDA's primary jurisdiction since the FDA's particular expertise would be required to determine if a drug is legally "effective." *Cf. JHP Pharms.*, 52 F. Supp. 3d at 1003 ("A determination of whether the Defendants' products are 'safe' or 'effective' might well fall within the primary jurisdiction of the FDA, or even be precluded entirely."). But there is no need for the Court to determine whether Imprimis's drug is "effective" as defined by the FDA. Rather, the Court only needs to determine whether Imprimis's drug is demonstrably more or less effective than topical medications. To do so, the Court need only compare the success rates of different drugs for treating infection and inflammation. It does not need to answer technical and policy questions more appropriately addressed by the FDA, such as when a drug may be deemed "effective" for use.

Accordingly, the Court DENIES Imprimis's Motion to Dismiss as to Allergan's Lanham Act false advertising claim to the extent that claim is premised on Imprimis's statement that its product is more effective than topical medications.

4. Statement Regarding Surgeon Preference

Finally, Imprimis argues that a statement it made about surgeons preferring Dropless Therapy fails to support a Lanham Act false advertising claim. On its website, Imprimis claims that "95% of cataract surgeons surveyed would prefer Dropless Therapy." Compl. ¶ 80. Allergan argues that statement is false and misleading because it relies on an unscientific survey. *Id.* ¶ 80; Opp'n at 10–11. In response, Imprimis argues that the statement is mere puffery in part because the statement does not compare Dropless Therapy to any other product. Mot. at 23–24; Reply at 16–17.

A plaintiff may demonstrate that a statement based on product testing is literally false by demonstrating "that such tests are not sufficiently reliable to permit one to conclude with reasonable certainty that they established the claim made." *Southland*, 108 F.3d at 1139 (internal quotations omitted). Even if the tests are reliable, the plaintiff can succeed by showing that the tests do not establish the proposition asserted by the defendant. *Id.* (citing *Castrol, Inc. v. Quaker State Corp.*, 977 F.2d 57, 62–63 (2d Cir. 1992)). A claim can be literally false "by necessary implication." *Id.*

Here, Imprimis's statement relies on a 2014 survey of twenty-one surgeons. Compl. ¶ 80. A survey of only twenty-one surgeons may not be "sufficiently reliable to permit one to conclude with reasonable certainty that [it] established the claim made." *Southland*, 108 F.3d at 1139 (internal quotations omitted). In addition, Imprimis's alleged failure to fully inform the surveyed surgeons that Dropless Therapy was an unapproved new drug, or about any of the risks associated with the treatment, also cuts against the reliability of the survey. *See* Compl. ¶ 80; *Litton Industries, Inc. v. FTC*, 676 F.2d 364, 367–68 (9th Cir. 1982) (upholding FTC complaint that defendant's advertising "lacked a reasonable basis").

Imprimis contends that its 95% preference claim is not actionable because Imprimis did not advertise that the surgeons prefer Dropless Therapy to some other product. Reply at 16. Imprimis's argument is unavailing—the fact that the statement does not name a competing product does not save it. "[T]he claim must always be analyzed in its full context." *Southland*, 108 F.3d at 1139. On its website, Imprimis not only makes its preference claim, but it also claims that Dropless Therapy is superior to topical

medications. *See* Compl. ¶¶ 79–80. Viewed together, Imprimis necessarily implied that those surgeons prefer their product to other forms of cataract surgery treatment.

Accordingly, the Court DENIES Imprimis's Motion to Dismiss as to Allergan's Lanham Act false advertising claim to the extent that claim is based on Imprimis's statement that "95% of surgeons prefer Dropless Therapy."

B. Unfair Competition Law Claim

Allergan's UCL claim is premised on three violations of California law: (1) false advertising in violation of the Sherman law; (2) manufacturing and selling unapproved drugs in violation of the Sherman law; and (3) compounding drugs in violation of California compounding regulations. *See* Compl. ¶¶ 82–86, 93–107. Imprimis argues that Allergan's UCL claim should be dismissed because Allergan has failed to satisfy the UCL's standing requirement, and because Allergan does not plead any underlying violation of California law. Mot. at 24; Reply at 18. Allergan maintains that it has sufficiently stated a claim under the UCL for the same reasons it stated a Lanham Act claim. Opp'n at 14 n.7, 25.

The UCL prohibits any "unlawful, unfair, or fraudulent business act or practice." Cal. Bus. & Prof. Code § 17200. "[The UCL] thereby 'borrows' violations from other laws by making them independently actionable as unfair competitive practices." *AT&T Mobility LLC v. AU Optronics Corp.*, 707 F.3d 1106, 1107 n.1 (9th Cir. 2013) (internal quotations omitted). According to the California Supreme Court, the UCL "establishes three varieties of unfair competition—acts or practices which are unlawful, or unfair, or fraudulent." *Cel-Tech Commc'ns, Inc. v. Los Angeles Cellular Tel. Co.*, 20 Cal. 4th 163, 180 (1999) (internal citation and quotation marks omitted). In other words "[e]ach prong of the UCL is a separate and distinct theory of liability." *Kearns v. Ford Motor Co.*, 567 F.3d 1120, 1127 (9th Cir. 2009).

Under the "unlawful" prong, the UCL incorporates other state laws, and violations of those laws are independently actionable. *Chabner v. United Omaha Life Ins. Co.*, 225 F.3d 1042, 1048 (9th Cir. 2000). The "unfair" prong addresses business practices that "offend[] an established public policy or when the practice is immoral, unethical, oppressive, unscrupulous or substantially injurious to consumers." *Smith v. State Farm Mut. Auto. Ins. Co.*, 93 Cal. App. 4th 700, 719 (2001). Lastly, the "fraudulent" prong of the UCL prohibits business practices if "members of the public are likely to be deceived." *Comm. on Children's Television v. Gen. Foods Corp.*, 35 Cal. 3d 197, 211 (1983).

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES – GENERAL

In this case, Allergan's UCL claims are primarily predicated on the "unlawful" prong. Allergan alleges that Imprimis is violating California's Sherman Law by flouting that law's drug-approval requirements and by falsely advertising its products. Compl. ¶¶ 82–86, 93–97. Allergan also alleges that Imprimis is violating California regulations regarding drug compounding. *Id.* ¶¶ 98–107 (citing 16 Cal. Code Regs. § 1735.2, *et seq.*). Thus, Allergan sufficiently alleges that Imprimis is engaged in "an act or practice, committed pursuant to business activity, that is at the same time forbidden by law." *Bernardino v. Planned Parenthood Fed. Of Am.*, 115 Cal. App. 4th 322, 351 (2004).

Nevertheless, Imprimis argues that, in order to establish standing under the UCL to bring a claim based on a theory of misrepresentation, Allergan must demonstrate actual reliance on the allegedly misleading statements. *See* Mot. at 24–25 (citing *Kwikset Corp. v. Superior Court*, 51 Cal. 4th 310 (2011)); *see also* Reply at 18–19. Allergan argues that there is no need to plead reliance where a UCL claim is based on the UCL's "unlawful" prong. *See* Opp'n at 25 (citing *Bruton v. Gerber Prods. Co.*, 2017 WL 3016740 at *2 (9th Cir. July 17, 2017).

As an initial matter, Imprimis's argument is only addressed to claims based on a fraud theory—that is, Allergan's UCL false advertisement claim. *See* Reply at 18 (quoting *Kwikset*, 51 Cal. 4th at 320–21). However, Allergan also brings UCL claims alleging that Imprimis violated the Sherman Law's drug-approval requirements and California's drug compounding regulations. *See* Compl. ¶¶ 82–26, 98–107. These claims are not "based on a fraud theory." *Kwikset*, 51 Cal. 4th at 326. Rather, these claims are based on Imprimis's allegedly unlawful business practices, which purportedly give Imprimis a competitive edge. *See* Compl. ¶¶ 119, 121. The reliance requirement about which Imprimis argues is irrelevant to these claims. *See Youngevity Int'l, Corp. v. Smith*, 224 F. Supp. 3d 1022, 1031 (S.D. Cal. 2016). Rather, the UCL makes these violations independently actionable. *Cel-Tech*, 20 Cal. 4th at 180.

As for Allergan's UCL false advertising claim, whether competitors must demonstrate their own reliance on a defendant's allegedly misleading statement remains an open question. *See L.A. Taxi Coop. v. Uber Techs., Inc.*, 114 F. Supp. 3d 852, 866 (N.D. Cal. 2015). To support its contention that reliance must be established for such claims, Imprimis cites *Kwikset Corp. v. Superior Court*, in which the California Supreme Court addressed a consumer class action and held that the passage of Proposition 64 narrowed the reach of the UCL. *Kwikset*, 51 Cal. 4th at 322 (2011). After the passage of Proposition 64, plaintiffs asserting cases "based on a fraud theory involving false advertising and misrepresentations to consumers" must show causation, which requires establishing reliance because "reliance is the causal mechanism of fraud." *Kwikset*, 51

Cal. 4th at 326 (quoting *In re Tobacco II Cases*, 46 Cal. 5th 298, 326 (2009)). The causation requirement applies with equal force to consumer cases brought under the "unlawful" and "unfair" prongs when the claims are based on misrepresentation. *Id.* at 326 n.9. At the same time, however, the California Supreme Court "express[ed] no views concerning the proper construction of the cause requirement in other types of cases" and reiterated the general principle that the UCL's purpose "is to protect both consumers and competitors by promoting fair competition." *Id.* at 320, 326 n.9. (internal quotations omitted). Notably, *Kwikset* only involved claims of misrepresentation brought by consumers; it did not discuss claims between business competitors like Allergan and Imprimis. *See id.* at 317.

In fact, no California court has explicitly considered whether the reliance requirement applies to a false advertising claim brought by a company against its competitor. Federal courts addressing this issue have disagreed about whether a competitor plaintiff must plead their own reliance, or whether pleading consumer reliance is sufficient. *See L.A. Taxi Coop.*, 114 F. Supp. 3d at 866–67 (collecting cases). A majority of courts have concluded that competitor plaintiffs must allege their own reliance on the alleged misrepresentations, while a minority do not read *Kwikset* and Proposition 64 as reaching competitor claims. *Id.*; *see, e.g.*, *O'Connor v. Uber Techs., Inc.*, 58 F. Supp. 3d 989, 1002 (N.D. Cal. 2014) ("UCL fraud plaintiffs must allege their *own* reliance."); *VP Racing Fuels, Inc. v. Gen. Petroleum Corp.*, 2010 WL 1611398 at *3 n.3 (E.D. Cal. Apr. 20, 2010) (commenting that a competing corporation "is not the type of plaintiff whose standing was targeted by California voters through Proposition 64").

The Court declines to extend the California Supreme Court's reasoning in *Kwikset* to this case. First, as noted above, *Kwikset* and the cases preceding it involve consumer claims, not claims between competitors. *See Kwikset*, 51 Cal. 4th at 327–329. Here, Allergan and Imprimis are competitors, and therefore *Kwikset* is distinguishable on its face.

Second, Proposition 64 was passed in order to "prevent abusive UCL actions by attorneys whose clients had not been 'injured in fact' or used the defendant's product or service, and 'to ensure that only the California Attorney General and local public officials [are] authorized to file and prosecute actions on behalf of the general public.'" *Buckland v. Threshold Enters., Ltd.*, 155 Cal. App. 4th 798, 812–13 (2007) (citing Prop. 64, §§ 1(b), (e), (f)). As amended, the relevant portions of the UCL allow actions "by a person who has suffered injury in fact and has lost money or property as a result . . . ." Cal. Bus. & Prof. Code §§ 17204, 17535. Unlike consumer plaintiffs prior to the passage of Proposition 64, competitor plaintiffs like Allergan do suffer an "injury in fact . . . as a

result" of the competitor defendant's actions—loss of market share and sales due to the defendant's misleading advertising diverting customers. Therefore, Proposition 64's purpose of preventing actions by plaintiffs who have not suffered an actual injury does not apply to competitor plaintiffs.

Third, applying *Kwikset*'s reliance requirement to competitor claims, particularly those based on the "unlawful" prong of the UCL, makes little sense. False advertising claims between competitors are fundamentally different from false advertising claims by consumers. Even though the predicate unlawful act for both types of claims is based on misrepresentation, competitor plaintiffs are not concerned with the deceptive activity simply because it's deceptive. Competitor plaintiffs are concerned with the loss of sales and market share *as a result of* the deceptive activity. In contrast, consumer plaintiffs are concerned with the deceptive activity itself and suffer a wholly different type of harm from competitors—getting hoodwinked into purchasing a product or service. It is hard to imagine a scenario, though, in which a competitor plaintiff would rely on a competitor defendant's misleading advertisements and suffer injury. After all, situations in which a company would purchase its competitor's products are few and far between. A company may purchase its competitor's products to conduct market research or, where the competitor's products are unprotected by intellectual property law, in an attempt to reverse engineer a particular feature. Unlike consumers, however, a company is not likely to purchase its competitor's products simply because it saw and relied on an ad. Thus, imposing the reliance requirement on competitor claims would impose a superficial hurdle on competitor plaintiffs seeking to stop or recover for damages caused by their competitor's false advertising. *Kwikset* does not appear to go so far.

Finally, the California Supreme Court has acknowledged that "the UCL is a chameleon." *Aryeh v. Canon Business Solutions, Inc.*, 55 Cal. 4th 1185, 1196 (2013). "Given the widely varying nature of the [UCL], it makes sense to acknowledge that a UCL claim in some circumstances might support the potential application of one or another exception, and in others might not." *Id.* (internal citations and quotations omitted). Because the consumer-competitor distinction is one such circumstance, the Court holds that *Kwikset* is inapplicable to this case. Allergan's UCL claim based on false advertising therefore survives Imprimis's Motion.

Accordingly, the Court DENIES Defendant's Motion to Dismiss as to Plaintiff's UCL claim.

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES – GENERAL

Case No. SA CV 17-1551-DOC (JDEx) Date: November 14, 2017
Page 22

V. Disposition

For the reasons set forth above, the Court DENIES Defendant's Motion to Dismiss.

The Clerk shall serve this minute order on the parties.

MINUTES FORM 11 Initials of Deputy Clerk: djl

CIVIL-GEN

CERTIFICATE OF SERVICE

I hereby certify that on December 1, 2017, I served or caused to be served copies of this Appendix to Petition for a Writ of Mandamus via Hand Delivery or Overnight Mail to the following:

The Honorable Lisa R. Barton
Secretary
U.S. International Trade Commission
500 E Street, S.W.
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Respectfully submitted,

/s/ *Ashley C. Parrish*
Ashley C. Parrish

Counsel for Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Ltd.

Dated: December 1, 2017