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MEMORANDUM

From: Steven B. Steinborn
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Date: April 30, 2014

RE: FDA Finalizes Rule Limiting Permissible Omega-3 FDAMA Nutrient Content Claims

The ability to make nutrient content claims for omega-3 fatty acids in foods was significantly curtailed by a recently issued final regulation by the Food and Drug Administration (FDA). 1/ The rule finalizes a 2007 proposal by FDA regarding nutrient content claims for alpha-linolenic acid (ALA), docosahexaenoic acid (DHA), and eicosapentaenoic acid (EPA) submitted by several manufacturers under the procedures established by the Food and Drug Administration Modernization Act of 1997 (FDAMA). 2/ The rule prohibits nutrient content claims regarding DHA, EPA, and ALA contained in a notification by several seafood processors (Seafood Processors); claims for DHA in a notification by Martek Biosciences Corp. (Martek); and claims regarding DHA and EPA in a notification by Ocean Nutrition Canada, Ltd. (Ocean Nutrition); while allowing the continued use of a nutrient content claim for ALA contained in Martek's notification. 3/ The rule will take effective on January 1, 2016.

The rule provides specific guidance on what omega-3 claims FDA deems appropriate as well as how FDA interprets key language in FDAMA.

Background on the Notifications

In 2004 and 2005, FDA received three separate FDAMA notifications regarding nutrient content claims for certain omega-3 fatty acids:

- The Seafood Processors' notification defined "high" nutrient content claims for DHA and EPA and "high," "good source," and "more" claims for ALA, relying on statements contained in a report by the Institute of Medicine (IOM). The claims were based on a reference value of 130mg per day of DHA and EPA and 1.3g per day for ALA.

1/ FDA, Final Rule, Food Labeling: Nutrient Content Claims; Alpha-Linolenic Acid, Eicosapentaenoic Acid, and Docosahexaenoic Acid Omega-3 Fatty Acids, 79 Fed. Reg. 23262 (Apr. 28, 2014).

2/ FDAMA authorizes the use of nutrient content claims based on an authoritative statement by a scientific body of the U.S. government that has responsibility for public health protection or nutrition research or by the National Academy of Sciences (NAS) that "identifies the nutrient level to which the claim refers." A manufacturer wishing to use a FDAMA claim in food labeling must submit a notification containing the claim to FDA at least 120 days before marketing the food bearing the claim.

3/ The Appendix to this memorandum summarizes the omega-3 FDAMA nutrient content claims still permitted under this rule.

- The Martek notification defined "high" nutrient content claims for DHA and "high," "good source," and "more" claims for ALA, also drawing on the IOM report. The claims were based on a reference value of 160mg per day of DHA and 1.6mg per day for ALA.
- The Ocean Nutrition notification defined a "high" claim for DHA and EPA combined, based also on the IOM report, and using 160mg as the daily value for DHA and EPA combined.

Under FDAMA, the nutrient content claim may be used in food labeling unless or until FDA implements a regulation prohibiting the claim contained it the notification.

FDA's Analysis of the Claims Contained in the Notifications

FDA grouped its analysis by nutrient due to similarity between the claims and the authoritative statements on which they relied.

DHA and EPA claims

FDA concluded that the IOM report provided insufficient support for a FDAMA nutrient content claim for DHA or EPA because the report failed to identify a specific recommended intake value to serve as the reference value. FDA in the final rule interpreted FDAMA as requiring the authoritative statement to contain a "single, precise nutrient level," for the nutrient in question, one that "could serve as a basis for setting a [Daily Value]." According to FDA, the agency "do[es] not require that this nutrient level be an RDI or a DRV, but the nutrient level must be a single reference value" that identifies "a specific amount of the nutrient in question." FDA concluded that although the IOM report contains discussion of DHA and EPA consumption, the report never identifies a specific recommended nutrient level for either nutrient. The agency pointed to the different reference values for DHA and EPA reflected in the separate notifications as underscoring the lack of a clear, specific nutrient level in the IOM report.

Therefore, because the authoritative statement does not identify the nutrient level to which the claim refers, FDA concluded that the statutory prerequisites for a FDAMA claim were not met for the DHA and EPA nutrient content claims notifications. The final rule will prohibit the DHA and EPA claims contained in all three notifications.

ALA Claims

FDA concluded that the Seafood Processors' ALA nutrient content claim used an improper reference value for ALA and therefore should be prohibited. FDA explained that the IOM report identified several age-gender group specific adequate intake levels for ALA, including 1.6g per day for males age 14 and older and 1.1g per day for females age 14 or older. The reference value in the Seafood Processors notification was derived by taking a population-weighted average of these adequate intake levels. But this approach differs from FDA's own method—the "population-coverage approach"—for deriving reference values used for food labeling. Using the population-coverage approach, FDA "would use the highest Recommended Daily Allowance (RDA) or [adequate intake] for adults and children 4 or more years of age (excluding values for pregnant and lactating women) to serve as the label reference value." In essence, according to FDA, the agency "take[s] the highest number to use as the label reference value, while the seafood processors would take an average of the various numbers," which leads to inconsistency between nutrient content claims and risks overstating the contribution a particular food makes to a consumer's recommended consumption of a given nutrient. The final rule therefore prohibits the ALA nutrient content claim contained in the Seafood Processor's notification.

FDA addressed the Martek ALA nutrient content claim briefly, explaining that the agency would not take regulatory action on the Martek ALA nutrient content claim notification because that claim used the population-coverage approach to derive the reference value for ALA. Because FDA has not prohibited the Martek ALA nutrient content claim, products bearing this nutrient content claim "will be allowed to remain on the market at this time."

Effective Date

The final rule will take effect on January 1, 2016, which is the uniform effective date for food labeling regulations issued in 2013 and 2014.

Effect on Other Omega-3 Claims

FDA notes that this final rule does not prevent manufacturers from communicating information about the DHA and EPA content of their products because several other avenues exist, including amount claims (e.g., "X mg of EPA and DHA omega-3 fatty acids per serving") on conventional foods and dietary supplements, simple percentage claims and comparative percentage claims on dietary supplements, and a qualified health claim describing the potential health benefits of consuming EPA and DHA. 4/

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This final rule alters the landscape for marketing foods using nutrient content claims for EPA, DHA, and ALA under the affected notifications. Manufacturers marketing foods using omega-3 claims should review their labeling to determine whether this rule will require label revisions. Further, manufacturers considering preparing FDAMA notifications for nutrient content claims should carefully review FDA's analysis of the notifications in this final rule.

We will continue to monitor this and other labeling developments. Please contact us if you have any questions.

4/ FDA, Letter Responding to Health Claim Petition dated November 3, 2003 (Martek Petition): Omega-3 Fatty Acids and Reduced Risk of Coronary Heart Disease (Docket No. 2003Q-0401), http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm072932.htm; FDA, Letter Responding to Health Claim Petition dated June 23, 2003 (Wellness petition): Omega-3 Fatty Acids and Reduced Risk of Coronary Heart Disease (Docket No. 2003Q-0401), http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm072936.htm.

Appendix – Summary of Omega-3 Nutrient Content Claims Permitted By the Final Rule

Claim	Full Claim	Conditions for Claim
High	"Excellent source of ALA. ("High in ALA," "Rich in ALA") Contains __mg of ALA per serving, which is __% of the 1.6 g Daily Value for ALA."	≥ 320 mg of ALA per RACC (≥ 20% of 1.6 g/day)
Good Source	"Good source of ALA. ("Contains ALA," "Provides ALA") Contains __mg of ALA per serving, which is __% of the 1.6 g Daily Value for ALA"	≥ 160 mg of ALA per RACC (≥ 10% of 1.6 g/day)
More	"More ALA" ("Fortified with ALA," "Enriched with ALA," "Added ALA," "Extra ALA," "Plus ALA") Contains __% more of the Daily Value for ALA per serving than [reference food]. This product contains __mg of ALA which is __% of the Daily Value for ALA (1.6 g)."	≥ 160 mg of ALA more per RACC than an appropriate reference food (≥ 10% of 1.6 g/day)