

MEMORANDUM

From: Steven B. Steinborn
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Date: April 27, 2018

Re: FDA Takes Initial Action on Ocean Spray Cranberries, Inc. Health Claim Petition for Cranberry Product and UTIs in Women

On September 8, 2017, Ocean Spray Cranberries, Inc. (Ocean Spray) originally submitted a health claim petition to the Food and Drug Administration (FDA) for approval of a health claim tying together the consumption of cranberry products and the reduced risk of urinary tract infections (UTIs) in healthy women. ^{1/} More recently, on February 20, 2018, the FDA sent a letter to Ocean Spray stating that it is proceeding to review the petition as one for a qualified health claim. ^{2/} All of this information has now been posted in the agency docket. Comments on this qualified health claim petition will be accepted until May 7, 2018, and the FDA expects to issue a final decision on the claim by October 5, 2018.

This memorandum summarizes Ocean Spray's petition, the studies cited in support of Ocean Spray's claim, the discussion concerning cranberry as an eligible "substance," and the FDA's response.

The Proposed Health Claim

Ocean Spray's petition originally requested that FDA authorize health claim language that recognizes the "well supported" relationship between frequent consumption of eligible cranberry products and the reduced risk of recurrent UTIs in healthy women. It requests that FDA approve several proposed illustrative model health claims, and also "accommodate labeling flexibility by explicitly authorizing the use of alternate claim language, in alignment with First Amendment requirements."

The proposed model health claims are:

- By consuming one serving of cranberry products each day, like [X amount of this identified cranberry product], healthy women who have had a urinary tract infection (UTI) may reduce their risk of recurrent UTI.
- Consuming one serving of cranberry products each day, like an [X amount of this identified cranberry product], may help prevent recurrent urinary tract infection (UTI) in healthy women.

^{1/} The health claim petition and supporting documents are available at <https://www.regulations.gov/docket?D=FDA-2018-Q-0739>.

^{2/} The FDA letter is available at <https://www.regulations.gov/document?D=FDA-2018-Q-0739-0079>.

- Consuming one serving of a food containing cranberries or cranberry juice each day, like an [X amount serving of this identified cranberry product] may help prevent recurrent urinary tract infection (UTI) in healthy women.

The “substance” of the petition’s health claim is “cranberry,” which Ocean Spray has defined to include “the whole cranberry fruit and cranberry juice, including forms of these cranberry foods that vary in moisture content, including dehydrated fruit, juice concentrate, and powdered whole cranberry fruit and fruit juice.” The petition states that other eligible substances would be “cranberry products,” encompassing conventional food and dietary supplements. All cranberry products under the petition’s proposed health claim would be required to contain cranberry “in amounts that are at least equivalent to the cranberry content of one serving of 27% cranberry juice cocktail or one serving of whole fresh cranberries, based on ‘cranberry fruit equivalents,’ a unit of measure that accounts for the total phenolic content of fresh cranberries on a per cranberry basis.”

The Science

The petition states that all of the scientific information available supports the relationship between daily consumption of cranberry products and reduced risk of recurrent UTIs in women, due to the high polyphenol content of the fruit. The evidence that Ocean Spray relies on to meet the FDA’s significant scientific agreement (SSA) standard ^{3/} includes randomized control trials (finding that cranberry consumption lowered the risk of recurrent UTI by 20 to 58%), systemic reviews and meta-analyses, and ex vivo studies (linking cranberry with bacterial anti-adhesion activity). The petition also cites support for cranberry consumption from the 2015 Dietary Guidelines for Americans, and the Scottish Intercollegiate Guidelines Network.

Ocean Spray states that the above scientific evidence should be relied upon, and that the health claims should be permitted, as recurrent UTIs in healthy women pose a public health problem in the United States. The company reasons that while recurrent UTI is not itself responsible for morbidity burdens, the antibiotics used to treat UTIs can be. Therefore, the petition concludes that informing consumers of the advantages of cranberry products as related to UTIs “would have significant public health benefits.”

Nutritive Value

One condition of a health claim is that the substance must fall within the definition of a “food.” A food has traditionally been defined as a substance that must “contribute taste, aroma, or nutritive value” and “retain that attribute when consumed at levels that are necessary to justify a claim.” ^{4/} Ocean Spray states that all forms of cranberry (including fresh whole cranberries, dried cranberries, expressed cranberry juice, cranberry juice concentrate, reconstituted cranberry juice, and dehydrated and powdered forms of whole cranberries and cranberry juice) qualify under this standard, due to cranberry’s “well established history” as food “in a wide variety of conventional food forms.” The petition goes on to state that “regardless of the form, cranberry is a food substance that is consumed primarily, if not solely, for ‘food purposes,’ including taste, aroma and/or nutritive value,” and that “these ‘food’ attributes of cranberry are retained regardless of whether cranberry is

^{3/} To be approved by the FDA as an authorized health claim, there must be SSA among qualified experts that the claim is supported by the totality of publicly available scientific evidence for a substance/disease relationship. The FDA has stated that the SSA standard is intended to be a strong standard that provides a high level of confidence in the validity of the substance/disease relationship. See *Guidance for Industry: Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements*, available at <https://www.fda.gov/OHRMS/DOCKETS/98fr/995424GD.pdf>.

^{4/} 21 C.F.R. § 101.14(b)(3)(i).

consumed in the form of a conventional food or dietary supplement.” A lengthy footnote references *Nutrilab, Inc. v. Schweiker* ^{5/}, and asserts that cranberry substance is “readily distinguishable from articles that do not qualify as ‘food’ under the criteria established” in that case. Ocean Spray says that while the taste and aroma of cranberries is present in the proposed products in “varying degrees” the court in *Nutrilab* “rejected the notion” that food must always “be consumed ‘solely’ for taste, aroma, or nutritive value.”

FDA Response

Notwithstanding that the original petition sought an unqualified health claim, FDA responded to Ocean Spray on February 20, 2018, advising that it had reclassified the petition as a “qualified health claim” petition and will evaluate the science and proposed claims accordingly. This change in review is significant, as it indicates that the FDA did not believe the health claim would meet the SSA standard.

Qualified health claims are qualified to convey to consumers the shortcomings of the supporting science, as determined by FDA. ^{6/} Therefore, should the FDA ultimately approve a qualified health claim, one should anticipate that any claims allowed by FDA will be markedly different than the original claim sought by Ocean Spray.

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We will continue to monitor developments related to the qualified health claim for cranberry product and UTIs in women. Please let us know if you have any questions.

^{5/} 713 F.2d 335 (7th Cir. 1983).

^{6/} More information on qualified health claims is available at <https://www.fda.gov/Food/LabelingNutrition/ucm2006877.htm>.