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E-ALERT | Food & Drug

April 28, 2014

FDA FINALIZES THE RULE PROHIBITING MOST OMEGA-3 NUTRIENT CONTENT CLAIMS

Today, FDA published a final rule in the Federal Register that prohibits most nutrient content claims for foods, including dietary supplements, that contain the omega-3 fatty acids docosahexaenoic acid (DHA), eicosapentaenoic acid (EPA), and alpha-linolenic acid (ALA).[1] This rule finalizes FDA's proposed rule, which was issued in 2007, without making any substantive changes to that proposal. Under the final rule, all DHA and EPA claims and some ALA claims that were previously permitted are now prohibited from appearing on food labels. This final rule follows on the heels of FDA's substantial proposed rules regarding changes to nutrition labeling of packaged foods and dietary supplements, which were issued in March.[2]

Background on Omega-3 Nutrient Content Claims

The nutrient content claims at issue in the final rule were permitted to appear on food labels because the agency originally had not objected to industry notifications submitted under the nutrient content claim notification procedure the FDA Modernization Act of 1997 (FDAMA) established. Under the FDAMA notification process, manufacturers and distributors may use a health claim or nutrient content claim in food and dietary supplement labeling if (1) the claim is based on a published, authoritative statement by certain federal scientific bodies or the National Academy of Sciences (NAS); (2) the claim identifies the nutrient level to which it refers; and (3) FDA does not object to the claim within 120 days of receipt of the notification.

Three different notifications were filed with FDA between 2004 and 2006 regarding nutrient content claims for DHA, EPA, and ALA in the labeling of conventional foods and dietary supplements. The claims relied on authoritative statements by the Institute of Medicine (IOM) of the NAS, but each of the notifications proposed slightly different claims and qualifying criteria. The 2007 proposed rule described FDA's intention to prohibit the DHA and EPA claims and certain of the ALA claims.

Impact of the Final Rule on Omega-3 Nutrient Content Claims

- **DHA and EPA claims.** All of the nutrient content claims for DHA and EPA in the submitted notifications would be prohibited because they were not based on an authoritative statement that identifies a nutrient level to which the claims refer.

  Several comments submitted in response to the proposed rule argued that the IOM statements serving as the basis for the claims permit a calculation of a value for DHA and EPA that can be considered a "nutrient level" and described FDA's position as unduly restrictive. FDA disagreed, explaining that it considers the term "nutrient level" to mean "a reference value that is similar to a label reference value for use in nutrition labeling, i.e., that reflects a recommended or defined

[1] The final rule is available here.

[2] For more information about these proposed rules, please see our client alert, available here.

intake level that could serve as a basis for setting a [daily value] that could be used to characterize a given level of a nutrient (here, DHA or EPA) for purposes of nutrition labeling."

- **ALA claims.** Today's rule will prohibit the ALA claims in one of the three notifications (the Three Seafood Companies Notification) because the claims are based on a daily value determined by a method different from the method FDA uses to establish daily values for nutrients. FDA currently bases label reference values on the "population-coverage" approach, under which the agency selects the highest reference value established according to age and gender. The ALA claim submitted by the Three Seafood Companies was based on a "population-weighted average" approach, whereby the submitters computed a population-weighted average of the age and gender-specific recommended average daily intake levels for ALA using 2005 projected U.S. census data. The ALA daily value in the Three Seafood Companies Notification thus represented a "central" value of the nutrient requirement of the base population, around which individual requirements vary.

  Several comments argued that the FDCA does not require FDA to use a specific approach (*e.g.*, population-coverage versus population-weighted), but the agency disagreed. According to FDA, the statute "requires that a claim based on an authoritative statement have a nutrient level identified in the statement and be stated in a manner that enables the public to comprehend the information provided and to understand the relative significance of such information in the context of the daily diet." The use of two different approaches, the agency contended, would "result in inconsistent and conflicting nutrient content claims on food labels." Under the final rule, FDA will prohibit ALA claims based on the population-weighted approach but, at least for the time being, will not take regulatory action with respect to ALA claims submitted in the Martek Notification, which were based on the population-coverage approach. The agency decided to take this compromise approach because "it may be some time before any rulemaking related to the [daily value advanced notice of proposed rulemaking] is finalized."

  The following ALA nutrient content claims will be allowed to remain on the market "at this time":

Nutrient Content Claim for ALA	**Conditions for Making the Claim[3]**
"High"	Greater than or equal to 320 mg of ALA per Reference Amount Customarily Consumed (RACC) (greater than or equal to 20% of 1.6 g/day)
"Good Source"	Greater than or equal to 160 mg of ALA per RACC (greater than or equal to 10% of 1.6 g/day)
"More"	Greater than or equal to 160 mg of ALA more per RACC than an appropriate reference food (greater than or equal to 10% of 1.6 g/day)

  Given the agency's qualifications to its position on permissible ALA nutrient content claims, this issue may be one that remains in flux over the longer term.

[3] These nutrient content claims must also comply with all applicable FDA regulations regarding the making of such claims.

Covington & Burling LLP is experienced in advising clients on matters related to the labeling of conventional foods and dietary supplements and is available to provide individualized compliance counseling concerning these issues. If you have any questions concerning the material discussed in this client alert, please contact the following members of our Food and Drug practice group:

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