

Articles

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Exactly How Much Omega-3 Is in There?

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On April 28, 2014, the Food and Drug Administration (FDA) issued a **Final Rule** prohibiting certain "nutrient content claims" for docosahexaenoic acid (DHA), eicosapentaenoic acid (EPA), and alpha-linolenic acid (ALA) omega-3 fatty acids. Although the nutrient content claims for DHA, EPA and the ALA based on the population-weighted approach were rejected, FDA stated that no regulatory action would be taken against nutrient content claims for ALA based on the population-coverage adequate-intake (AI) level.

It is uncertain whether these actions will protect the public health. Indeed, the complexities associated with developing reference values for nutrients based on Reference Daily Intakes (RDIs) or Daily Reference Values (DRVs) raise issues as to whether consumers understand the meaning of nutrient content claims such as "good source" or "high in." Moreover, it appears that First Amendment issues may be raised under this Final Rule considering commercial speech may have been unnecessarily limited merely because such nutrient content claims rely on more than one method of assessing a nutrient level.

Background

In 2004 and 2005, FDA received three separate notifications submitted under Section 403(r)(2)(G) of the Food and Drug Administration Modernization Act of 1997 (FDAMA) to permit nutrient content claims for DHA, EPA, and ALA. All three notifications were based on statements made in a September 2002 report by the Institute of Medicine (IOM). Although FDA did not object to these notifications within 120 days, in November 2007, a **Proposed Rule** on these claims was published. The Final Rule, which makes no substantive changes to the Proposed Rule, will take effect on January 1, 2016, with a transition period that is consistent with the next uniform compliance date for labeling regulations.

Prohibited Nutrient Content Claims for DHA, EPA, and ALA

EPA and DHA – Failure to Identify an Appropriate Nutrient Level:

With respect to DHA and EPA, FDA stated that the IOM report did not meet the statutory requirement for an authoritative statement for which a nutrient content claim may be made because it did not provide a "nutrient level" based on RDI or DRV. FDA further stated that because no nutrient level was identified, the nutrient content claim did not provide meaningful information to consumers.

ALA – Based on Population-Weighted Approach:

For ALA, the nutrient content claims based on a "population-weighted" AI level approach was rejected because existing references to food labeling nutrient levels are based on the population-coverage approach. When evaluating the two notifications for similar nutrient content claims for ALA, FDA concluded that the population-coverage AI level is consistent with existing reference values. In addition, FDA further stated that two different reference values for ALA would be misleading and lead to inconsistent and conflicting nutrient content claims on foods.

Permitted Nutrient Content Claims for ALA

Although not explicitly approved, FDA stated that it is taking no regulatory action at this time regarding the nutrient content claims for ALA based on the population-coverage AI level. The specific ALA nutrient content claims are provided in the table below.

Nutrient Content Claim for ALA	Conditions for Making Such a Claim
High...	≥ 320 mg of ALA per reference amount customarily consumed (RACC) (≥ 20% of 1.6 g/day)

Good Source...	≥ 160 mg of ALA per RACC (≥ 10% of 1.6 g/day)
More...	≥ 160 mg of ALA more per RACC than an appropriate reference food (≥ 10% of 1.6 g/day)

Going Forward

Foods and dietary supplement companies with products that include omega-3 fatty acid nutrient content claims should begin to assess compliance with the Final Rule. Notably, however, the Final Rule identifies certain types of claims for DHA, EPA and ALA that remain lawful, including (1) statements about the amount or percentage of a nutrient in a food (*i.e.*, "X mg of EPA and DHA omega-3 fatty acids per serving."); (2) structure/function claims concerning omega-3 fatty acids; and (3) qualified health claims about the relationship between EPA and DHA and the reduced risk for coronary heart disease.

If you have questions or concerns regarding this or other matters related to food and dietary supplement labeling, please contact the authors of this alert or any other attorneys from Venable's [FDA Group](#).