

## food industry lawflash

April 29, 2014

## FDA Rule Prohibits Certain Nutrient Content Claims for Omega-3 Fatty Acids

*The final rule prohibits label claims of food products, including dietary supplements, that are “high in,” “rich in,” or an “excellent source of” DHA or EPA and allows some nutrient content claims for ALA.*

On April 28, the U.S. Food and Drug Administration (FDA or the Agency) published a final rule (the Rule), prohibiting statements on labels of food products, including dietary supplements, that claim products are “high in,” “rich in,” or an “excellent source of” docosahexaenoic acid (DHA) or eicosapentaenoic acid (EPA) as well as some such claims for alpha-linolenic acid (ALA).<sup>1</sup> The Rule will affect hundreds of product categories, requiring costly labeling changes that must be made by January 1, 2016. Product inventory manufactured through December 31, 2015 will not be affected, assuming marketplace acceptance.

### Background

“Nutrient content claims” are labeling claims that characterize the level of a nutrient in a food. Under the Federal Food, Drug, and Cosmetic Act (FD&C Act), nutrient content claims, such as “high in,” are allowed only for nutrients for which a reference level for the claim has been set. FDA has not established nutrient levels that can serve as the basis for nutrient content claims for DHA, EPA, or ALA.

In 2004 and 2005, FDA received three notifications for nutrient content claims for DHA, EPA, and ALA, asserting that the Institute of Medicine of the National Academies (IOM) had issued authoritative statements that identified nutrient reference levels for DHA, EPA, and ALA on which nutrient content claims could be based. These notifications identified multiple, but, in some cases, conflicting, nutrient reference levels of DHA, EPA, and ALA. The Agency issued the Rule, in part, because FDA determined that IOM’s statements on DHA and EPA did not establish nutrient levels for those omega-3 fatty acids, and, thus, there is not a sufficient basis for making nutrient content claims. Accordingly, the Rule prohibits all DHA and EPA nutrient content claims. With regard to the two sets of nutrient content claims for ALA that were identified in the notifications, FDA determined that one of the sets of claims, which was based on a population-weighted approach to establish a reference amount customarily consumed (RACC) of ALA, did not meet the requirements of the FD&C Act. Therefore, FDA is only allowing ALA claims that are based on a population-coverage-derived RACC. The nutrient content claims are described in the below charts.

1. Food Labeling: Nutrient Content Claims; Alpha-Linolenic Acid, Eicosapentaenoic Acid, and Docosahexaenoic Acid Omega-3 Fatty Acids, 79 Fed. Reg. 23,262 (proposed Apr. 28, 2014), available at <http://www.gpo.gov/fdsys/pkg/FR-2014-04-28/pdf/2014-09492.pdf>.

## Permitted and Prohibited Nutrient Content Claims

Accordingly, the following charts summarize the status of permitted and prohibited nutrient content claims.

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)

Nutrient Content Claim for DHA/EPA	Conditions for Making Such a Claim
No Claims Allowed	N/A

## Hundreds of Product Categories Implicated

Comments submitted by interested parties regarding the Agency's analysis of the proposed rule's impact suggested that there are hundreds of product categories affected by the Rule. The broad-ranging product categories identified in the comments include, but are not limited to, the following:

- Seafood
- Pasta
- Eggs
- Fresh and shelf-stable milks
- Spoonable yogurts
- Yogurt drinks
- Fermented milk drinks
- Cheeses
- Butters
- Fat-based spreads
- Juices
- Juice smoothies
- Soy milks
- Packaged breads
- Meats from grass-fed animals
- Packaged meats
- Baby foods
- Chocolate confections
- Cooking oils
- Packaged soups
- Ice creams
- Nutritional bars
- Frozen pizzas

## Compliance Dates

The Rule will become effective on the next uniform compliance date for labeling regulations (i.e., January 1, 2016), and it will apply to food labeling regulations that FDA issues between January 1, 2013 and December 31, 2014. The Agency will **not** give small firms more time to comply with the Rule than other firms because FDA concluded it did not want inconsistent labeling on food products.

## Commercial Implications

Food manufacturers with products labeled with omega-3 fatty acid claims should begin reviewing their product labels and labeling, including websites and other marketing materials, to assess compliance with the Rule and should arrange for relabeling, if necessary. Retailers will need to work closely with suppliers and contract manufacturers to verify compliance and timelines for any necessary label changes. Products with DHA and/or EPA nutrient content claims in the distribution chain before January 1, 2016 may be sold with the old labels, but

FDA encourages manufacturers to use up their labeling inventory between now and the compliance date.

## Contacts

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