

Contains Nonbinding Recommendations

Food Labeling: Nutrient Content Claims; Alpha-Linolenic Acid, Eicosapentaenoic Acid, and Docosahexaenoic Acid Omega-3 Fatty Acids; Guidance for Industry Small Entity Compliance Guide

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Food Labeling: Nutrient Content Claims; Alpha-Linolenic Acid, Eicosapentaenoic Acid, and Docosahexaenoic Acid Omega-3 Fatty Acids; Guidance for Industry¹ Small Entity Compliance Guide

This guidance represents the current thinking of the Food and Drug Administration's (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. Introduction

In the Federal Register of April 28, 2014 (79 FR 23262), the Food and Drug Administration (FDA or we) issued a final rule entitled “Food Labeling: Nutrient Content Claims; Alpha-Linolenic Acid, Eicosapentaenoic Acid, and Docosahexaenoic Acid Omega-3 Fatty Acids” (“the rule”). The rule prohibits certain nutrient content claims for foods, including conventional foods and dietary supplements, that contain omega-3 fatty acids based on our determination that such nutrient content claims do not meet the requirements of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

We issued the rule in response to three notifications submitted to us. One notification concerning nutrient content claims for Alpha-Linolenic Acid (ALA), Docosahexaenoic Acid (DHA), and Eicosapentaenoic Acid (EPA) was submitted collectively by Alaska General Seafoods, Ocean Beauty Seafoods, Inc., and Trans-Ocean Products, Inc. (the seafood processors notification); a second notification concerning nutrient content claims for ALA, DHA, and EPA was submitted by Martek Biosciences Corp. (the Martek notification); and a third notification concerning nutrient content claims for DHA and EPA was submitted by Ocean Nutrition Canada, Ltd. (the Ocean Nutrition notification). The rule prohibits the nutrient content claims for DHA and EPA set forth in the three notifications and the nutrient content claims for ALA set forth in the seafood processors notification. We did not take regulatory action with respect to the nutrient content claims for ALA set forth in the Martek notification and, therefore, these claims will be allowed to remain on the market (79 FR 23262).

This rule is effective January 1, 2016.

¹ This guidance has been prepared by the Office of Nutrition and Food Labeling in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

We have prepared this Small Entity Compliance Guide in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Public Law 104-121, as amended by Public Law 110-28). This guidance document restates in plain language the legal requirements set forth in the rule, and is intended to assist small entities in complying with the rule (21 CFR 101.8). The rule is binding and has the full force and effect of law.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe our current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in our guidances means that something is suggested or recommended, but not required.

In the remainder of this guidance, "you" refers to individuals and entities making nutrient content claims that are subject to the rule.

II. Who is Subject to the Rule?

You may be subject to the rule if you make a nutrient content claim for DHA and EPA, and certain nutrient content claims for ALA.

A. What are "Nutrient Content Claims?"

"Nutrient content claims" are labeling claims that characterize the level of a nutrient in a food (see section 403(r)(1)(A) of the FD&C Act).

B. Where are Nutrient Content Claims subject to this rule defined?

The nutrient content claims subject to this rule are defined in § 101.54. "High" is defined as 20 percent or more of the Reference Daily Intake (RDI) or the Daily Reference Value (DRV) per reference amount customarily consumed (RACC) (§ 101.54(b)). "Good source" is defined as 10 to 19 percent of the RDI or DRV per RACC (§ 101.54(c)). "More" is defined as at least 10 percent more of the RDI or DRV per RACC than an appropriate reference food (§ 101.54(e)). Synonyms for each of these terms also are set forth in our regulations; for example, the terms "rich in" and "excellent source of" are considered to be equivalent to the term "high" (§ 101.54(b)) (79 FR 23262 at 23263, footnote 1).

C. Which Statute Established a Notification Process for Nutrition Content Claims?

The Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. 105-115) amended the FD&C Act to provide, among other things, for the filing of notifications as an alternative to the petition process for nutrient content claims set forth in section 403(r)(4) of the FD&C Act (21 U.S.C. 343(r)(4)) (see section 403(r)(2)(G) of the FD&C Act (21 U.S.C. 343(r)(2)(G))).

D. What are the Requirements for Submitting a Notification for a Prospective Nutrient Content Claim?

Section 403(r)(2)(G) of the FD&C Act requires that a notification for a prospective nutrient content claim be submitted to FDA at least 120 days before a food bearing the claim may be introduced into interstate commerce. The notification must contain specific information including: (1) The exact wording of the prospective nutrient content claim, (2) a concise description of the basis upon which the notifier relied for determining that the requirements for an authoritative statement in section 403(r)(2)(G)(i) of the FD&C Act have been satisfied, (3) a copy of the authoritative statement that serves as the basis for the claim, and (4) a balanced representation of the scientific literature relating to the nutrient level for the claim. The claim must be an accurate representation of the authoritative statement and must be stated in a manner that enables the public to comprehend the information provided by the claim and to understand the relative significance of such information in the context of the total daily diet. Furthermore, the authoritative statement that is the basis for the nutrient content claim must be currently in effect and identify the nutrient level to which the claim refers (section 403(r)(2)(G) of the FD&C Act).

E. Who can provide an authoritative statement that identifies the nutrient level to which the Nutrient Content Claim refers?

According to section 403(r)(2)(G)(i) of the FD&C Act, an authoritative statement that identifies the nutrient level to which the claim refers can be provided by a scientific body of the U.S. Government with official responsibility for public health protection or research directly relating to human nutrition, or by the National Academy of Sciences or any of its subdivisions, such as the Institute of Medicine.

III. What Types of Nutrient Content Claims are Prohibited by the Rule?

The rule prohibits the nutrient content claims for DHA and EPA set forth in the seafood processors, Martek, and Ocean Nutrition notifications (the three notifications) and nutrient content claims for ALA based on a population-weighted approach set forth in the seafood processors notification.

In brief, the seafood processors notification set forth "high" nutrient content claims for both DHA and EPA, whereas the Martek notification set forth a "high" nutrient content claim only for DHA and the Ocean Nutrition notification set forth a "high" nutrient content claim for DHA and EPA combined. In addition, the seafood processors notification set forth "high," "good source," and "more" claims for ALA (79 FR 23262 at 23263).

The prohibited nutrient content claims are as follows:

- The seafood processors notification specified that one of the following two statements would accompany “high” nutrient content claims for DHA or EPA:
 - “Contains _ mg of [DHA/EPA] per serving, which is _ % of the Daily Value for [DHA/EPA] (130 mg).”
 - “Contains _ % of the Daily Value for [DHA/EPA] per serving. The Daily Value for [DHA/EPA] is 130 mg.” As indicated in the notification, use of [DHA/EPA] is intended to mean that either EPA or DHA would be used as the subject of the claim.
- The Martek notification proposed the following exact wording for “high” nutrient content claims for DHA:
 - “ ‘Excellent source of DHA.’ (‘High in DHA,’ ‘Rich in DHA’) Contains _ mg of DHA per serving, which is _ % of the 160 mg Daily Value for DHA.” [Products would need to contain at least 32 mg of DHA per RACC to qualify for the claim.]
- The Ocean Nutrition notification proposed the following exact words for “high” nutrient content claims for DHA and EPA combined:
 - “ ‘Excellent source of Omega-3 EPA and DHA.’ (‘High in Omega-3 EPA and DHA;’ ‘Rich in Omega-3 EPA and DHA’). Contains _ mg of EPA and DHA combined per serving, which is _ % of the 160 mg Daily Value for a combination of EPA and DHA.”
- The seafood processors notification specified that one of the following two statements would accompany “high” and “good source” claims for ALA:
 - “Contains _ mg of ALA per serving, which is _ % of the Daily Value for ALA (1.3 g).”
 - “Contains _ % of the Daily Value for ALA per serving. The Daily Value for ALA is 1.3 g.”

A. Why Are the Nutrient Content Claims for DHA and EPA Prohibited by the Rule?

We are prohibiting the nutrient content claims for DHA and EPA set forth in the three notifications because they are not based on an authoritative statement that identifies a nutrient level to which the claims refer, as required by the FD&C Act.

The notifications referenced statements from the report entitled “Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein and Amino Acids” from the Institute of Medicine (IOM) of the National Academy of Sciences. We found that the IOM statements do not reflect a recommended or defined intake level of DHA and/or EPA that could serve as a basis for setting a Daily Value (DV) that could be used to characterize a given level of DHA and/or EPA (79 FR 23262 at 23265).

B. Why Are Nutrient Content Claims for ALA Based on a Population-Weighted Approach Prohibited By the Rule?

We are prohibiting the nutrient claims for ALA set forth in the seafood processors notification because the claims were based on a reference value that was determined by a different approach than reference values already established for other nutrients (i.e., DVs). The FD&C Act 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 (section 403(r)(2)(G)(iv) of the FD&C Act). There were two different approaches to set a reference value in the notifications for ALA (i.e., the population-weighted approach² used in the seafood processors notification and the population-coverage approach³ used in the Martek notification). We determined that using two different approaches to set a reference value for ALA would result in inconsistent and conflicting nutrient content claims on food labels. Such inconsistencies make meaningful product-to-product comparisons impossible. To enable the public to comprehend the information provided in nutrient content claims and to understand the relative significance of that information in the context of the daily diet, as required by section 403(4)(2)(G)(iv) of the FD&C Act, qualifying ALA levels for nutrient content claims in food labeling must be based on a single nutrient value determined using the same approach for reference values for other nutrients, which is currently the population-coverage approach established in the 1993 final rule for determining DVs (58 FR 2206, January 6, 1993). Therefore, to prevent inconsistent and conflicting claims on food labels, we are not taking regulatory action with respect to ALA claims based on the population-coverage approach, but are prohibiting claims based on the population-weighted approach.

C. Which Nutrient Content Claims for ALA Are Allowed to Remain on the Market?

The rule explained that FDA is taking no regulatory action with respect to the nutrient content claims for ALA based on the population-coverage approach set forth in the Martek notification.⁴

² This approach looked at the various adequate intake levels (AIs) that the IOM identified for different age and gender groups (excluding children under 4 years of age and pregnant and lactating women) and averaged out all of those numbers taking into account the predominance of the various groups within the population, to arrive at their label reference value (79 FR 23262 at 23263).

³ This approach used the highest Recommended Daily Allowance (RDA) or AI for adults and children 4 or more years of age (excluding values for pregnant and lactating women) to serve as the label reference value (79 FR 23262 at 23263).

⁴ The Martek notification proposed “high,” “good source,” and “more” claims for ALA. The notification proposed the following exact words for these claims:

“ ‘Excellent source of ALA.’ (‘High in ALA,’ ‘Rich in ALA’) Contains 1 mg of ALA per serving, which is 1 % of the 1.6 g Daily Value for ALA.’ [Products would need to contain at least 320 mg of ALA per RACC to qualify for the claim.]

“ ‘Good source of ALA.’ (‘Contains ALA,’ ‘Provides ALA’) Contains 1 mg of ALA per serving, which is 1 % of the 1.6 g Daily Value for ALA.’ [Products would need to contain at least 160 mg of ALA per RACC to qualify for the claim.]

Therefore, those claims will be allowed to remain on the market (see Table 1)(79 FR 23262 at 23269).

Table 1 – Nutrient Claims

Nutrient Content Claim for ALA	Conditions for Making the Claim⁵
High	≥ 320 mg of ALA per 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)

IV. When Did the Rule Become Effective?

The rule became effective January 1, 2016.

“ ‘More ALA.’ (‘Fortified with ALA,’ ‘Enriched with ALA,’ ‘Added ALA,’ ‘Extra ALA,’ ‘Plus ALA’) Contains 1 % more of the Daily Value for ALA per serving than [reference food]. This product contains 1 mg of ALA which is 1 % of the Daily Value for ALA (1.6 g).” [Products would need to contain at least 160 mg or more ALA per RACC than an appropriate reference food and would comply with the requirements for relative claims found at § 101.13(j).]

⁵ Nutrient content claims must comply with all applicable FDA regulations regarding the making of such claims (79 FR 23262 at 23269).