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FDA Allows Third Nutrient Content Claim Notification for Specific Omega-3 Fatty Acids Under FDAMA Authoritative Statement Procedure

Between 2004 and 2006, companies filed three notifications with FDA regarding nutrient content claims for the omega-3 fatty acids docosahexaenoic acid (DHA), eicosapentaenoic acid (EPA) and alpha-linolenic acid (ALA) in the labeling of conventional foods and dietary supplements.¹ These claims are based upon authoritative statements by the Institute of Medicine (IOM) of the National Academy of Sciences (NAS), and have been allowed under the notification provision established by the FDA Modernization Act of 1997 (FDAMA). The claims are now available for any product meeting the criteria set forth in the notifications, as described below.

I. Basis for Notifications

FDAMA amended the Federal Food, Drug, and Cosmetic Act (FDCA) to allow manufacturers and distributors to use health claims or nutrient content claims in food and dietary supplement labeling if such claims are based on current, published, authoritative statements from certain federal scientific bodies, as well as from the NAS. Before such claims may be used in labeling, a notification must be submitted to FDA demonstrating that the statement upon which the claims rely is an authoritative statement meeting the criteria set forth in the FDAMA amendments. If FDA does not object to the notification within 120 days, the claims are deemed authorized. The submitter and any other manufacturer or distributor may then use the claims in accordance with the criteria set forth in the notification. FDA can subsequently overturn the claim, but must issue a regulation or obtain a court order to do so.

While all three notifications were based upon authoritative statements made by the IOM in its September 5, 2002 report, *Dietary Reference Intakes: Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein and Amino Acids* (IOM Macronutrients Report), each proposed slightly different claims and qualifying criteria, which are summarized below.

II. ALA

Both the Three Seafood Companies Notification and the Martek Notification addressed ALA claims, delineating criteria for “Good source,” “Excellent source,” and “More” claims.² For ALA, the claims criteria under the Three Seafood Companies Notification are more lenient.

¹ The first notification was submitted on January 16, 2004, by Alaska General Seafoods, Ocean Beauty Seafoods, Inc., and Trans-Ocean Products, Inc. (Three Seafood Companies Notification). The second was submitted on January 21, 2005, by Martek Biosciences Corporation (Martek Notification). The third was submitted on December 9, 2005 by Ocean Nutrition Canada, Ltd. (Ocean Nutrition Notification).

² Under all three Notifications, established synonyms for “good source,” “excellent source,” and “more” may be used.

A. Three Seafood Companies Notification³

The Three Seafood Companies Notification was based on a population-weighted average adequate intake (AI) level for ALA of 1.3 g/day, and established the following claim criteria:

- Good source is between 130 and 260 mg ALA per RACC;
- Excellent source is 260 mg or more ALA per RACC; and
- More is at least 130 mg more ALA per RACC than the reference food.

All claims must state “omega-3” before or after “ALA”, or in parentheses, such as “(an omega-3)”. Good source and excellent source claims must be accompanied by one of the following statements:

“Contains [x] mg of ALA per serving, which is [x]% of the Daily Value for ALA (1.3 g).”

or

“Contains [x]% of the Daily Value for ALA per serving. The Daily Value for ALA is 1.3g.”

“More” claims must be accompanied by:

“[x]% (10% or greater) more of the Daily Value of ALA per serving than [reference food]. This product contains [x] mg ALA omega-3 per serving, which is [x]% of the Daily Value for ALA omega-3 (1.3 g). [Reference food] contains [x] mg ALA omega-3 per serving.”

B. Martek Notification

The Martek Notification was based on an AI for ALA of 1.6 g/day, which is the AI for adult males set forth in the IOM Macronutrients Report. The Martek Notification established the following claim criteria:

- Good source is between 160 and 320 mg ALA per RACC;
- Excellent source is 320 mg or more ALA per RACC; and
- More is at least 160 mg more ALA per RACC higher than the reference food.

It is not necessary to use the term “omega-3” in these claims. Good source and excellent source claims must be accompanied by one of the following statements:

“Contains [x] mg of ALA per serving, which is [x] % of the 1.6g Daily Value for ALA.”

“More” claims must be accompanied by:

“Contains [x] % more of the Daily Value of ALA per serving than [reference food]. This product contains [x] mg ALA, which is [x] % of the Daily Value for ALA (1.6 g).”

³ The Three Seafood Companies Notification was described in detail in Covington & Burling LLP’s July 28, 2004 client alert.

III. DHA

Both the Three Seafood Companies Notification and the Martek Notification addressed DHA, and both established only “excellent source” claims for this nutrient. For DHA, the claims criteria under the Martek Notification are more lenient.

A. Three Seafood Companies Notification

The Three Seafood Companies Notification relied upon an AI for DHA of 130g/day, and required products to contain at least 130 mg DHA per RACC – the entire AI for DHA – in order to bear “excellent source of DHA” claims. This approach differs from FDA regulatory requirements for excellent source claims generally, which permit such claims to be made on products containing 20% of the Daily Value (DV), per RACC, of the nutrient for which the claim is made.

All claims must contain “omega-3” before or after DHA, or in parentheses, such as “(an omega-3)”. The claims must be accompanied by one of the following statements:

“Contains [x] mg of DHA per serving, which is [x]% of the Daily Value for DHA (130 mg).”

or

“Contains [x]% of the Daily Value for DHA per serving. The Daily Value for DHA is 130 mg.”

B. Martek Notification

The Martek Notification established a qualifying level for “excellent source of DHA” of at least 32 mg DHA per RACC. This is based on 20% of a 160 mg/d DHA AI, and therefore follows the traditional FDA regulatory requirement for “excellent source” claims.

All claims must contain “omega-3” before or after DHA, or in parentheses, such as “(an omega-3)”. Excellent source claims must be accompanied by the following statement:

“Contains [x] mg of DHA per serving, which is [x] % of the 160 mg Daily Value for DHA.”

IV. EPA

Only the Three Seafood Companies Notification addressed claims for EPA alone, and established criteria for only “excellent source of EPA” claims. As with DHA claims under this Notification, “excellent source of EPA” claims are based upon an AI for EPA of 130g/day, and products must contain at least 130 mg EPA per RACC – the entire AI for EPA – in order to bear these claims.

All claims must contain “omega-3” before or after EPA, or in parentheses, such as “(an omega-3)”. The claims must be accompanied by one of the following statements:

“Contains [x] mg of EPA per serving, which is [x]% of the Daily Value for EPA (130 mg).”

or

“Contains [x]% of the Daily Value for EPA per serving. The Daily Value for EPA is 130 mg.”

V. DHA and EPA in Combination

Only the Ocean Nutrition Canada Notification addressed claims for DHA and EPA in combination⁴. That Notification established only excellent source claims for this combination, with a qualifying level of at least 32 mg EPA and DHA combined per RACC.

All claims must contain “omega-3” before EPA and DHA. Excellent source claims, such as, “Excellent source of Omega 3 EPA and DHA,” must be accompanied by the following statement:

“Contains [x] mg of EPA and DHA combined per serving, which is [x] % of the 160 mg Daily Value for a combination of EPA and DHA.”

* * *

General criteria for nutrient content claims must also be satisfied when using any of the foregoing claims. Covington & Burling LLP is happy to provide counsel on the use of these nutrient content claims for specific omega-3 fatty acids.

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This information is not intended as legal advice, which may often turn on specific facts. Readers should seek specific legal advice before acting with regard to the subjects mentioned herein.

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⁴ Under the Three Seafood Companies Notification, where a product contains enough DHA and EPA to make individual “excellent source” claims for each nutrient, it appears plausible to combine the claims into one statement. That is, where the product contains 130 mg DHA and 130 mg EPA, it seems possible to make claims such as “High in DHA and EPA omega-3s” and “Contains [x]% of the Daily Value for DHA and [x]% of the Daily Value for EPA per serving. The Daily Value for DHA and EPA is 130 mg each.”