(ii) Accrued profits on such position held at the futures commission merchant.

(2) [Reserved]

3. Section 150.3 is amended by revising paragraph (a) introductory text, adding a new paragraph (a)(2), and adding a new paragraph (c) to read as follows:

§ 150.3 Exemptions.

(a) *Positions which may exceed limits.* The position limits set forth in § 150.2 of this part may be exceeded to the extent such positions are established and liquidated in an orderly manner and are:

* * * * *

(2) Risk management positions, as defined in § 150.1(j), that fulfill the following requirements:

(i) Such risk management positions must comply with the following conditions:

(A) The positions must be passively managed;

(B) The positions must be unleveraged; and

(C) The positions must not be carried into the spot month.

(ii) Entities intending to hold risk management positions pursuant to the exemption in § 150.3(a)(2) must apply to the Commission and receive Commission approval. Such applications must include the following information:

(A) In the case of an exemption based on a fiduciary obligation, as described in § 150.1(j)(1), an application must include:

(*1*) A description of the underlying index or group of commodities, including the commodities, the weightings, the method and timing of re-weightings, the selection of futures months, and the timing and criteria for rolling from one futures month to another;

(*2*) A description of the ''fiduciary obligation;''

(*3*) The actual or anticipated value of the underlying funds to be invested in commodities within the next fiscal or calendar year and the method for calculating that value, as well as the equivalent numbers of futures contracts in each of the § 150.2 markets for which the exemption is sought;

(*4*) A description of the manner in which the funds to be invested in commodities will be set aside;

(*5*) A statement certifying that the requirements of this exemption are met and will be observed at all times going forward and that the Commission will be notified promptly of any material changes in this information; and

(*6*) Such other information as the Commission may request.

(B) In the case of an exemption based on a portfolio diversification plan, as described in § 150.1(j)(2), an application must include:

(*1*) A description of the investment index or group of commodities, including the commodities, the weightings, the method and timing of re-weightings, the selection of futures months, and the timing and criteria for rolling from one futures month to another;

(*2*) A description of the entire portfolio, including the total size of the assets, the asset classes making up the portfolio, and a description of the allocation among the asset classes;

(*3*) The actual or anticipated value of the underlying funds to be invested in commodities and the method for calculating that value, as well as the equivalent numbers of futures contracts in each of the § 150.2 markets for which the exemption is sought;

(*4*) A description of the manner in which the funds to be invested in commodities will be set aside;

(*5*) A statement certifying that the requirements of this exemption are met and will be observed at all times going forward and that the Commission will be notified promptly of any material changes in this information; and

(*6*) Such other information as the Commission may request.

(iii) Whenever the purchases or sales that a person wishes to qualify under this risk management exemption shall exceed the amount provided in the person's most recent filing pursuant to this section, or the amount previously specified by the Commission pursuant to this section, such person shall file with the Commission a statement that updates the information provided in the person's most recent filing and provides the reasons for this change. Such statement shall be filed at least ten business days in advance of the date that such person wishes to exceed those amounts and if the notice filer is not notified otherwise by the Commission within the 10-day period, the exemption will continue to be effective. The Commission may, upon call, obtain such additional materials from the applicant or person availing themselves of this exemption as the Commission deems necessary to exercise due diligence with respect to granting and monitoring this exemption.

(iv) Entities holding risk management positions pursuant to the exemption in § 150.3(a)(2) shall immediately report to the Commission in the event that they know, or have reason to know, that any person holds a greater than 25% interest in such position.

* * * * *

(c) The Commission hereby delegates, until such time as the Commission orders otherwise, to the Director of the Division of Market Oversight, or the Director's designee, the functions reserved to the Commission in § 150.3(a)(2) of this chapter.

Issued by the Commission this 20th day of November, 2007, in Washington, DC.

David Stawick,

Secretary of the Commission.

[FR Doc. E7–22992 Filed 11–26–07; 8:45 am]

BILLING CODE 6351–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket Nos. 2004N–0217, 2005P–0189, and 2006P–0137]

RIN No. 0910–ZA28

Food Labeling: Nutrient Content Claims; Alpha-Linolenic Acid, Eicosapentaenoic Acid, and Docosahexaenoic Acid Omega-3 Fatty Acids

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) proposes to issue this rule finding that certain nutrient content claims for foods, including conventional foods and dietary supplements, that contain omega-3 fatty acids, do not meet the requirements of the Federal Food, Drug, and Cosmetic Act (the act) and may not appear in food labeling. This rule is being proposed in response to three notifications submitted to FDA under the act. 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).

FDA has reviewed the information included in the three notifications and is proposing to prohibit 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 controlling statutory authority. FDA is also proposing to prohibit the nutrient content claims for ALA set forth in the seafood processors notification because they are based on a daily value that was determined by a different method than daily values already established for other nutrients. Because of the different methodology used to set the daily value, the ALA claims set forth in the seafood processors notification do not enable the public to comprehend the information provided in the claims and to understand the relative significance of such information in the context of the daily diet, as required by the controlling statutory authority. FDA is proposing to take no regulatory action with respect to the nutrient content claims for ALA set forth in the Martek notification. Therefore, if this proposed rule is finalized without change, these claims will be allowed to remain on the market.

DATES: Submit written or electronic comments by February 11, 2008.

ADDRESSES: You may submit comments, identified by Docket Nos. 2004N–0217, 2005P–0189, and 2006P–0137 by any of the following methods:

Electronic Submissions

Submit electronic comments in the following ways:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- Agency Web site: *http://www.fda.gov/dockets/ecomments*. Follow the instructions for submitting comments on the agency Web site.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301–827–6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD–ROM submissions]: Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal or the agency Web site, as described in the *Electronic Submissions* portion of this paragraph.

Instructions: All submissions received must include the agency name and Docket No(s). and Regulatory Information Number (RIN) (if a RIN number has been assigned) for this rulemaking. All comments received may be posted without change to *http://www.fda.gov/ohrms/dockets/default.htm*, including any personal information provided. For additional information on submitting comments, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.fda.gov/ohrms/dockets/default.htm* and insert the docket number(s), found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Vincent de Jesus, Center for Food Safety and Applied Nutrition (HFS–830), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 301–436–1450.

SUPPLEMENTARY INFORMATION:

I. Background

A. Section 403(r) of the Act

On November 8, 1990, President George H.W. Bush signed into law the Nutrition Labeling and Education Act of 1990 (the 1990 amendments) (Public Law 101–535), which amended the act. Section 403(r)(1)(A) of the act (21 U.S.C. 343(r)(1)(A)), which was added by the 1990 amendments, states that a food for human consumption is misbranded if a claim is made in its label or labeling that expressly or implicitly characterizes the level of any nutrient of the type required to be declared in nutrition labeling, unless such claim uses terms defined in regulations by FDA under section 403(r)(2)(A) of the act.[1]

In 1993, FDA established regulations that implemented the 1990 amendments (58 FR 2066 to 2941, January 6, 1993). Among these regulations, § 101.13 (21 CFR 101.13) sets forth general principles for nutrient content claims (see 58 FR 2302, January 6, 1993). Other sections in part 101, subpart D (21 CFR part 101, subpart D), define specific nutrient content claims, such as ''high,'' ''good source,'' and ''more,'' and provide that claims such as these must be made in relation to reference values set out in regulations by FDA. For example, to bear the claim ''high in fiber'' in its label or labeling, a food must contain 20 percent or more of the reference value for fiber set out in 21 CFR 101.9(c)(9). Other provisions set forth the procedures whereby a person who wishes to make a nutrient content claim not already defined by regulation may petition the agency to authorize that claim under section 403(r)(4) of the act (see 21 CFR 101.69). A petitioner bears the burden of establishing the scientific basis for a proposed nutrient content claim.

On November 21, 1997, President William J. Clinton signed the Food and Drug Administration Modernization Act (FDAMA) into law (Public Law 105–115), which, among other things, added new sections (r)(2)(G) and (r)(2)(H) to the act. These sections provide for the filing of notifications as an alternative to the petition process in section 403(r)(4) of the act. Under the notification process, the scientific basis for a nutrient content claim or health claim is established through reliance on an authoritative statement.

Section 403(r)(2)(G) of the act requires that a notification of the 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 the following: (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) 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 a prospective nutrient content claim. An authoritative statement must have been published by a scientific body of the U.S. Government that has official responsibility for public health protection or research directly relating to human nutrition or the National Academy of Sciences (NAS) or any of its subdivisions. In addition, an authoritative statement must identify the nutrient level to which the claim refers and must be currently in effect. Thus, the requirements of 403(r)(2)(G) of the act are not met by a statement that does not identify the nutrient level to which the claim refers.

FDA considers the term ''nutrient level'' as used in section 403(r)(2)(G) of the act to mean a reference value that is similar to a label reference value for use in nutrition labeling. To date, FDA has established by regulation two sets of label reference values: Reference Daily Intakes (RDIs) and Daily Reference Values (DRVs) (see 21 CFR

[1]The requirements in section 403(r)(2) of the act for nutrient content claims, apply to foods and food labeling unless an exemption applies for the food or the claim under section 403(r)(2) of the act, another section of the act, or FDA regulations.

101.9(c)(8)(iv) and 101.9(c)(9), respectively). FDA based its RDIs on Recommended Daily Allowances (RDAs) and Estimated Safe and Adequate Daily Dietary Intakes (ESADDIs) established by NAS. FDA based its DRVs on recommendations in the NAS Diet and Health Report, the Surgeon General's Report on Nutrition and Health, and the 1990 Dietary Guidelines for Americans. FDA uses RDIs and DRVs as Daily Values (DVs) for purposes of nutrition labeling. Thus, FDA considers DVs to be a specific set of reference values established by regulation (58 FR 2079 at 2125, January 6, 1993).

A DV for a particular nutrient is used to calculate the percent DV that a serving of food provides for that nutrient, based on the assumption of a 2,000 calorie per day diet. The percent DV is listed in the Nutrition Facts and Supplement Facts boxes in nutrition labeling and provides consumers with an overall reference value for the nutrient. DVs are intended to help consumers understand the relative significance of information about the amount of certain nutrients in a food in the context of a total daily diet, and to help consumers compare the nutritional values of food products.

In the preamble to one of its regulations implementing the 1990 amendments (1990 preamble), FDA drew a distinction between the term ''Daily Value,'' or ''DV,'' used as a proper noun, and the term ''daily value,'' used in a more generic sense. As noted above, DVs are established by regulation. By contrast, ''daily values'' are alternate values that are not established by regulation, such as those based on alternate daily caloric requirements (i.e., 2,500 calories per day) (58 FR 2079 at 2125, January 6, 1993). Notwithstanding this distinction between ''Daily Values'' or ''DVs'' and ''daily values,'' FDA and industry have occasionally used the term ''Daily Value'' or ''DV'' to refer to alternate values that are not established by regulation, such as the quantity of a nutrient that has been proposed for use in nutrition labeling, or that is the basis for the use of a claim with respect to which FDA has taken no regulatory action under section 403(r)(2)(H) of the act (21 U.S.C. 343(r)(2)(H)).[2]

FDA intends to maintain the distinction between ''Daily Values'' or ''DVs'' and ''daily values'' that it articulated in its 1990 preamble. FDA has not established by regulation any DV for ALA, DHA, or EPA. Therefore, this proposal uses the term ''daily value'' when referring to the quantity of ALA, DHA, and EPA on which the nutrient content claims at issue are based, unless the proposal is quoting a claim submitted by one of the notifiers.

Under section 403(r)(2)(H) of the act, a nutrient content claim authorized under section 403(r)(2)(G) may be made beginning 120 days after submission of the notification until the following occurs: (1) FDA issues an effective regulation that prohibits or modifies the claim; (2) the agency issues a regulation finding that the requirements under section 403(r)(2)(G) have not been met; or (3) a district court of the United States in an enforcement proceeding under chapter III of the act has determined that the requirements under section 403(r)(2)(G) have not been met.

B. The IOM Final Report

In 2005, the Food and Nutrition Board of the Institute of Medicine (IOM) of the National Academy of Sciences published a report titled ''Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids'' (IOM Final Report, Ref. 1). The report is one in a series that presents a comprehensive set of reference values for nutrient intakes for healthy U.S. and Canadian individuals and populations. Publication of the IOM Final Report was preceded by release in 2002 of a prepublication copy under the same title (IOM Prepublication Report, Ref. 2).

In relevant part, the IOM Final Report establishes Dietary Reference Intakes (DRIs) for a number of nutrients that are essential[3] in the human diet (e.g., linoleic acid) or provide a beneficial role in human health (e.g., total fiber). According to the IOM Final Report, DRIs ''comprise a set of reference values for specific nutrients, each category of which has special uses.'' These reference values ''include the Estimated Average Requirement (EAR), Recommended Daily Allowance (RDA), AI, and Tolerable Upper Intake Level (UL).''[4]

An RDA is an estimate of the minimum daily average dietary intake level that meets the nutrient requirements of nearly all (97 to 98 percent) healthy individuals in a particular life stage and gender group. The setting of an RDA is contingent on there being sufficient scientific evidence to establish an EAR, which is the average daily nutrient intake level estimated to meet the requirement of half the healthy individuals in a particular life stage and gender group.

If there is insufficient scientific evidence to establish an EAR, then an AI is established instead of an RDA (assuming there is sufficient data to support establishment of an AI). An AI is the recommended average daily intake level that is assumed to be adequate based on observed or experimentally determined approximations or estimates of nutrient intake by a group (or groups) of apparently healthy people.

Among other nutrients, the IOM Final Report addresses omega-3 fatty acids, including ALA, EPA, and DHA. These fatty acids are also called *n*-3 fatty acids because the first double bond is located at the third carbon from the methyl end of the molecule (Ref. 4). For ALA, the IOM Final Report does not establish a DRI in the form of an RDA because there is insufficient scientific evidence to establish an EAR. As noted, if there is insufficient scientific evidence to establish an EAR, then no RDA is established. Instead, the IOM Final Report establishes AIs for different life stage groups (e.g., girls ages 9 through 13, boys ages 14 through 18). Those AIs are based on median intakes in the United States, where an omega-3 fatty acid deficiency is nonexistent in healthy individuals. The IOM Final Report does not establish a DRI in any form for either EPA or DHA.

II. The Three Notifications Submitted to FDA

A. The Seafood Processors Notification

On January 16, 2004, FDA received a nutrient content claim notification for foods, including conventional foods and dietary supplements, containing ALA, EPA, and DHA omega-3 fatty acids submitted jointly in the seafood processors notification under section 403(r)(2)(G) of the act (Ref. 5). The notification stated that the nutrient content claims it proposed were based upon authoritative statements made in the IOM Prepublication Report (Ref. 2). As of May 16, 2004, it has been permissible to make the nutrient content claims set forth in the notification.

[2] See, e.g., FDA's statement titled ''Nutrient Content Claims Notification for Choline Containing Foods,'' August 30, 2001, and also the notifications addressed by this rulemaking.

[3] The criteria for essentiality of a nutrient are that absence of the nutrient from the diet results in characteristic signs of a deficiency disease and these signs are prevented only by the nutrient itself or a specific precursor of it. (Ref. 3 Carpenter and Harper, Modern Nutrition in Health and Disease).

[4] The IOM Final Report also establishes Acceptable Macronutrient Distribution Ranges (AMDRs) for some nutrients. AMDRs are ranges of macronutrient intakes that are associated with reduced risk of chronic disease, while providing recommended intakes of other essential nutrients. AMDRs are not considered to be a type of DRI.

The notification proposed ''high,'' ''good source,'' and ''more'' claims for ALA, and ''high'' claims for DHA and EPA. With respect to specific authoritative statements that identify a nutrient level for ALA, the seafood processors notification referenced the following age-gender group specific AIs identified in the IOM Prepublication Report: 0.9 grams/day (g/day) for males and females age 4 to 8 years; 1.2 g/day for males age 9 to 13 years; 1.0 g/day for females age 9 to 13 years; 1.6 g/day for males 14 and more years of age; and 1.1 g/day for females 14 and more years of age. Also, the notification quoted the following as authoritative statements that identify a nutrient level for ALA, EPA, and DHA: ''Because of a lack of evidence for determining the requirement for *n*-3 fatty acids, an AI [for ALA] is set based on the highest median intake of [ALA] by adults in the United States where a deficiency is basically nonexistent in free-living populations * * * and rounding. Small amounts of EPA and DHA can contribute towards reversing an *n*-3 fatty acid deficiency * * * EPA and DHA can contribute up to 10 percent of the total *n*-3 fatty acid intake and therefore up to this percent can contribute toward the AI for [ALA] * * *'' (Ref. 2, p. 8 to 38).

In calculating a qualifying level for the basis of the ''high,'' ''good source,'' and ''more'' claims for ALA, the seafood processors notification set 1.3 g as a daily value for ALA and applied the specific percentages of this value as qualifying levels for the three ALA nutrient content claims as outlined in 21 CFR 101.54.[5] The value of 1.3 g was a result of computing a population-weighted average of age and gender-specific AIs for ALA, using 2005 projected U.S. census data. The notification acknowledged that there is currently in effect a nutrient content claim for choline that is based on the highest age and gender-specific AI for that nutrient (Refs. 6 and 7). Nonetheless, the notification set a daily value for ALA using a population-weighted average because a recent report from the IOM, titled ''Dietary Reference Intakes: Guiding Principles for Nutrition Labeling and Fortification'' (IOM Guiding Principles Report, Ref. 8), recommended setting new DVs based on this method, rather than on the highest age and gender-specific AI.

In setting a qualifying level for the ''high'' claim for EPA or DHA, the seafood processors notification set 130 milligrams (mg) as the daily value for EPA or DHA (i.e., 10 percent of the daily value for ALA) and set 130 mg (i.e., equal to the daily value) as the qualifying level for the ''high'' claim. The notification did not request ''good source'' or ''more'' claims for EPA or DHA.

Also, the seafood processors notification specified accompanying statements for the above claims. The ''high'' and ''good source'' claims would include one of the following statements:

(1) ''Contains ___ mg of [DHA/EPA/ALA] per serving, which is ___ % of the Daily Value for [DHA/EPA (130 mg) or {ALA (1.3 g)}].''

(2) ''Contains ___ % of the Daily Value for [DHA/EPA/ALA] per serving. The Daily Value for [{DHA/EPA is 130 mg} or [ALA is 1.3 g]].''

For ''more'' claims, the notification specified that the claims would be accompanied by statements such as: ''___ % [10 % or greater] more of the Daily Value for ALA per serving than [reference food]. This product contains ___ mg ALA omega-3 per serving, which is ___ % of the Daily Value for ALA omega-3 (1.3 g). [Reference food] contains ___ mg ALA omega-3 per serving.''

To qualify for ''high'' claims for ALA, the product would need to contain at least 260 mg of ALA per reference amount customarily consumed (RACC). To qualify for ''good source'' claims for ALA, the product would need to contain at least 130 mg of ALA per RACC. To qualify for ''more'' claims for ALA, the product would need to contain at least 130 mg or more of ALA per RACC than the reference food. To qualify for ''high'' claims for EPA or DHA, the product would need to contain at least 130 mg of EPA or DHA per RACC.

B. The Martek Notification

On January 21, 2005, FDA received a notification of nutrient content claims for foods, including conventional foods and dietary supplements, containing ALA and DHA omega-3 fatty acids in the Martek Notification, under section 403(r)(2)(G) of the act (Ref. 9). The notification stated that the nutrient content claims were based upon authoritative statements made in the IOM Prepublication Report (Ref. 2). As of May 22, 2005, it has been permissible to make the nutrient content claims set forth in the notification.

The notification proposed ''high,'' ''good source,'' and ''more'' claims for ALA, and ''high'' claims for DHA. With respect to specific authoritative statements that identify a nutrient level for ALA, the Martek notification cited AIs for ALA identified in the IOM Prepublication Report (i.e., 1.6 grams per (g)/ day for adult men and 1.1 g/day for adult women, specifically) and cited the following sentence: ''While intake levels much lower than the AI occur in the United States without the presence of a deficiency, the AI can provide the beneficial health effects associated with the consumption of *n*-3 fatty acids'' (Ref. 2, p. 8–2). As authoritative statements that identify a nutrient level for DHA, the notification cited the following statements from the IOM Prepublication Report the following: (1) ''EPA and DHA can contribute up to 10 percent of the total *n*-3 fatty acid intake and therefore up to this percent can contribute towards the AI for alpha-linolenic acid;'' (2) ''The AMDR for [ALA] is set at 0.6 to 1.2 percent of energy. Up to 10 percent of this range can be consumed as [EPA] and/or [DHA];'' and (3) ''A growing body of literature suggests that higher intakes of [ALA], [EPA] and [DHA] may afford some degree of protection against CHD. Because the physiological potency of EPA and DHA is much greater than that for [ALA] acid, it is not possible to estimate one AMDR for all *n*-3 fatty acids. Up to 10 percent of the AMDR can be consumed as EPA and/or DHA.''

In determining nutrient qualifying levels for the proposed ''excellent,'' ''good source,'' and ''more'' claims for ALA, the Martek notification set 1.6 g as the daily value for ALA and applied specific percentages of this value as qualifying levels for these claims as outlined in § 101.54. The Martek notification based the daily value for ALA on the AI of 1.6 g identified for adult males in the IOM Prepublication Report, making no adjustments for intakes based on population-weighted averages. The Martek notification took issue with the seafood processors notification because that notification set a daily value for ALA based on a population-weighted method rather than the historically used highest age and gender-specific reference value.

In determining a qualifying level of nutrient for the proposed ''excellent'' claim for DHA, the Martek notification set 160 mg as the daily value for DHA (i.e., 10 percent of the daily value for ALA) and applied 32 mg or more (i.e., 20 percent of the daily value for DHA) as a qualifying level for the claim. The Martek notification proposed the following exact words for the claims:

(1) '' 'Excellent source of ALA.' ('High in ALA,' 'Rich in ALA') Contains ___ mg

[5] For a ''high'' claim, the food must contain 20 percent or more of the reference value per reference amount customarily consumed. For a ''good source'' claim, the food must contain 10 to 19 percent of the reference value per reference amount customarily consumed. For a ''more'' claim, the food must contain at least 10 percent more of the reference value per reference amount customarily consumed than an appropriate reference food.

of ALA per serving, which is ___ % 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.]

(2) '' 'Good source of ALA.' ('Contains ALA,' 'Provides ALA') Contains ___ mg of ALA per serving, which is ___ % 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.]

(3) '' 'More ALA.' ('Fortified with ALA,' 'Enriched with ALA,' 'Added ALA,' 'Extra ALA,' 'Plus ALA') Contains ___ % more of the Daily Value for ALA per serving than [reference food]. This product contains ___ mg of ALA which is ___ % 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 21 CFR 101.13(j).]

(4) '' '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.]

C. The Ocean Nutrition Notification

On December 9, 2005, FDA received a notification of nutrient content claims for foods, including conventional foods and dietary supplements, containing both EPA and DHA omega-3 fatty acids in the Ocean Nutrition notification, under section 403(r)(2)(G) of the act (Ref. 10). The notification stated that the nutrient content claims were based upon authoritative statements made in the IOM prepublication report (Ref. 2). As of April 9, 2006, it has been permissible to make the nutrient content claims set forth in the notification.

The Ocean Nutrition notification proposed ''high'' claims for EPA and DHA combined. With respect to specific authoritative statements that identify the nutrient level for EPA and DHA combined, the Ocean Nutrition notification referenced the AI for adult males of 1.6 g per day of ALA identified in the IOM Prepublication Report (Ref. 2). In addition, the notification referenced the following statements from the IOM Prepublication Report (Ref. 2): (1) ''EPA and DHA can contribute up to 10 percent of the total *n*-3 fatty acid intake and therefore up to this percent can contribute towards the AI for [ALA],'' and (2) ''The AMDR for [ALA] is set at 0.6 to 1.2 percent of energy. Up to 10 percent of this range can be consumed as [EPA] and/or [DHA].'' The notification contended that a combination of EPA and DHA is the most appropriate basis for establishing nutrient content claims derived from the IOM Prepublication Report.

In calculating a nutrient qualifying level for the proposed ''excellent source'' claim for the combination of EPA and DHA, the Ocean Nutrition notification set 1.6 g as a daily value for ALA and 160 mg as a daily value for the combination of EPA and DHA (i.e., 10 percent of the daily value for ALA), and used 32 mg or more (i.e., 20 percent of the daily value for the combination of EPA and DHA) as a qualifying level for the ''excellent source'' claim.

The Ocean Nutrition notification proposed the following exact words for the claims:

'' '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 EPA and DHA combined per serving, which is ___% of the 160 mg Daily Value for a combination of EPA and DHA.''

III. Basis for the Proposed Action

FDA has reviewed the three notifications submitted in support of the claims for ALA, EPA, and DHA. With respect to the claims for ALA in the Martek notification, FDA proposes to take no regulatory action at this time. FDA expresses no opinion as to whether those claims are supported by a statement that satisfies the requirements of section 403(r)(2)(G) of the act for authoritative statements. In the November 2, 2007, **Federal Register** (72 FR 62149), we have published an Advance Notice of Proposed Rulemaking (ANPRM) soliciting comment on how daily values for nutrients should be calculated, including the appropriateness of using an AI to set a DV.[6]

With respect to the claims for ALA in the seafood processors notification, FDA proposes to prohibit those claims because they are based on a population-weighted average of the AIs for ALA. The population-weighted average approach to determining DVs for nutrients is different from the ''population coverage'' approach that FDA has used to date and continues to use, pending any possible rulemaking based on the issuance of the agency's ANPRM on DV issues.[7] The concurrent use of two different methods to set daily values on which nutrient content claims in food labeling are based creates an inconsistency that could lead to consumer confusion about such claims, as discussed more fully below. Therefore, FDA proposes to conclude that the ALA claims set forth in the seafood processors notification do not enable the public to comprehend the information provided and to understand the relative significance of such information in the context of the daily diet, as required by section 403(r)(2)(G)(iv) of the act. A claim that does not meet the requirements of section 403(r)(2)(G) of the act may not be made on the label or labeling of food.

With respect to claims for EPA and DHA, whether singly or in combination, FDA proposes to conclude that the IOM statements submitted as the basis of the claims do not meet the requirements of section 403(r)(2)(G) of the act in two respects. First, none of the statements identify the nutrient level to which the claims refer (i.e., daily values for EPA and DHA that can serve as the basis for the requested nutrient content claims) (see section 403(r)(2)(G)(i) of the act). Second, in the absence of a nutrient level for EPA and DHA derived from the authoritative statement of a scientific body defined in 403(r)(2)(G)(i) of the act, the requested claims do not convey meaningful information about EPA and DHA content because they lack an adequate scientific basis. Thus, the claims do not enable the public to comprehend the information provided and to understand the relative significance of such information in the context of the daily diet, as required by section 403(r)(2)(G)(iv) of the act.

In this regard, FDA notes that the setting of daily values and qualifying levels for claims in food labeling on the basis of statements that do not identify the nutrient level to which the claims refer can result in inconsistent and conflicting claims that confuse consumers. The requirement in section 403(r)(2)(G) of the act that an authoritative statement identify the nutrient level to which the claim refers helps to ensure consistency in the use of a particular nutrient content claim

[6] In one other instance, FDA has taken no regulatory action with respect to a notification that proposed a nutrient content claim based on an AI. The nutrient content claim for choline (Ref. 7) was based upon a reference value that the notifier set using the AIs established by the IOM in 1998 for that nutrient (Ref. 8). Choline is essential in the human diet and the AIs for that nutrient were established based upon experimental data demonstrating prevention of alanine aminotransferase abnormalities in healthy men.

[7] FDA seeks comment in the ANPRM on whether the agency should continue to use the population-coverage approach or switch to the population-weighted average approach to setting DVs. The agency's reasons for adopting the population-coverage approach to set DVs in 1993 are discussed in the final rule entitled ''Reference Daily Intakes and Daily Reference Values'' (see 58 FR 2206 at 2211, January 6, 1993).

among different products from different manufacturers.

The notification process in section 403(r)(2)(G) of the act provides a mechanism for authorizing a new nutrient content claim based on an authoritative statement by a scientific body of the United States 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. Under this expedited process, the scientific basis for a nutrient content claim is established through reliance on an authoritative statement of one of the scientific bodies designated in section 403(r)(2)(G), which has already reviewed the relevant scientific evidence. Therefore, when FDA is reviewing a notification under section 403(r)(2)(G) , the agency does not conduct an independent review of the body of scientific evidence associated with the proposed nutrient content claim. Rather, FDA's review is limited to considering whether the authoritative statement and the proposed nutrient content claim meet the requirements of section 403(r)(2)(G) of the act. (In contrast, the agency will conduct its own review of the scientific evidence for the proposed claim when a nutrient content claim petition is submitted under section 403(r)(4) of the act (see 21 CFR 101.69).)

FDA notes that all of the notifications at issue in this rulemaking relied on statements made in the IOM Prepublication Report. For purposes of this proposed rule, FDA has evaluated the claims in the notifications in light of relevant statements made in the IOM Final Report. Unless stated otherwise, those statements may be presumed to be identical to statements made in the IOM Prepublication Report.

A. ALA

The following statement in the IOM Final Report is pertinent to this proposed rule and is identical to a statement made in the IOM Prepublication Report that was cited by all three of the notifications: ''The AI for [ALA] is 1.6 and 1.1 g/day for men and women, respectively.'' (Ref. 1, Summary, p. 9). ALA is essential in the human diet. The IOM established AIs for ALA based upon the median intake of ALA by different gender and life stage groups in the United States, where a deficiency is basically nonexistent in free-living populations (see pages 427, 469 to 472, 1051 to 1051) (Ref. 1).

At this time, FDA proposes to take no regulatory action with respect to the nutrient content claims for ALA in the Martek notification. FDA notes that those claims are based on a daily value that the notifier set using the highest gender and life-stage AI (i.e., 1.6 g/day of ALA for men ages 19 years and older). Assuming, without deciding the issue, that it is appropriate to use an AI to set a DV, the population-coverage approach used by Martek in this notification ensures that the nutritional needs of almost all segments of the population are covered. This approach is consistent with the method that FDA has used in determining DVs to date (see 58 FR 2206 at 2211, January 6, 1993).

In contrast, FDA proposes to prohibit the claims for ALA in the seafood processors notification because those claims are based on a daily value that the notifier set using a population-weighted average of AI reference values (1.3 g/day).[8] A daily intake level based on a population-weighted average of AI values may not be adequate for some segments of the population (e.g., men ages 19 and over). Use of the population-weighted average approach in the seafood processors notification also results in a daily value for ALA that is inconsistent with the daily value for ALA claims based on the population-coverage approach used in the Martek ALA notification. As discussed in the preceding paragraph, FDA is proposing no regulatory action concerning nutrient content claims for ALA based on the Martek ALA notification, which means that such claims will continue to be permitted on food labels if this rule is finalized as proposed.

The inconsistency between the population-weighted average method used to set the daily value for ALA in the seafood processors notification and the population coverage method used for that purpose in the Martek notification is likely to result in inconsistent and conflicting nutrient content claims on food labels.. For example, a food labeled as a ''good source'' of ALA must contain at least 160 mg of ALA per RACC under the criteria in the Martek notification, while another food containing only 130 mg ALA per RACC would also be able to bear the same ''good source'' claim under the criteria in the seafood processors notification. Such inconsistencies make meaningful product-to-product comparisons of ALA content based on label claims impossible. To enable the public to comprehend the information provided in nutrient content claims and understand the relative significance of that information in the context of the daily diet, as required by section 403(r)(2)(G)(iv) of the act, qualifying ALA levels for nutrient content claims in food labeling must be based on a single daily value determined using the same method as the DVs for other nutrients.

FDA recognizes that the IOM Guiding Principles Report recommends setting new DVs based on a population-weighted average of reference values. However, that report disclaims any intent to make regulatory recommendations; rather, the guiding principles it provides are recommendations that FDA may accept or reject as appropriate to its activities. As previously noted, in the November 2, 2007, **Federal Register** (72 FR 62149), we have published an ANPRM that seeks comment on the appropriateness of using a population-weighted average, as opposed to a population-coverage approach, to set a DV. In the interim, FDA's position continues to be that the population-coverage approach should be used, for the reasons discussed in the 1993 final rule on DVs (58 FR 2206 at 2211) and for consistency with the manner in which FDA has determined DVs for nutrients to date.

Therefore, FDA is proposing to find that the nutrient content claims for ALA set forth in the seafood processors notification do not meet the requirements of the act.

B. EPA and DHA

The following statements about EPA and DHA in the IOM Final Report are pertinent to this proposed rule and are essentially similar to statements made in the IOM Prepublication Report that were cited by one or more of the notifications:

''[EPA] and [DHA] contribute approximately 10 percent of the total *n*-3 fatty acid intake and therefore this percent contributes toward the AI for [ALA].''

''Small amounts of EPA and DHA can contribute towards reversing an *n*-3 fatty acid deficiency * * * and can therefore contribute toward the AI for [ALA]. EPA and DHA contribute approximately 10 percent of the total *n*-3 fatty acid intake and therefore this percent contributes toward the AI for [ALA].''

''The AMDR for [ALA] is set at 0.6 to 1.2 percent of energy. Ten percent of this range can be consumed as [EPA] and/or [DHA].''

''Approximately 10 percent of the AMDR for *n*-3 fatty acids ([ALA]) can be

[8] FDA's proposal to prohibit the claims for ALA in the seafood processors notification should not be read as an endorsement of the use of an AI to set a DV. As previously noted, FDA has published an ANPRM to seek comment on the appropriateness of using an AI to set a DV, among other issues.

consumed as EPA and/or DHA (0.06 to 0.12 percent of energy).''[9]

FDA proposes to conclude that these statements do not identify a nutrient level, or reference value, for EPA and/or DHA that FDA could use to establish by regulation a label reference value for use in nutrition labeling. As noted, the IOM Final Report establishes reference values in the form of DRIs for a number of nutrients. DRIs include the EAR, RDA, AI, and UL. The IOM Final Report does not establish an EAR, RDA, AI, or UL for EPA or DHA. The ''approximately 10 percent'' statements in the IOM Final Report are not reference values. They do not reflect a recommended or defined intake level of EPA and/or DHA that could serve as a basis for setting a DV that could be used to characterize a given level of EPA and/or DHA for purposes of nutrition labeling.

In summary, FDA proposes to conclude that the statements cited by the three notifications and the essentially similar statements in the IOM Final Report do not identify a nutrient level to which the EPA and DHA claims refer, and therefore do not meet the requirements of section 403(r)(2)(G) of the act for authoritative statements. In the absence of an authoritative statement that identifies the nutrient level to which a claim refers, the requirements of section 403(r)(2)(G) of the act are not met. Therefore, FDA proposes to find that any nutrient content claim pertaining to EPA or DHA that is made on the label or labeling of a food renders that food misbranded under section 403(r) of the act.

FDA recognizes that consumption of EPA and/or DHA may provide health benefits and that industry may wish to alert consumers to those benefits. There are numerous lawful means of doing so. Under 21 CFR 101.13(i)(3), the label or labeling of a food may contain a statement about the amount or percentage of a nutrient if the statement does not in any way implicitly characterize the level of the nutrient in the food and is not false or misleading in any respect. For example, a conventional food or a dietary supplement may bear a statement such as ''Contains x mg of EPA and DHA omega-3 fatty acids per serving.'' Also, under 21 CFR 101.13(q)(3)(ii)(A), dietary supplements are permitted to bear simple percentage claims (e.g., 40 percent EPA and DHA omega-3 fatty acids), and under 21 CFR 101.14(q)(3)(ii)(B), they are permitted to bear comparative percentage claims (e.g., ''four times the EPA and DHA omega-3 fatty acids per capsule (80 mg) as in 100 mg of menhaden oil (20 mg)''). In addition, the potential health benefits of consuming EPA and DHA can be communicated to consumers by using the qualified health claim about the relationship between EPA and DHA and reduced risk of CHD (Refs. 11 and 12).

[9]Generally, in place of ''approximately 10 percent'' and ''this percent,'' the IOM Prepublication Report stated ''up to 10 percent'' and ''up to this percent.''

IV. Environmental Impact

We have carefully considered the potential environmental effects of this action. FDA has determined under 21 CFR 25.30(k) that this action is of a type that does not have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). FDA has determined that this proposed rule is not a significant regulatory action as defined by the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Based on FDA's review of the labels in the marketplace, FDA does not believe that a substantial number of small entities will be significantly affected. The agency requests comment on whether this rule will have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $127 million, using the most current (2006) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

Benefit-Cost Analysis

1. The Need for This Regulation

We discussed the legal and regulatory need for this proposed rule in section III of this document.

2. Options

We analyzed two regulatory options: (1) Take no new regulatory action; and (2) prohibit the EPA and DHA claims and the ALA claims based on a daily value of 1.3 grams, but allow the ALA claims based on a daily value of 1.6 grams.

Option 1: Take No New Regulatory Action

This option would result in no change to the current situation, and so would result in no costs or benefits. This is not a viable option under FDA's current statutory and regulatory framework, as we discussed earlier in this preamble. However, we use this option as the basis for comparing the costs and benefits of other regulatory options.

Option 2: Take the Regulatory Actions as Described in the Proposed Rule

FDA received the first notification from the seafood processors on January 16, 2004. Because FDA did not issue a regulation prohibiting the use of these nutrient content claims within 120 days, ''high'' claims for ALA, EPA, and DHA, as well as ''good source'' and ''more'' claims for ALA have been permissible since May 16, 2004. A second notification, from Martek, received on January 21, 2005, notified FDA of ''high'' claims for ALA and DHA, as well ''good source'', and ''more'' claims for ALA. A third notification, from Ocean Nutrition, received on December 9, 2005, notified FDA of a ''high'' claim and an ''excellent source'' claim for EPA and DHA combined. All of these claims became permissible 120 days after the FDA received the respective notifications because the agency did not issue a regulation prohibiting them. A cost of this rule will be label changes for products bearing claims that are prohibited. These costs may be lower if producers can schedule regulatory label changes to coincide with their scheduled label changes.

Number of Labels Affected

FDA does not have data on the number of products bearing an ALA, EPA, DHA, or EPA plus DHA nutrient content claim on the label. Therefore, we attempt to estimate a range for the number of products that may bear an affected nutrient content claim.

Products whose eligibility will be affected by this rule:

- Have levels of DHA greater than 32 mg.;
- Have levels of EPA greater than 130 mg.;
- Have levels of EPA and DHA combined of greater than 32 mg.;
- Have levels of ALA greater than 130 mg and less than 160 mg for ''good source'' or ''more'' claim; and
- Have levels of ALA greater than 260 mg and less than 320 mg for ''high'' claim.

In this analysis, we distinguish between levels of DHA greater than 32 mg and less than 130 mg and levels greater than 130 mg, because FDA received the notification for ''high'' claims for foods with more than 32 mg of DHA in January of 2005 and the notification for ''high'' claims for foods with more than 130 mg of DHA in January of 2004. The longer a claim has been in effect, the more likely that it is in use by manufacturers. More time allows manufacturers to integrate the label change with other packaging changes. Also, if a food is reformulated to meet claim requirements, it may take more time to test the new formulation and put it into the marketplace. In addition to label changes due to loss of claims, products that refer to the ALA daily value of 1.3 g have to alter their packaging to refer to the revised daily value of 1.6 g. FDA was not able to undertake a comprehensive review of labels in the marketplace to determine how many products currently have labels with an affected nutrient content claim. Instead, FDA went through a multi-step process to estimate the likely number of claims in the marketplace.

1. We determined which products are eligible to make a nutrient content claim.

2. We conducted an informal review of these products in local groceries and online groceries to determine if any were making an affected nutrient content claim.

3. We determined how many labels there were in the marketplace for each of the products eligible to make an affected nutrient content claim.

4. We estimated the number of products likely to make an affected claim based on the number of products in the marketplace, the results of the informal review, and the length of time the claim had been in effect.

EPA and DHA occur naturally in some fish, with higher levels in fattier fish. Many dietary supplements, particularly fish oils, contain EPA and DHA. ALA is present in some nuts and nut oils, flaxseeds and flaxseed oil, vegetable oils, and in many prepared foods that include flaxseeds, nuts, or oils as an ingredient. We searched an online grocer for all packaged fish and seafood products and expanded this list by a review of all canned, frozen, and refrigerated fish and seafood products in the 1999 Infoscan supermarket scanner data collected by Information Resources, Inc. (IRI) (Ref. 13). The IRI Infoscan supermarket scanner data provide very specific information on individual food items. Infoscan store tracking is based primarily on all-store, census scanner data, which are collected weekly from more than 32,000 supermarket, drug, and mass merchandiser outlets across the United States. For these products, we determined the average serving size for each product type, for example, 2 ounces (oz) for canned tuna. We then used the United States Department of Agriculture (USDA) National Nutrient Database for Standard Reference (Ref. 14) to determine the levels of EPA and/or DHA in a serving size of that food. USDA updates this database frequently. We used the most current version available when we calculated these numbers. However, we have not recalculated the numbers with each subsequent update because we do not expect that doing so would affect our estimates to any significant degree. Therefore, the benefit of recalculating the numbers would probably not justify the time and cost of doing so. We classified all products whose levels of EPA and/or DHA exceeded the threshold for a nutrient content claim as potential claim losers. Tables 1 and 2 of this document show the products and their levels of EPA and/or DHA. Table 2 reflects a 3–oz serving size for cooked fish.

TABLE 1.—DHA AND/OR EPA LEVELS OF CANNED SEAFOOD AND FISH

Canned Foods	Serving Size	DHA (mg)	EPA (mg)	EPA or DHA Eligible ≥ 130 mg	DHA Eligible ≥ 32 mg	EPA plus DHA Eligible ≥ 32 mg
Herring	2 oz	668	550	Yes	Yes	Yes
Mackerel	2 oz	452	246	Yes	Yes	Yes
Caviar	.5 oz	539	389	Yes	Yes	Yes
Salmon	2 oz	459	481	Yes	Yes	Yes
White Tuna in water	2 oz	358	133	Yes	Yes	Yes
Sardines	2 oz	288	268	Yes	Yes	Yes
Anchovies	.5 oz	123	73	No	Yes	Yes
Shrimp, mixed species	2 oz	126	146	Yes	Yes	Yes
Oyster	2 oz	130	120	Yes	Yes	Yes
Canned shrimp	3 oz	249	214	Yes	Yes	Yes
Light Tuna in water	2 oz	127	27	No	Yes	Yes
Crabmeat	2 oz	71	81	No	Yes	Yes
White Tuna in oil	2 oz	101	38	No	Yes	Yes
Light Tuna in oil	2 oz	58	15	No	Yes	Yes

TABLE 1.—DHA AND/OR EPA LEVELS OF CANNED SEAFOOD AND FISH—Continued

Canned Foods	Serving Size	DHA (mg)	EPA (mg)	EPA or DHA Eligible ≥ 130 mg	DHA Eligible ≥ 32 mg	EPA plus DHA Eligible ≥ 32 mg
Gefiltefish	1.5 oz	19	32	No	No	Yes

TABLE 2.—DHA AND/OR EPA LEVELS OF FROZEN AND REFRIGERATED SEAFOOD AND FISH

Frozen and Refrigerated	Serving Size	DHA (mg)	EPA (mg)	EPA or DHA Eligible ≥ 130 mg	DHA Eligible ≥ 32 mg	EPA plus DHA Eligible ≥ 32 mg
Salmon	3 oz	1099	525	Yes	Yes	Yes
Mackerel	3 oz	1016	555	Yes	Yes	Yes
Tuna	3 oz	757	241	Yes	Yes	Yes
Herring	3 oz	733	603	Yes	Yes	Yes
Albacore Tuna	3 oz	535	198	Yes	Yes	Yes
Trout	3 oz	449	172	Yes	Yes	Yes
Sardines	3 oz	433	402	Yes	Yes	Yes
Mussels	3 oz	430	235	Yes	Yes	Yes
Pollock	3 oz	383	77	Yes	Yes	Yes
Squid	3 oz	323	138	Yes	Yes	Yes
Other (fish sticks)	6 sticks	216	144	Yes	Yes	Yes
Halibut	3 oz	248	60	Yes	Yes	Yes
Oyster	3 oz	245	225	Yes	Yes	Yes
Sole/Flounder	3 oz	219	207	Yes	Yes	Yes
Whiting	3 oz	200	241	Yes	Yes	Yes
Shrimp	3 oz	189	219	Yes	Yes	Yes
Grouper	3 oz	187	23	Yes	Yes	Yes
Perch	3 oz	179	68	Yes	Yes	Yes
Yellowfin Tuna	3 oz	154	31	Yes	Yes	Yes
Haddock	3 oz	138	65	Yes	Yes	Yes
Cod	3 oz	131	3	Yes	Yes	Yes
Clams	3 oz	124	117	No	Yes	Yes
Lobster	3 oz	118	290	Yes	Yes	Yes
Catfish	3 oz	109	42	No	Yes	Yes
Crab	3 oz	96	239	Yes	Yes	Yes
Scallop	3 oz	92	76	No	Yes	Yes
Octopus	3 oz	69	65	No	Yes	Yes
Snapper	3 oz	43	3	No	Yes	Yes
Gefiltefish/Whitefish/Pike	3 oz	38	63	No	Yes	Yes
Crawfish	3 oz	23	99	No	No	Yes
Orange Roughy	3 oz	2	2	No	No	No

FDA was not able to carry out a similar systematic review of foods for ALA claims, because a much wider range of foods may meet the ALA claim. However, only a small proportion of foods have ALA levels between 130 and 160 mg (for ''good source'' and ''more'' claims) and ALA levels between 260 and 320 mg (for ''high'' claim), and therefore will lose their eligibility. In addition to foods that naturally contain these fatty acids, some manufacturers have been increasing the levels of ALA, EPA, or DHA in their products. Foods, such as eggs and milk, can be enriched with ALA, EPA, or DHA by manipulating the diet of chickens and cows, respectively. Also, manufacturers can add ALA to their products by including ingredients like flaxseed oil or ground flaxseed. To find ALA-, EPA-, or DHA-enriched foods, we searched the Internet using keyword searches and in local grocery stores.

FDA searched three local grocery stores for products bearing claims involving ALA, EPA, or DHA. FDA found one new line of products making an ALA claim: pasta with ground flaxseeds to increase the ALA content. This product meets the level of ALA needed to make a ''good source'' ALA claim under both the 130 and 160 mg levels. FDA did not find any products making a ''high'' claim. However, the labels refer to an ALA daily value of 1.3 g, so they will have to be changed to reflect the 1.6 g daily value. FDA also searched the Internet to find food products that are likely to include a nutrient content claim. FDA found several brands of eggs, one with added DHA and many with added ALA. FDA reviewed 12 Web sites for ALA- or DHA-enriched eggs. In many cases the Web sites provided a picture of the egg carton, but did not give the full label information. For the ALA eggs, nutrition information on the Web site always emphasized the omega-3 content (which is appropriate on the label or in the labeling of the product as long as the statement does not in any way implicitly characterize the level of the nutrient in the food and it is not false or misleading in any respect (e.g., ''100 mg omega-3 fatty acids per serving'') (21 CFR 101.13(i)(3)), not the specific ALA content. However, the Web site for the DHA-enriched eggs emphasized the DHA content and the DHA daily value established under the seafood processors notification. Based on the Internet review, FDA thinks it unlikely that any of the ALA-enriched eggs would be making an affected claim and likely that the DHA-enriched egg would make an affected claim. The DHA-enriched eggs included processed and shell eggs and were sold in six different packages. FDA also searched a major online drugstore that compiles dietary supplements sold by many other online retailers. This Web site also provided all the labeling information in the dietary supplement package. FDA searched for dietary supplements using the keywords EPA, DHA, fish oil, and ALA. The searches resulted in 53 hits for EPA, 49 hits for DHA, 55 hits for fish oil, and 48 hits for ALA. Many of the products in the searches overlapped. In reviewing these products, FDA found two dietary supplements making affected claims. Overall, these searches were limited and ad hoc and do not constitute a representative sample of the marketplace. Table 3 of this document presents the affected stock keeping units (SKUs). Every product and package size combination represents an SKU. Therefore, the number of SKUs corresponds to the number of product labels.

TABLE 3.—CLAIMS FOUND IN THE MARKETPLACE

Product	Number of Manufacturers	Number of SKUs
Dietary supplements	2	2
Eggs	1	6
Pasta	1	6

Because FDA is unsure about whether the egg product that we identified actually makes a claim, the actual number of SKUs may be slightly lower than FDA indicates in Table 3 of this document. However, because our searches were not representative and we did not perform a comprehensive review of food labels, there are likely to be more claims in the marketplace than we were able to identify using the ad-hoc search procedure we discussed above. For the categories of food FDA was able to identify as containing more than the qualifying levels of EPA and/or DHA, FDA counted the number of SKUs in the 1999 IRI database by downloading all canned, frozen, and refrigerated seafood and fish from the database, then further breaking down these categories into types of seafood and fish using the information provided in each record. FDA only counted branded products, because private label brands make claims infrequently. In the IRI data, the type of fish is usually represented by an abbreviation in the product name, like ''abtn'' for albacore tuna. So, we counted the number of each type of fish using the abbreviations in the name provided by IRI. For some products, we were not able to identify the fish or we could not find data on the EPA and/or DHA contents. Most of the foods in the IRI data that did not specify the type of fish were breaded fish fillets or fish sticks. Therefore, for the ''other'' category of fish we assigned the usual serving size and EPA and DHA levels for fish sticks. Some fish and seafood had multiple levels of EPA and DHA in the USDA Nutrient Laboratory database, depending on the specific variety. If we were not able to determine the relevant type of fish or seafood, we used the median value in the database for the type of fish or seafood. Because 1999 is the most recent IRI data available to us, we needed to correct for changes in the marketplace since 1999. To do so, we used the USDA food disappearance data to estimate changes in the availability of seafood on the market between 1999 and 2003 (the most recent year for which data is available) (Ref. 15). FDA then adjusted the 1999 IRI data by the growth in the relevant seafood category. FDA made an additional adjustment to the count of potentially affected products based on the usual frequency of scheduled label changes. Table 4 of this document presents the proportion of branded SKUs that are typically redesigned within a given period of time. Therefore, FDA estimates that 67 percent of labels would have been redesigned in the timeframe since the seafood processors notification went into effect, 33 percent of the labels would have been redesigned since the Martek notification went into effect, and 5 percent of the labels would have been redesigned since the Ocean Nutrition notification went into effect. In tables 5 and 6 of this document, FDA presents an estimate of the number of labels (SKUs) in the market currently eligible to make an EPA and/or DHA claim. Because foods eligible to make ALA claims include nuts and nut oils and flaxseed and flaxseed oils, as well as foods that include one of these sources as an ingredient, FDA was not able to estimate the number of foods eligible to make an ALA claim. However, only foods with between 130 mg and 160 mg of ALA or foods with between 260 mg and 320 mg of ALA will have a change in their eligibility status, which should be a relatively small number of the total number of eligible foods. Also, we do not count the number of packages of enriched foods because we did not have a comprehensive, up-to-date database of foods enriched with ALA, EPA, or DHA.

TABLE 4.—FREQUENCY OF LABEL REDESIGNS

Time period	Proportion of SKUs
6-month	5 percent

TABLE 4.—FREQUENCY OF LABEL REDESIGNS—Continued

Time period	Proportion of SKUs
12-month	33 percent

TABLE 4.—FREQUENCY OF LABEL REDESIGNS—Continued

Time period	Proportion of SKUs
24-month	67 percent
36-month	100 percent

TABLE 5.—NUMBER OF CANNED FOODS ELIGIBLE TO MAKE AN EPA AND/OR DHA CLAIM

Canned Foods	EPA or DHA Eligible at 130 mg	DHA Eligible at 32 mg	EPA plus DHA Eligible at 32 mg	Adjusted SKUs
Salmon	Yes	Yes	Yes	335
Sardines	Yes	Yes	Yes	282
Gefiltefish	No	No	Yes	161
Light Tuna in water	No	Yes	Yes	130
Shrimp, mixed species	Yes	Yes	Yes	146
Anchovies	No	Yes	Yes	116
Oyster	Yes	Yes	Yes	111
Shrimp	Yes	Yes	Yes	104
Crabmeat	No	Yes	Yes	93
Herring	Yes	Yes	Yes	93
Light Tuna in oil	No	Yes	Yes	76
Mackerel	Yes	Yes	Yes	84
White Tuna in water	Yes	Yes	Yes	58
Caviar	Yes	Yes	Yes	33
White Tuna in oil	No	Yes	Yes	9
Number of SKUs eligible	1,246	1,540	1,701	
Adjusted for time since eligibility	835	508	85	

TABLE 6.—NUMBER OF FROZEN AND REFRIGERATED SEAFOOD AND FISH ELIGIBLE TO MAKE AN EPA AND/OR DHA CLAIM

Frozen and Refrigerated	EPA or DHA Eligible at 130 mg	DHA Eligible at 32 mg	EPA plus DHA Eligible at 32 mg	Adjusted SKUs
Shrimp	Yes	Yes	Yes	1,272
Salmon	Yes	Yes	Yes	329
Other	Yes	Yes	Yes	116
Tuna	Yes	Yes	Yes	249
Herring	Yes	Yes	Yes	242
Oyster	Yes	Yes	Yes	228
Crab	Yes	Yes	Yes	155
Octopus	No	Yes	Yes	160
Cod	Yes	Yes	Yes	95
Lobster	Yes	Yes	Yes	126
Scallop	No	Yes	Yes	101
Whiting	Yes	Yes	Yes	82

TABLE 6.—NUMBER OF FROZEN AND REFRIGERATED SEAFOOD AND FISH ELIGIBLE TO MAKE AN EPA AND/OR DHA CLAIM—Continued

Frozen and Refrigerated	EPA or DHA Eligible at 130 mg	DHA Eligible at 32 mg	EPA plus DHA Eligible at 32 mg	Adjusted SKUs
Clams	No	Yes	Yes	75
Crawfish	No	No	Yes	80
Albacore Tuna	Yes	Yes	Yes	78
Sole/Flounder	Yes	Yes	Yes	61
Catfish	No	Yes	Yes	55
Haddock	Yes	Yes	Yes	37
Squid	Yes	Yes	Yes	43
Pollock	Yes	Yes	Yes	31
Mussels	Yes	Yes	Yes	39
Orange Roughy	No	No	No	30
Gefiltefish/Whitefish/Pike	No	Yes	Yes	19
Halibut	Yes	Yes	Yes	17
Trout	Yes	Yes	Yes	19
Perch	Yes	Yes	Yes	18
Yellowfin Tuna	Yes	Yes	Yes	7
Mackerel	Yes	Yes	Yes	9
Snapper	No	Yes	Yes	7
Grouper	Yes	Yes	Yes	3
Sardines	Yes	Yes	Yes	4
Number of SKUs eligible	3,335	3,677	3,757	
Adjusted for time since eligibility	2,234	1,213	188	

Cost of Label Changes

Producers who will be affected by this rule are likely to go through several steps to modify their labels to come into compliance with the proposed requirements. The producers will do the following: (1) Conduct administrative activities, (2) alter the graphic design, (3) conduct prepress activities, engrave plates or cylinders, and (4) print and manufacture labels. Producers incur costs associated with each step of the process. The first step requires that producers read and develop a strategy to comply with the proposed requirements. Second, they will develop a new graphic design for the label that complies with the proposed requirements. Third, a prepress operator will convert the new design into printing plates or cylinders. Fourth, the new labels will be printed. The costs associated with label changes will also vary depending on whether the label change can be coordinated with a scheduled label change. There may be an additional inventory cost to producers if they have to dispose of already printed labels.

FDA contracted with RTI International to estimate the costs of label changes to producers (Ref. 16). RTI estimated the costs associated with each of these steps, as well as the cost of discarded inventory of unused labels. Manufacturers regularly redesign their labels, so RTI only estimated a cost associated with the label change if the regulatory label change could not be done with a regularly scheduled label change. The estimated schedule for label changes is presented in table 4 of this table. Tables 7 and 8 present estimates of per SKU cost of a label change.

TABLE 7.—COST OF LABEL CHANGE (PER SKU) FOR SEAFOOD AND PASTA (IN 2005 DOLLARS)

	Canned Seafood	Frozen Seafood	Refrigerated Seafood	Pasta
Administrative	$200	$200	$400	$500
Graphic	$800	$900	$1,400	$1,600

TABLE 7.—COST OF LABEL CHANGE (PER SKU) FOR SEAFOOD AND PASTA (IN 2005 DOLLARS)—Continued

	Canned Seafood	Frozen Seafood	Refrigerated Seafood	Pasta
Prepress	$1,200	$500	$800	$900
Engraving	$2,900	$700	$1,100	$1,300
Inventory	$0	$0	$0	$0
Total	$5,100	$2,300	$3,700	$4,300

TABLE 8.—COST OF LABEL CHANGE (PER SKU) FOR DIETARY SUPPLEMENTS AND EGGS (IN 2005 DOLLARS)

	Dietary Supplement Liquid	Dietary Supplement Pills	Processed Eggs	Shell Eggs
Administrative	$900	$900	$500	$500
Graphic	$3,300	$2,200	$1,600	$1,600
Prepress	$2,100	$2,100	$1,100	$1,100
Engraving	$2,100	$2,100	$900	$900
Inventory	$0	$100	$0	$500
Total	$8,400	$7,400	$4,100	$4,600

Based on our ad hoc searching, it is clear that not all products eligible to make an affected claim are making a claim. Overall, we estimate that at least 14 product labels will have to be changed as a result of this rule. Table 9 of this document presents an estimate of the cost associated with known label changes. This is probably an underestimate of the labeling cost because FDA has not conducted a comprehensive review of food labels to identify the number of products bearing these claims and we have probably underestimated the number of such claims. However, we are uncertain about the true number of existing claims.

TABLE 9.—LOWER BOUND ESTIMATE OF TOTAL COSTS FROM LABELING CHANGES

Product	Number of SKUs	Cost of Label Change*
Dietary supplements	2	$5,200
Eggs	6	$8,600
Pasta	6	$8,500
Total	14	$22,300

*Assumes 67 percent of label changes can be made with regularly scheduled label changes.

To determine the number of dietary supplements that qualify for a nutrient content claim, FDA counted the number of dietary supplements that have fish oil, ALA, EPA, or DHA as an ingredient in the Dietary Supplement Sales Information database (Ref. 17). The Dietary Supplement Sales Information database is a survey of the ingredients in 3,000 dietary supplements. Based on a total count of 113 qualifying dietary supplements in the database, FDA estimates that the Internet review of dietary supplements covered approximately half of the qualifying dietary supplements, and so a likely estimate is that four dietary supplements would have to change their labels. In the search of local grocery stores, we reviewed approximately 200 fish and seafood packages. None of the labels we reviewed included an affected claim. However, it seems likely that each of the five companies that participated in notifications to FDA may make some nutrient content claim. Therefore, FDA estimates that it is likely that a label change would be required for six SKUs for each of the five manufacturers. FDA estimated 6 SKUs per manufacturer because the product lines identified for eggs and pasta that were making an affected nutrient content claim both included 6 SKUS. Finally, for the other two types of products we found that made a label claim, we estimate that, similar to dietary supplements, there are twice as many affected claims in the market. Table 10 of this document presents an estimate of the likely total cost of label changes.

TABLE 10.—LIKELY ESTIMATE OF TOTAL COSTS FROM LABELING CHANGES

Product	Number of SKUs	Cost of Label Change*
Dietary supplements	4	$10,400

TABLE 10.—LIKELY ESTIMATE OF TOTAL COSTS FROM LABELING CHANGES—Continued

Product	Number of SKUs	Cost of Label Change*
Notifiers	30	$39,200
Eggs	12	$17,200
Pasta	12	$17,000
Total	58	$83,800

*Assumes 67 percent of label changes can be made with regularly scheduled label changes

Health Effects

Benefits from a labeling rule typically arise from changes in consumption of nutrients, either increases in consumption of beneficial nutrients or decreases in consumption of detrimental nutrients. Consumption changes because the behavior of producers or consumers changes. Product reformulation, in which producers alter the composition of their product to qualify for a positive label claim or avoid a negative label statement, may lead to substantial changes in the consumption of certain beneficial nutrients. There may also be direct changes in consumer choices, if consumers purchase healthier food based on information they see on the label. Several studies have linked label use to improved diet (Refs. 18 and 19).

The removal of nutrient content claims for EPA and/or DHA may result in reduced consumption of EPA and DHA under two scenarios. First, consumption of these nutrients may be reduced if consumers choose not to purchase and consume products because they do not have the prohibited nutrient content claims on the label. Second, producers might face reduced incentives to increase levels of EPA and DHA in products, which might lead some producers to a decision not to reformulate. A review of the literature on product reformulation in a report on modeling manufacturers' decision to reformulate finds evidence that increased provision of nutrition information on labels leads manufacturers to reformulate to make healthier products or to attempt to market new healthier products (Ref. 20). If the continued availability of nutrient content claims for EPA and/or DHA would have encouraged producers to increase levels of EPA and/or DHA, there may be additional reductions in consumption of EPA and/or DHA due to lower levels in the food supply. However, because the agency has yet to conduct a review of the scientific evidence concerning the health effects of consuming EPA and DHA at different levels, we cannot determine whether the loss of these claims would have any impact on consumer health, either beneficial or detrimental.

Furthermore, FDA wishes to emphasize that this ruling does not affect the continuing availability of a qualified health claim that states, ''Supportive but not conclusive research shows that consumption of EPA and DHA omega-3 fatty acids may reduce the risk of CHD. One serving of [Name of the food] provides [ ] gram of EPA and DHA omega-3 fatty acids. [See nutrition information for total fat, saturated fat, and cholesterol content.].'' To make the qualified health claim, the product must contain EPA and DHA, and meet limits for cholesterol, saturated fat, total fat, and sodium and meet the 10 percent nutrient content requirement for vitamin C, vitamin A, iron, calcium, protein, or fiber (Ref. 21). Producers may opt to reformulate their products to use the qualified health claim.

Therefore, FDA estimates the quantitative costs of this rule to be $83,800 due entirely to projected labeling changes, and potential non-quantified costs associated with a potential forgone decrease in risk of CHD resulting from a possible decrease in the consumption of EPA and/or DHA.

Benefits

This option would prevent consumers from mistakenly interpreting ''high,'' ''good source,'' and ''more'' claims relating to the level of EPA and/or DHA in food to imply that an authoritative scientific body has determined that consumers should consume a particular level of EPA and/or DHA per day. This, in turn, might prevent some consumers from forming an incorrect assessment of the relationship of the levels of EPA and/or DHA in particular foods to such recommended levels. This could generate a health benefit because if consumers base their consumption patterns on an incorrect assessment of the significance of the amount of EPA and/or DHA in particular foods, then they might change their consumption patterns in ways that could be detrimental to their health. For example, some consumers might believe they would not receive any additional benefit from consuming additional food containing EPA and/or DHA after eating a food that is labeled as being ''high'' in those nutrients even though they might actually benefit significantly from additional amounts of those nutrients. Alternatively, some consumers might believe that it is worthwhile to forgo a certain level of other nutrients in order to consume a food that is ''high'' level of EPA and/or DHA when, in fact, they could obtain nearly the same benefit from a food with less EPA and/or DHA. FDA does not have sufficient information to quantify this potential benefit.

VI. The Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed rule contains no collection of information. Therefore clearance by OMB under the Paperwork Reduction Act of 1995 is not required.

VII. Federalism Analysis

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed rule, if finalized as proposed, would have a preemptive effect on State law. Section 4(a) of the Executive order requires agencies to ''construe * * * a Federal Statute to preempt State law only where the statute contains an express preemption provision, there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.'' Section 403A of the act (21 U.S.C. 343–1) is an express preemption provision. In relevant part, section 403A(a)(5) of the act (21 U.S.C. 343–1(a)(5)) provides that: ''* * * no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce— * * * (5) any requirement respecting any claim of the type described in section 403(r)(1) made

in the label or labeling of food that is not identical to the requirement of section 403(r) * * *''.

Currently, this provision operates to preempt States from imposing nutrient content claim labeling requirements concerning ALA, EPA, DHA, and EPA and DHA combined because no such requirements have been imposed by FDA under section 403(r) of the act. Under FDA's authority under section 403(r)(2)(H) of the act, the agency proposes to find that the requirements of section 403(r)(2)(G) have not been met with respect to the nutrient content claims for EPA and DHA in the seafood processors notification, the nutrient content claim for DHA in the Martek notification, and the nutrient content claim for EPA and DHA in the Ocean Nutrition notification. FDA also proposes to prohibit the nutrient content claims for ALA in the seafood processors notification.

Although this proposed rule, if finalized as proposed, would have preemptive effect in that it would preclude States from promulgating any nutrient content claim labeling requirements for ALA, EPA, DHA, and EPA and DHA combined that are not identical to those required by this proposed rule, this preemptive effect would be consistent with what Congress set forth in section 403A of the act. Section 403A(a)(5) of the act displaces both state legislative requirements and state common law duties. *Medtronic* v. *Lohr, 518 U.S. 470, 503 (1996)* (Breyer, J., concurring in part and concurring in judgment); *id. at 510* (O'Connor, J., joined by Rehnquist, C.J., Scalia, J., and Thomas, J., concurring in part and dissenting in part); *Cipollone* v. *Liggett Group, Inc., 505 U.S. 504, 521 (1992)* (plurality opinion); *id. at 548-49* (Scalia, J., joined by Thomas, J., concurring in judgment in part and dissenting in part).

FDA believes that the preemptive effect of the proposed rule, if finalized as a proposed, would be consistent with Executive Order 13132. Section 4(e) of the Executive order provides that ''when an agency proposes to act through adjudication or rulemaking to preempt State law, the agency shall provide all affected State and local officials notice and an opportunity for appropriate participation in the proceedings.'' FDA's Division of Federal and State Relations is inviting the States' participation in this rulemaking by providing notice via fax and e-mail transmission to State health commissioners, State agriculture commissioners, food program directors, and drug program directors as well as FDA field personnel of FDA's publication of the proposed rule prohibiting the nutrient content claims for ALA, EPA, DHA, and EPA and DHA combined set forth in the three FDAMA notifications received by FDA. The notice provides the States with further opportunity for input on the rule. It advises the States of FDA's publication of the proposed rule and encourages the States and local governments to review the notice of proposed rulemaking and to provide any comments to the docket (Docket No. 2004N–0217, 2005P–0189, or 2006P–0137).

In conclusion, FDA has determined that the preemptive effects of this proposed rule, if finalized as proposed, are consistent with Executive Order 13132.

VIII. Effective Date

FDA is proposing to make this regulation effective on the uniform compliance date for food labeling regulations established by the agency that is applicable to the publication date of the final rule.

IX. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that in January 2008, the FDA Web site is expected to transition to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. After the transition date, electronic submissions will be accepted by FDA through the FDMS only. When the exact date of the transition to FDMS is known, FDA will publish a **Federal Register** notice announcing that date.

X. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen between 9 a.m. and 4 p.m., Monday through Friday, except on Federal Government holidays. (FDA has verified the Web site addresses, but is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

1. Institute of Medicine of the National Academies, ''Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids,'' Summary, Chapter 8, and Chapter 11, the National Academies Press, Washington, DC, 2005.

2. Institute of Medicine of the National Academies, Prepublication Copy, ''Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids,'' Summary, Chapter 8, and Chapter 11, the National Academies Press, Washington, DC, 2002.

3. Carpenter, K.J. and A.E. Harper, ''Evolution of Knowledge of Essential Nutrients,'' in *Modern Nutrition in Health and Disease*, Eds. M.E. Shils, M. Shike, A.C. Ross, B. Caballero, and R.J. Cousins, Philadelphia, P.A.: Lippincott Williams & Wilkins, p. 7, 2006.

4. Stryer, L., *Biochemistry*, Fourth Edition, New York: W.H. Freeman and Co., p. 604, 1995.

5. Alaska General Seafoods, Ocean Beauty Seafoods, Inc., and Trans-Ocean Products, Inc. ''Notification for a Nutrient Content Claim Based on an Authoritative Statement,'' Item CP1, Docket No. 2004N–0217, Division of Dockets Management, May 15, 2004.

6. U.S. Food and Drug Administration, ''Nutrient Content Claims Notification for Choline Containing Foods,'' (*http://www.cfsan.fda.gov/~dms/flcholin.html*) August 30, 2001.

7. Institute of Medicine of the National Academies, ''Dietary Reference Intakes for Thiamin, Riboflavin, Niacin, Vitamin B6, Folate, Vitamin B12, Pantothenic Acid, Biotin, and Choline,'' the National Academies Press, Washington, DC, pp. 390 to 422, 1998.

8. Institute of Medicine of the National Academies, ''Dietary Reference Intakes: Guiding Principles for Nutrition Labeling and Fortification,'' the National Academies Press, Washington, DC, pp. 82 to 95, 2003.

9. Martek Biosciences Corporation, ''Notification for a Nutrient Content Claim Based on an Authoritative Statement,'' Item CP1, Docket 2005P–0189, Division of Dockets Management, May 23, 2005.

10. Ocean Nutrition Canada, ''Notification for a Nutrient Content Claim Based on an Authoritative Statement,'' Item CP1, Docket No. 2006P–0137, Division of Dockets Management, December 9, 2005.

11. A letter from William K. Hubbard, FDA to Jonathan W. Emord, Esq., Emord & Associates, P.C., (*http://www.cfsan.fda.gov/~dms/ds-ltr38.html*), September 8, 2004.

12. A letter from William K. Hubbard, FDA to Martin J. Hahn, Esq., Hogan & Hartson, L.L.P., (*http://www.cfsan.fda.gov/~dms/ds-ltr37.html*), September 8, 2004.

13. Information Resources, Inc., (IRI), download, (*http://www.infores.com/public/us/content/infoscan/fooddrugmass.htm*), 1999.

14. U.S. Department of Agriculture, Agricultural Research Service, USDA National Nutrient Database for Standard Reference, Release 17, Nutrient Data Laboratory Home Page (http://www.nal.usda.gov/fnic/foodcomp), 2004.

15. U.S. Department of Agriculture Economic Research Service, Food Consumption Data System (http://www.ers.usda.gov/data/foodconsumption/Index.htm), 2005.

16. RTI International, ''FDA Labeling Cost Model,'' Prepared for FDA, January, 2003.

17. RTI International, ''Dietary Supplement Sales Information,'' Prepared for FDA, October 1999.

18. Neuhouser, M.L., A.R. Kristal, and R.E. Patterson, ''Use of Food Nutrition Labels Associated with Lower Fat Intake,'' *Journal of the American Dietetic Association*, vol. 53, pp. 45 to 50, 53, 1999.

19. Kim, S., R.M. Nayga, Jr., and O. Capps, Jr., ''The Effect of Food Label Use on Nutrient Intakes: An Endogenous Switching Regression Analysis,'' *Journal of Agricultural and Resource Economics*, vol. 25, pp. 215 to 231, 2000.

20. RTI International, ''Modeling the Decision to Reformulate Food and Cosmetics,'' Prepared for FDA, October 2003.

21. U.S. Food and Drug Administration, ''Summary of Qualified Health Claims Permitted,'' Accessed at *http://www.cfsan.fda.gov/~dms/qhc-sum.html#omega3* on September 26, 2005.

Dated: November 19, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–22991 Filed 11–26–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR PART 1305

[Docket No. DEA—303P]

RIN 1117–AB15

New Single-Sheet Format for U.S. Official Order Form for Schedule I and II Controlled Substances (DEA Form 222)

AGENCY: Drug Enforcement Administration (DEA), Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Drug Enforcement Administration (DEA) is proposing to amend its regulations to implement a new format for order forms (DEA Form 222) which are issued by DEA to DEA registrants to allow them to order schedule I and/or II controlled substances. The present format utilizes a three-part, carbon-copy form with Copies 2 and 3 replicating Copy 1. The proposed format will employ a single-sheet form. The new form will have enhanced security features and will be easier for DEA registrants to use.

DATES: Written comments must be postmarked, and electronic comments must be sent, on or before January 28, 2008.

ADDRESSES: To ensure proper handling of comments, please reference ''Docket No. DEA–303P'' on all written and electronic correspondence. Written comments being sent via regular mail should be sent to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, *Attention:* DEA Federal Register Representative/ODL. Written comments sent via express mail should be sent to DEA Headquarters, *Attention:* DEA Federal Register Representative/ODL, 8701 Morrissette Drive, Springfield, VA 22152. Comments may be sent directly to DEA electronically by sending an electronic message to *dea.diversion.policy@usdoj.gov*. Comments may also be sent electronically through *http://www.regulations.gov* using the electronic comment form provided on that site. An electronic copy of this document is also available at the *http://www.regulations.gov* Web site. DEA will accept electronic comments containing MS Word, WordPerfect, Adobe PDF, or Excel files only. DEA will not accept any file format other than those specifically listed here.

Posting of Public Comments: Please note that all comments received are considered part of the public record and made available for public inspection online at *http://www.regulations.gov* and in the Drug Enforcement Administration's public docket. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter.

If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be posted online or made available in the public docket, you must include the phrase ''PERSONAL IDENTIFYING INFORMATION'' in the first paragraph of your comment. You must also place all the personal identifying information you do not want posted online or made available in the public docket in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be posted online or made available in the public docket, you must include the phrase ''CONFIDENTIAL BUSINESS INFORMATION'' in the first paragraph of your comment. You must also prominently identify confidential business information to be redacted within the comment. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be posted online or made available in the public docket.

Personal identifying information and confidential business information identified and located as set forth above will be redacted and the comment, in redacted form, will be posted online and placed in the Drug Enforcement Administration's public docket file. If you wish to inspect the agency's public docket file in person by appointment, please see the **FOR FURTHER INFORMATION CONTACT** paragraph.

FOR FURTHER INFORMATION CONTACT: Mark W. Caverly, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, Telephone (202) 307–7297.

SUPPLEMENTARY INFORMATION:

Background

Legal Authority

The Drug Enforcement Administration (DEA) administers the Controlled Substances Act (CSA) (21 U.S.C. 801 *et seq.*) as amended. DEA regulations implementing this statute are published in Title 21 of the Code of Federal Regulations (CFR), Parts 1300 to 1316. These regulations are designed to establish a framework for the legal distribution of controlled substances to ensure that there is a sufficient supply of these drugs for legitimate medical purposes while deterring their diversion to illegal purposes. Controlled substances are those substances listed in the schedules of the CSA and 21 CFR 1308.11–1308.15, and generally include narcotics, stimulants, depressants, hallucinogens, and anabolic steroids that have potential for abuse and physical and psychological dependence.

Controlled substances are divided into five schedules. Schedule I substances are drugs which have a high potential for abuse and no currently accepted medical use in treatment in the United States. They may be used only for research, chemical analysis, or manufacture of other drugs. Schedule II substances have legitimate medical uses, but a high potential for abuse and physical and psychological dependence, and are subject to more stringent controls than other legitimate controlled substances. Schedule III through V substances have legitimate medical uses; however, they have a lower potential for abuse and physical and psychological dependence than do schedule II controlled substances.

The CSA and DEA regulations require that persons involved in the manufacture, distribution, research, dispensing, import, and export of controlled substances register with DEA, keep track of all stocks of controlled substances, and maintain records to