Rule

Food Additives Permitted for Direct Addition to Food for Human Consumption; Vitamin D3

A Rule by the Food and Drug Administration on 08/12/2014

ACTION Final Rule.

SUMMARY The Food and Drug Administration (FDA or we) is amending the food additive regulations to provide for the safe use of vitamin D_3 as a nutrient supplement in meal replacement beverages that are not intended for special dietary use in reducing or maintaining body weight and for use in foods that are sole sources of nutrition for enteral feedings. We are taking this action in response to a petition filed by Abbott Laboratories (Abbott).

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Tuesday, August 12, 2014

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Department of Health and Human Services
Food and Drug Administration

Dates:
This rule is effective August 12, 2014. See section VII ``Objections'' for further information on the filing of objections. Submit either electronic or written objections and requests for a hearing by September 11, 2014. The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of August 12, 2014.

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RELATED TOPICS

- Food additives
- Reporting and recordkeeping requirements

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Docket Name
Abbott Laboratories; Filing of Food Additive Petition

Public Comments
1 comment

DATES:

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ADDRESSES:

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You may submit either electronic or written objections and requests for a hearing identified by Docket No. FDA-2012-F-0138, by any of the following methods:

Electronic Submissions

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Submit electronic objections in the following way:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.

Written Submissions

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Submit written objections in the following ways:

- Mail/Hand delivery/Courier (for paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. FDA-2012-F-0138 for this rulemaking. All objections received will be posted without change to *http://www.regulations.gov*, including any personal information provided. For detailed instructions on submitting objections, see the "Objections" heading of the SUPPLEMENTARY INFORMATION section.

Docket: For access to the docket to read background documents or objections received, go to *http://www.regulatio*

ns.gov and insert the docket number, 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:

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Judith Kidwell, Center for Food Safety and Applied Nutrition (HFS-265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835, 240-402-1071.

SUPPLEMENTARY INFORMATION:

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I. Background

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In the **Federal Register** of March 6, 2012 (77 FR 13232), FDA announced that Abbott Laboratories, 3300 Stelzer Rd., Columbus, OH 43219, had filed a food additive petition (FAP 2A4788). The petition proposed that FDA amend the food additive regulations in § 172.380 (21 CFR 172.380), *Vitamin D* $_3$, to provide for the safe use of vitamin D $_3$ as a nutrient supplement in meal replacement beverages and meal replacement bars that are not intended for special dietary use in reducing or maintaining body weight and for use in foods that are sole sources of nutrition for enteral tube feeding. After the document was published, Abbott amended the petition to exclude the proposed use of vitamin D $_3$ in meal replacement bars. This final rule is a complete response to the petition.

Abbott has requested that we amend § 172.380 to authorize the use of vitamin D $_3$ as a nutrient supplement at levels not to exceed 500 International Units (IU) per 240 milliliters (mL) (prepared beverage) in meal replacement beverages that are not intended for special dietary use in reducing or maintaining body weight and that are represented for use such that the total amount of vitamin D $_3$ provided by the product does not exceed 1,000 IU per day, and at levels not to exceed 1.0 IU per kilocalorie (kcal) in food represented for use as a sole source of nutrition for enteral feeding.

Vitamin D comprises a group of fat-soluble seco-sterols and comes in many forms. The two major physiologically relevant forms are vitamin D $_2$ and vitamin D $_3$. Vitamin D without a subscript represents either vitamin D $_2$ or vitamin D $_3$ or both. Vitamin D is affirmed as generally recognized as safe (GRAS) for use in food as a nutrient supplement in § 184.1950(c)(1) (21 CFR 184.1950(c)(1)) in accordance with § 184.1(b)(2) (21 CFR 184.1(b)(2)), with the following specific limitations:

Category of food	Maximum levels in food (as served)
Breakfast cereals	350 IU/100 grams (g).

Grain products and pasta	90 IU/100 g.
Milk	42 IU/100 g.
Milk products	89 IU/100 g.

Additionally, under § 184.1950(c)(2) and (c)(3), vitamin D is affirmed as GRAS for use in infant formulas and margarine, respectively. Under § 172.380, vitamin D_3 is approved for use as a food additive as a nutrient supplement in calcium-fortified fruit juices and fruit juice drinks; meal replacement and other type bars, soy protein-based meal replacement beverages represented for special dietary use in reducing or maintaining body weight; and cheese and cheese products as defined therein. Under § 172.379, vitamin D_2 is approved for use as a food additive as a nutrient supplement in soy beverages, soy beverage products, soy-based butter substitute spreads, and soy-based cheese substitutes and soy-based cheese substitute products. Under § 172.381, vitamin D_2 bakers yeast is approved for use as a food additive as a source of vitamin D_2 and as a leavening agent in yeast-leavened baked goods and baking mixes and yeast-leavened baked snack foods.

Vitamin D is essential for human health. The major function of vitamin D is the maintenance of blood serum concentrations of calcium and phosphorus by enhancing the absorption of these minerals in the small intestine. Vitamin D deficiency can lead to abnormalities in calcium and bone metabolism, such as rickets in children or osteomalacia in adults. Excessive intake of vitamin D elevates blood plasma calcium levels (hypercalcemia) by increased intestinal absorption and/or mobilization from the bone.

To ensure that vitamin D is not added to the U.S. food supply at levels that could raise safety concerns, FDA affirmed vitamin D as GRAS with specific limitations as listed in § 184.1950. Under § 184.1(b)(2), an ingredient affirmed as GRAS with specific limitations may be used in food only within such limitations, including the category of food, functional use of the ingredient, and level of use. Any addition of vitamin D to food beyond those limitations set out in § 184.1950 requires either a food additive regulation or an amendment of § 184.1950.

To support the safety of the proposed uses of vitamin D_3, Abbott submitted dietary exposure estimates of vitamin D from the proposed uses of vitamin D_3, as well as all current dietary sources for four scenarios: (1) Background exposure from naturally occurring sources of vitamin D and currently regulated uses of vitamin D at levels reported in the U.S. Department of Agriculture Food and Nutrient Database for Dietary Studies, which represent typical vitamin D levels in foods; (2) background exposure plus exposure from yeast-

leavened baked goods and baking mixes and yeast-leavened snack foods containing 400 IU vitamin D/100 g food as served (at the time that Abbott submitted their petition, the petition to amend the food additive regulations for the use of vitamin D_2 bakers yeast was under review); (3) background exposure, exposure from yeast-containing baked products containing 400 IU vitamin D/100 g food, and from dietary supplement use; and (4) background exposure, exposure from yeast-containing baked products containing 400 IU vitamin D/100 g food, dietary supplements, and the proposed uses in meal replacement beverages and bars. They compared these intake estimates to the Tolerable Upper Intake Level (UL) for vitamin D established by the Institute of Medicine (IOM) of the National Academies. Abbott also submitted a number of publications pertaining to human clinical studies on vitamin D. Based on this information, which is discussed in section II, Abbott concluded that the proposed uses of vitamin D_3 in meal replacement beverages that are not intended for special dietary use in reducing or maintaining body weight and in foods that are sole sources of nutrition for enteral feeding are safe.

II. Evaluation of Safety

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To establish with reasonable certainty that a food additive is not harmful under its intended conditions of use, we consider the projected human dietary exposure to the additive, the additive's toxicological data, and other relevant information (such as published literature) available to us. We compare an individual's estimated daily intake (EDI) of the additive from all food sources to an acceptable intake level established by toxicological data. The EDI is determined by projections based on the amount of the additive proposed for use in particular foods and on data regarding the amount consumed from all food sources of the additive. We commonly use the EDI for the 90th percentile consumer of a food additive as a measure of high chronic dietary intake.

A. Acceptable Intake Level for Vitamin D

In 1997, the Standing Committee on the Scientific Evaluation of Dietary Reference Intakes of the Food and Nutrition Board at the IOM conducted an extensive review of toxicology and metabolism studies on vitamin D published through 1996. The IOM published a detailed report that included a UL for vitamin D for infants, children, and adults. At that time, the IOM established a UL for vitamin D of 2,000 IU/per day (p/d) for children 1 to 18 years of age and adults, and a UL of 1,000 IU/p/d for all infants.

In 2011, the IOM conducted an extensive review of relevant published scientific literature on vitamin D to update current dietary reference intakes and ULs for vitamin D. Based on this information, the IOM revised the ULs for vitamin D and developed a report on their findings (Ref. 1). In their 2011

assessment of vitamin D, the IOM established a UL of 1,000 IU/p/d for infants 0 months to 6 months of age and a UL of 1,500 IU/p/d for infants 6 months to 12 months of age. For children 1 year to 3 years of age, the IOM established a UL of 2,500 IU/p/d; for children 4 years to 8 years of age, the IOM established a UL of 3,000 IU/p/d. For children 9 years to 18 years of age and adults, the IOM established a UL of 4,000 IU/p/d.

The IOM considers the UL as the highest average daily intake level of a nutrient that poses no risk of adverse effects when the nutrient is consumed over long periods of time. The UL is determined using a risk assessment model developed specifically for nutrients and considers intake from all sources: Food, water, nutrient supplements, and pharmacological agents. The dose-response assessment, which concludes with an estimate of the UL, is built upon three toxicological concepts commonly used in assessing the risk of exposures to chemical substances: No-observed-adverse-effect level, lowest-observed-effect level, and an uncertainty factor.

B. Estimated Daily Intake for Vitamin D

1. Meal Replacement Beverages

For the proposed use of vitamin D_3 in meal replacement beverages that are not intended for special dietary use in reducing or maintaining body weight, Abbott provided dietary intake estimates for vitamin D for seven population groups, assuming typical vitamin D levels in food. Although Abbott stated that their proposed uses do not include products for infants or children less than 9 years of age, Abbott included exposure estimates for children 1 to 3 years of age and 4 to 8 years of age. Because Abbott's exposure estimates differed in several aspects from the way in which we typically calculate dietary exposure, we conducted our own exposure estimate for vitamin D from: (1) The proposed use of vitamin D_3 in meal replacement beverages that are not intended for special dietary use in reducing or maintaining body weight; (2) current food uses of vitamin D (including regulated uses, naturally occurring sources of vitamin D, and dietary supplements); and (3) combined current and proposed food uses. We estimated the exposure to vitamin D for the overall U.S. population (1 year of age and older) and 10 population subgroups (including 2 subgroups for infants less than 12 months of age), assuming that all foods that can be fortified with vitamin D will be fortified at the maximum level permitted.

Our estimated exposure to vitamin D from all food sources for the overall U.S. population (1 years of age and older), including consumers of meal replacement beverages that are not intended for special dietary use in reducing or maintaining body weight, was 1,520 IU per person per day (IU/p/d) for the

90th percentile consumer, based on food consumption data in the 2007-2008 National Health and Nutrition Examination Survey (NHANES). Infants are not expected to consume meal replacement beverages; however, we included these subpopulations in our exposure assessment for completeness. According to the 2007-2008 NHANES, no meal replacement beverage consumption was reported for infants 0 months to 6 months of age, and only very limited consumption of meal replacement beverages was reported for infants 6 to 12 months of age. The cumulative exposure for infants 0 to 6 months of age and infants 6 to 12 months of age from all food sources of vitamin D, including the proposed uses and dietary supplements, was estimated to be 844 IU/p/d and 831 IU/p/d, respectively, for the 90th percentile consumer (Ref. 2).

2. Enteral Feeding Products

For the proposed use of vitamin D_3 for food represented as the sole source of nutrition for enteral feeding, Abbott indicated that there are many different methods available in the scientific literature for estimating caloric needs when using fortified enteral nutrition products as the sole source of nutrition. Abbott reported that the simplest method is to assume that a person requires 25-30 kcal per kilogram body weight per day (kcal/kg bw/d). Thus, a 60 kg person being fed only an enteral nutrition product would require 1,500 kcal to 1,800 kcal per day. Assuming the proposed vitamin D_3 fortification level of 1.0 IU/kcal in enteral products represented for use as the sole source of nutrition and the highest recommended caloric requirement of 30 kcal/kg bw/d, results in an estimated vitamin D_3 exposure of 1,800 IU/p/d for a 60 kg person (Ref. 3). As noted by Abbott, this level is far below the UL of 4,000 IU vitamin D for an adult. In addition, any person receiving vitamin D_3 from an enteral feeding product as their sole source of nutrition would be under the care of a doctor who would be monitoring the patient's vitamin D intake.

C. Safety of the Petitioned Uses of Vitamin D_3

FDA reviewed and evaluated the information submitted by Abbott regarding the safety of the dietary intake of vitamin D_3 that would result from the proposed uses in meal replacement beverages that are not intended for special dietary use in reducing or maintaining body weight and for use in foods that are sole sources of nutrition for enteral feeding. Abbott submitted scientific articles published subsequent to the 1997 IOM report and issuance of the August 29, 2012, final rule (77 FR 52228) authorizing the use of vitamin D_2 bakers yeast in yeast-leavened baked goods and baking mixes and yeast-leavened baked snack foods. Abbott concluded that these

recent publications support the safety of increases in the levels of vitamin D supplementation in humans that could result from the proposed uses. We concur with Abbott's conclusion (Ref. 4).

We considered the ULs established by the IOM relative to the intake estimates as the primary basis for assessing the safety of petitioned uses of vitamin D_3. We also reviewed the scientific articles on vitamin D intake submitted by Abbott, as well as other relevant published studies available to FDA since our previous evaluations of five food additive petitions for fortifying a variety of foods with vitamin D. The most recent petition resulted in our amendment of the food additive regulations in § 172.381 to allow for the safe use of vitamin D_2 bakers yeast as a source of vitamin D_2 and as a leavening agent in yeast-leavened baked goods and baking mixes and yeast-leavened baked snack foods (77 FR 52228, August 29, 2012). The four earlier food additive petitions also resulted in amendments of the food additive regulations to allow for the safe use of vitamin D as a nutrient supplement in certain foods (74 FR 11019, March 16, 2009; 70 FR 69435, November 16, 2005; 70 FR 37255, June 29, 2005; 70 FR 36021, June 22, 2005; and 68 FR 9000, February 27, 2003).

1. Meal Replacement Beverages

Depending on the age group, the IOM UL for vitamin D for the U.S. population 1 year of age and older ranges from 2,500 IU/p/d to 4,000 IU/p/d. The estimated exposure to vitamin D from all food sources, including the proposed use in meal replacement beverages that are not intended for special dietary use in reducing or maintaining body weight, at the 90th percentile for the overall U.S. population (1 years of age and older) is estimated to be 1,520 IU/p/d, which is below the lowest IOM UL in the range of ULs for the overall U.S. population (1 year of age and older), 2,500 IU/p/d. The estimated exposure to vitamin D from all food sources, including the proposed use in meal replacement beverages that are not intended for special dietary use in reducing or maintaining body weight, for infants 0 months to 6 months of age at the 90th percentile is 844 IU/p/d; for infants 6 months to 12 months of age, estimated exposure to vitamin D is 831 IU/p/d. Both of these estimates are below the respective IOM UL of 1,000 IU/p/d for infants 0 months to 6 months of age and 1,500 IU/p/d for infants 6 months to 12 months of age. Because the 90th percentile EDI of vitamin D from all current and proposed food sources for each population group is less than the corresponding IOM UL for that population group, we conclude that dietary intake of vitamin D_3 from the proposed use as a nutrient supplement in meal replacement beverages that are not intended for special dietary use in reducing or maintaining body weight is safe.

2. Enteral Feeding Products

Based on the proposed use level of 1.0 IU/kcal in enteral feeding products, the dietary exposure to vitamin D_3 is estimated to be 1,800 IU/p/d for a 60 kg person. This estimate is below the IOM UL of 4,000 IU/p/d for adults. Because the use of these products are intended for individuals under medical supervision and monitoring by a physician, we have no safety concerns regarding the proposed use of vitamin D_3 in enteral feeding products, and we conclude that this use is safe.

III. Conclusion

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Based on all data relevant to vitamin D_3 that we reviewed, we conclude that the petitioned use of vitamin D_3 as a nutrient supplement in meal replacement beverages that are not intended for special dietary use in reducing or maintaining body weight and for use in foods that are sole sources of nutrition for enteral feeding within the limits proposed by Abbott is safe. Consequently, we are amending the food additive regulations as set forth in this document. Additionally, the current regulation for the use of vitamin D_3 in food (§ 172.380) indicates that the additive must meet the specifications in the Food Chemicals Codex, 7th Edition (FCC 7). The more current FCC is the 8th Edition (FCC 8). Because the specifications for vitamin D_3 in FCC 8 are identical to those in FCC 7, we are amending § 172.380 by adopting the specifications for vitamin D_3 in FCC 8 in place of FCC 7.

IV. Public Disclosure

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In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that we considered and relied upon in reaching our decision to approve the petition will be made available for public disclosure (see FOR FURTHER INFORMATION CONTACT). As provided in § 171.1(h), we will delete from the documents any materials that are not available for public disclosure.

V. Environmental Impact

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We previously considered the environmental effects of this rule, as stated in the March 6, 2012, **Federal Register** document of petition for FAP 2A4788. We stated that we had determined, under 21 CFR 25.32(k), that this action "is of a type that does not individually or cumulatively have a significant effect on the human environment" such that neither an environmental assessment nor an environmental impact statement is required. We have not received any new information or comments that would affect our previous determination.

VI. Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

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VII. Objections

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If you will be adversely affected by one or more provisions of this regulation, you may file with the Division of Dockets Management (see ADDRESSES) either electronic or written objections. You must separately number each objection, and within each numbered objection you must specify with particularity the provision(s) to which you object, and the grounds for your objection. Within each numbered objection, you must specifically state whether you are requesting a hearing on the particular provision that you specify in that numbered objection. If you do not request a hearing for any particular objection, you waive the right to a hearing on that objection. If you request a hearing, your objection must include a detailed description and analysis of the specific factual information you intend to present in support of the objection in the event that a hearing is held. If you do not include such a description and analysis for any particular objection, you waive the right to a hearing on the objection.

It is only necessary to send one set of documents. Identify documents with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov*.

VIII. Section 301(ll) of the Federal Food, Drug, and Cosmetic Act

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Our review of this petition was limited to section 409 of the Federal Food, Drug, and Cosmetic Act (the FD Act) (21 U.S.C. 348). This final rule is not a statement regarding compliance with other sections of the FD Act. For example, the Food and Drug Administration Amendments Act of 2007, which was signed into law on September 27, 2007, amended the FD Act to, among other things, add section 301(*ll*) of the FD Act (21 U.S.C. 331(*ll*)). Section 301(*ll*) of the FD Act prohibits the introduction or delivery for introduction into interstate commerce of any food that contains a drug approved under section 505 of the FD Act (21 U.S.C. 355), a biological product licensed under section 351 of the Public Health Service Act (42 U.S.C. 262), or a drug or biological product for which substantial clinical investigations have been instituted and their existence has been made public, unless one of the exemptions in section 301(*ll*)(1) to (*ll*)(4) of the FD&C Act applies. In our review of this petition, FDA did not consider whether section 301(*ll*) of the FD&C Act or any of its exemptions apply to food containing this additive. Accordingly, this final rule should not be construed to be a statement that a food containing this additive, if introduced or delivered for introduction into interstate commerce, would not violate section 301(*ll*) of the FD&C Act. Furthermore, this language is included in all food additive final rules and

therefore should not be construed to be a statement of the likelihood that section 301(*ll*) of the FD&C Act applies.

IX. References

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The following sources are referred to in this document. References marked with an asterisk (*) have been placed on display at the Division of Dockets Management (see ADDRESSES), under Docket No. FDA-2012-F-0138, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at *http://www.regulations.gov*. References without asterisks are not on display; they are available as published articles and books.

1. Committee to Review Dietary Reference Intakes for Vitamin D and Calcium, Food and Nutrition Board, Institute of Medicine, "Dietary Reference Intakes for Calcium and Vitamin D," National Academies Press, Washington, DC, 2011.

*2. Memorandum from D. Folmer, Chemistry Review Group, Division of Petition Review, to J. Kidwell, Regulatory Group I, Division of Petition Review, December 11, 2013.

*3. Memorandum from D. Folmer, Chemistry Review Group, Division of Petition Review, to J. Kidwell, Regulatory Group I, Division of Petition Review, February 7, 2013.

*4. Memorandum from A. Khan, Toxicology Review Group, Division of Petition Review, to J. Kidwell, Regulatory Group I, Division of Petition Review, February 11, 2014.

List of Subjects in 21 CFR Part 172

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- Food additives
- Incorporation by reference
- Reporting and recordkeeping requirements

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 172 is amended as follows:

begin regulatory text

PART 172—FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

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1. The authority citation for 21 CFR part 172 continues to read as follows:

Authority:

21 U.S.C. 321, 341, 342, 348, 371, 379e.

2. Amend § 172.380 by revising paragraph (b) and by adding

paragraphs (c)(6) and (c)(7) to read as follows:

§ 172.380 Vitamin D

* * * * *

(b) Vitamin D_3 meets the specifications of the Food Chemicals Codex, 8th ed. (2012), pp. 1186-1187, which is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies from the United States Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852 (Internet address *http://www.usp.org*). Copies may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

(c) * * *

(6) At levels not to exceed 500 IU per 240 mL (prepared beverage) in meal replacement beverages that are not intended for special dietary use in reducing or maintaining body weight and that are represented for use such that the total amount of Vitamin D_3 provided by the product does not exceed 1,000 IU per day.

(7) At levels not to exceed 1.0 IU per kilocalorie in foods represented for use as a sole source of nutrition for enteral feeding.

end regulatory text

Dated: August 6, 2014.

Philip L. Chao,

Acting Director, Office of Regulations, Policy and Social Sciences, Center for Food Safety and Applied Nutrition.

[FR Doc. 2014-18969 Filed 8-11-14; 8:45 am]

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