4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. FDA-2015-D-1839]

The Food and Drug Administration's Policy on Declaring Small Amounts of Nutrients and Dietary Ingredients on Nutrition Labels; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA, we, or the Agency) is announcing the availability of a draft guidance for industry entitled "FDA's Policy on Declaring Small Amounts of Nutrients and Dietary Ingredients on Nutrition Labels: Guidance for Industry." The draft guidance, when finalized, will explain to manufacturers of conventional foods and dietary supplements our policy on determining the amount to declare on the nutrition label for certain nutrients and dietary ingredients that are present in a small amount.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on the draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Nutrition, Labeling, and Dietary Supplements, Center for Food Safety and Applied Nutrition (HFS-820), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send two self-addressed adhesive labels to assist the office in processing your request. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance.

Submit electronic comments on the draft guidance to http://www.regulations.gov. Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Carole Adler, Center for Food Safety and Applied Nutrition (HFS-820), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-2371.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a draft guidance for industry entitled "FDA's Policy on Declaring Small Amounts of Nutrients and Dietary Ingredients on Nutrition Labels: Guidance for Industry." We are issuing the draft guidance consistent with our good guidance practices regulation (21 CFR 10.115). The draft guidance represents the current thinking of FDA on our policy on declaring small amounts of nutrients and dietary ingredients on nutrition labels. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

The draft guidance, when finalized, will explain our nutrition labeling policy on declaring the nutrient values in conventional foods and dietary ingredient values in dietary supplements in

certain cases. Specifically, declaring small amounts of nutrients and dietary ingredients in the nutrition labeling may result in a conflict between 21 CFR 101.9(c)(1) through (8) and 21 CFR 101.9(g)(4)(ii) and 21 CFR 101.9(g)(5). In such cases, we are recommending manufacturers declare nutrients and dietary ingredients in accordance with § 101.9(c)(1) through (8). If the draft guidance is finalized, we intend to consider the use of our enforcement discretion with respect to the compliance requirements in § 101.9(g)(4)(ii)) and § 101.9(g)(5) when a conflict exists with § 101.9(c)(1) through (8).

We also are considering whether changes to our nutrition labeling regulations are needed, including changes to § 101.9(c) or (g), or both. If we determine that rulemaking is needed, we will consider whether to revise or withdraw the draft guidance.

II. Paperwork Reduction Act of 1995

The draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in § 101.9 have been approved under OMB control number 0910-0381.

III. Comments

Interested persons may submit either electronic comments regarding the draft guidance to http://www.regulations.gov or written comments regarding the draft guidance to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments 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, and will be posted to the docket at http://www.regulations.gov.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance document at http://www.fda.gov/FoodGuidances or http://www.regulations.gov. Use the FDA Web site listed in the previous sentence to find the most current version of the guidance.

Dated: July 24, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-18655 Filed: 7/29/2015 08:45 am; Publication Date: 7/30/2015]