4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-D-0542]

Guidance for Industry: Distinguishing Liquid Dietary Supplements From Beverages; Availability.

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a guidance for industry entitled "Distinguishing Liquid Dietary Supplements From Beverages." This guidance is intended to help dietary supplement and beverage manufacturers and distributors determine whether a product in liquid form is properly classified as a dietary supplement or as a beverage. This guidance describes the factors that distinguish liquid products that are dietary supplements from those that are conventional foods. Further, this guidance reminds manufacturers and distributors of dietary supplements and beverages about the requirements of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) regarding ingredients and labeling.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Nutrition, Labeling, and Dietary Supplements, Center for Food Safety and Applied Nutrition (HFS-800), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or to the Office of Food Additive Safety, Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send

two self-addressed adhesive labels to assist those offices in processing your request. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance.

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

FOR FURTHER INFORMATION CONTACT: Corey J. Hilmas, Center for Food Safety and Applied Nutrition (HFS-810), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-2375.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a guidance entitled "Guidance for Industry: Distinguishing Liquid Dietary Supplements From Beverages." This guidance is being issued consistent with our good guidance practices regulation (21 CFR 10.115). The guidance represents our current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternate approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

In the Federal Register of December 4, 2009 (74 FR 63759), we made available a draft guidance entitled "Draft Guidance for Industry: Factors That Distinguish Liquid Dietary Supplements From Beverages, Considerations Regarding Novel Ingredients, and Labeling for Beverages and Other Conventional Foods" and gave interested parties an opportunity to submit comments by February 2, 2010, for us to consider before beginning work on the final version of the guidance. The guidance is intended to help dietary supplement and beverage manufacturers

and distributors determine whether a product in liquid form is properly classified as a dietary supplement or as a beverage.

We have observed an increase in the marketing of liquid products with a wide array of ingredients and intended uses. Some of these products are marketed as dietary supplements, and others as conventional foods. In some instances, products may be misbranded because their labeling or other representations made about them are inconsistent with the product category under which they are being marketed. In addition, products may be excluded from the dietary supplement category because of representations that they are for use as conventional foods. The guidance is intended to describe the factors that dietary supplement and beverage manufacturers and distributors should consider when deciding whether to market a liquid product as a dietary supplement or a conventional food. Further, this guidance reminds manufacturers and distributors of dietary supplements and beverages about the requirements of the FD&C Act regarding ingredients and labeling.

We received several comments on the draft guidance and have modified the final guidance where appropriate. In addition, we made editorial changes to improve clarity. The guidance announced in this notice finalizes the draft guidance dated December 2009.

II. Comments

Interested persons may submit either electronic comments regarding the guidance to http://www.regulations.gov or written comments 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.

III. Electronic Access

Persons with access to the Internet may obtain the guidance at either 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: January 8, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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