4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2004-D-0544 (formerly 2004D-0487)]

A Dietary Supplement Labeling Guide: Chapter II. Identity Statement; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a revised guidance for industry entitled "A Dietary Supplement Labeling Guide: Chapter II. Identity Statement." This guidance is part of a longer guidance entitled "A Dietary Supplement Labeling Guide," which covers the most frequently raised questions about the labeling of dietary supplements using a question and answer format and is intended to help ensure that the dietary supplements sold in the United States are properly labeled. We are revising the guidance to correct an inaccurate statement.

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

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to http://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your

comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on http://www.regulations.gov.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2004-D-0544 (formerly 2004D-0487) for "A Dietary Supplement Labeling Guide: Chapter II. Identity Statement: Guidance for Industry." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at

http://www.regulations.gov or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on http://www.regulations.gov. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: http://www.fda.gov/regulatoryinformation/dockets/default.htm.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to http://www.regulations.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.

Submit written requests for single copies of the guidance to the Office of Dietary Supplement Programs, Center for Food Safety and Applied Nutrition (HFS-810), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Cara Welch, 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 revised guidance for industry entitled "A Dietary Supplement Labeling Guide: Chapter II. Identity Statement." We are issuing this guidance consistent with our good guidance practices (GGP) regulation (21 CFR 10.115). As with all FDA guidance, the guidance represents our current thinking on this topic. 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.

In April 2005, we issued a guidance for industry entitled "A Dietary Supplement Labeling Guide." The guidance covers the most frequently raised questions about the labeling of dietary supplements using a question and answer format and is intended to help ensure that the dietary supplements sold in the United States are properly labeled. We recently were made aware that the guidance was inaccurate in one detail. Specifically, in Chapter II, entitled

"Identity Statement," question 3 asked "Can the term 'dietary supplement' by itself be considered the statement of identity?" The response to the question said that it could not, but this response was not consistent with section 403(s)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 343(s)(2)(B)) and our regulations at 21 CFR 101.3(g). Thus, we are revising the guidance to state that the term "dietary supplement" may be used as the entire statement of identity for a dietary supplement and to explain the basis for that conclusion. We are also revising questions 1, 2, and 3 for clarity and consistency with 21 CFR 101.3(g) and FDA's guidance on statements of identity for conventional foods in "A Food Labeling Guide: Guidance for Industry" (available at http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/default.htm). The guidance announced in this notice revises the guidance dated April 2005.

This guidance is being implemented without prior public comment because the Agency has determined that such prior public participation is not feasible or appropriate (§ 10.115(g)(2)). The Agency made this determination because this guidance's primary revision of the existing guidance merely corrects an inaccurate statement to make the guidance consistent with the FD&C Act and FDA's regulations, and it would be inappropriate to solicit comment on whether or not a guidance should be consistent with requirements set forth in the statute and regulations. The guidance also contains other clarifying edits to existing guidance that do not set forth initial or changed interpretations of statutory or regulatory requirements. Although this guidance document is being implemented immediately, it remains subject to comment in accordance with the Agency's GGP regulation (§ 10.115(g)).

II. Electronic Access

Persons with access to the Internet may obtain the guidance at either http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/default.htm 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: March 2, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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