



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-0880]

Frequently Asked Questions About Medical Foods; Second Edition; 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 guidance for industry entitled "Frequently Asked Questions About Medical Foods; Second Edition." FDA published earlier versions of the guidance in May 1997 and May 2007. The second edition of the guidance provides responses to additional questions regarding the definition and labeling of medical foods and updates some prior responses.

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-2013-D-0880 for "Frequently Asked Questions About Medical Foods; Second Edition." 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 Office of Nutrition and Food Labeling, Center for Food Safety and Applied Nutrition (HFS-850), 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: Shawne Suggs-Anderson, Center for Food Safety and Applied Nutrition (HFS-850), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1451.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a guidance for industry, entitled "Frequently Asked Questions About Medical Foods; Second Edition." We are issuing this guidance consistent with our good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA 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 the **Federal Register** of August 13, 2013 (78 FR 49271), we announced the availability of a draft guidance for industry entitled "Frequently Asked Questions About Medical Foods; Second Edition." We invited comment on the draft guidance by October 15, 2013. On November 14, 2013, we reopened the comment period giving interested parties an additional 30 days until December 16, 2013, to submit comments (78 FR 68460).

This guidance is intended to provide industry with a convenient place to find answers to frequently asked questions about medical foods. FDA published earlier versions of the guidance in May 1997 and May 2007. This guidance is a second edition of the May 2007 guidance entitled "Guidance for Industry: Frequently Asked Questions About Medical Foods." The second edition of the guidance provides responses to additional questions regarding the

definition and labeling of medical foods and updates some of the prior responses. The second edition also provides FDA's thinking relating to the labeling of medical foods to be used under supervision by a physician, whether medical foods can be labeled with "Rx Only," and types of diseases and conditions that a medical food could be used to manage.

We received numerous 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 August 2013.

II. Paperwork Reduction Act of 1995

This 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 21 CFR 101.3, 101.4, 101.5, 101.15, and 101.105 have been approved under OMB control number 0910-0381. The collection of information under 21 CFR 1, part 1 subpart H has been approved under OMB control number 0910-0502. The collections of information in 21 CFR 113.100 and 114.100 (a) through (d) have been approved under OMB control number 0910-0037.

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: May 9, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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