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4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Draft Guidance for Industry on Frequently Asked Questions About Medical Foods; Second Edition; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA or we) is reopening the comment period for the draft guidance for industry entitled "Frequently Asked Questions About Medical Foods; Second Edition." We are reopening the comment period in response to requests for an extension to allow interested persons additional time to submit comments.

DATES: Submit either electronic or written comments by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit electronic comments on the draft guidance to http://www.regulations.gov.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: Shawne Suggs-Anderson, Center for Food Safety and Applied Nutrition (HFS-850), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1783.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of August 13, 2013 (78 FR 49271), we published a notice announcing the availability of an updated draft guidance for industry entitled "Frequently Asked Questions About Medical Foods; Second Edition." (We had published earlier versions of the guidance in May 1997 and May 2007.) The draft guidance, when finalized, will update some responses to questions that appeared in earlier versions of the guidance and add new questions and responses regarding the definition, labeling, and availability of medical foods. We invited comment on the draft guidance by October 15, 2013.

II. Request for Comments

Following publication of the August 13, 2013, notice of availability, we received requests for a 60-day extension of the comment period. The requesters explained that they needed more time to review the guidance, develop comments, and assemble data.

If all of the guidance in the August 13, 2013, version were new, a reopening of the comment period for 60 additional days might be warranted. However, much of the draft guidance remains unchanged from our last revision in 2007. The additional content focuses on FDA's thinking relating to use of medical foods under supervision by a physician, whether medical foods should be sold by prescription only, and types of diseases and conditions that a medical food could be used to manage. We are, therefore, reopening the comment period for the draft guidance for an additional 30 days, until [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. We believe that this reopening allows adequate time for interested persons to submit comments without significantly delaying further FDA action on this draft guidance. (We initially intended to extend the comment period, but,

due to the lapse in appropriations and resulting cessation of many government operations from October 1 through October 16, 2013, we were unable to issue a notice extending the comment period before October 15, 2013; consequently, we are reopening the comment period for an additional 30 days.)

III. How to Submit Comments

Interested persons may submit either electronic comments regarding the draft 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 may be posted to the docket at http://www.regulations.gov.

Dated: November 7, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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