to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW., Washington DC 20201. Attn: ACF Reports Clearance Officer. Email address: infocollection@acf.hhs.gov. All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency’s estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis, Reports Clearance Officer. [FR Doc. 2016–11325 Filed 5–12–16; 8:45 am]
BILLING CODE 4184–01–P

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.

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...
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.
[FR Doc. 2016–11268 Filed 5–12–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0221]

Agency Information Collection Activities; Proposed Collection; Submission for Office of Management and Budget Review; Food Labeling; Notification Procedures for Statements on Dietary Supplements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Fax written comments on the collection of information by June 13, 2016.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910–0331. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8450 Colesville Rd., COLD–1457, Silver Spring, MD 20993–0002, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Food Labeling: Notification Procedures for Statements on Dietary Supplements—21 CFR 101.93

OMB Control Number 0910–0331—Extension

Section 403(r)(6) of the FD&C Act (21 U.S.C. 343(r)(6)) and its implementing regulation, 21 CFR 101.93, require that we be notified by the manufacturer, packer, or distributor of a dietary supplement that it is marketing a dietary supplement product that bears on its label or in its labeling a statement provided for in section 403(r)(6) of the FD&C Act. These provisions require that we be notified, with a submission about such statements, no later than 30 days after the first marketing of the dietary supplement. Information that is required in the submission includes: (1) The name and address of the manufacturer, packer, or distributor of the dietary supplement product; (2) the text of the statement that is being made; (3) the name of the dietary ingredient or supplement that is the subject of the statement; (4) the name of the dietary supplement (including the brand name); and (5) the signature of a responsible individual or the person who can certify the accuracy of the information presented, and who must certify that the information contained in the notice is complete and accurate, and that the notifying firm has substantiation that the statement is truthful and not misleading.

We have developed an electronic form (Form FDA 3955) that interested persons will be able to use to electronically submit their notifications to us via FDA’s Unified Registration and Listing System (FURLS). Firms that prefer to submit a paper notification in a format of their own choosing will still have the option to do so, however. Form FDA 3955 prompts a respondent to include certain elements in their structure/function claim notification (SFCN) described in § 101.93 in a standard format electronically and helps the respondent organize their SFCN to include only the information needed for our review of the claim. Note that the SFCN, whether electronic or paper, is used for all claims made pursuant to section 403(r)(6) of the FD&C Act, including nutrient deficiency claims and general well-being claims in addition to structure/function claims. The electronic form, and any optional elements that would be prepared as attachments to the form (e.g., label), can be submitted in electronic format via FURLS. Submissions of SFCNs will continue to be allowed in paper format. We use this information to evaluate whether statements made for dietary