(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In the **Federal Register** of August 13, 2013 (78 FR 49271), we announced the availability of a draft guidance for industry entitled ''Frequently Asked Questions About Medical Foods; Second Edition.'' We invited comment on the draft guidance by October 15, 2013.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We received numerous comments on the draft guidance and have modified the final guidance where appropriate.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 The guidance announced in this notice finalizes the draft guidance dated August 2013.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.*

[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, 8455 Colesville Rd., COLE–14526, 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

ingredients or dietary supplements are permissible under section 403(r)(6) of the FD&C Act. Draft screenshots of Form FDA 3955 and instructions are available for comment at *http://www.fda.gov/Food/DietarySupplements/IndustryInfo/ucm485532.htm*.

*Description of Respondents:* Respondents to this collection of information include manufacturers, packers, or distributors of dietary supplements that bear section 403(r)(6) of the FD&C Act statements on their labels or labeling.

In the **Federal Register** of March 11, 2016 (81 FR 12910), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received one comment in support of the information collection.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

| 21 CFR section | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|---|---|---|---|---|
| 101.93 | 2,200 | 1 | 2,200 | 0.75 (45 minutes) | 1,650 |

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

We believe that there will be minimal burden on the industry to generate information to meet the notification requirements of section 403(r)(6) of the FD&C Act by submitting information regarding section 403(r)(6) of the FD&C Act statements on labels or in labeling of dietary supplements. We also believe that submission via FURLS will not affect the burden estimates. We are requesting only information that is immediately available to the manufacturer, packer, or distributor of the dietary supplement that bears such a statement on its label or in its labeling. We estimate that, each year, approximately 2,200 firms will submit the information required by section 403(r)(6) of the FD&C Act. This estimate is based on the average number of notification submissions received by us in the preceding 3 years. We estimate that a firm will require 0.75 hours to gather the information needed and prepare a communication to us, for a total of 1,650 hours ($2,200 \times 0.75$).

Dated: May 9, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2016–11272 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–2016–N–0001]**

### Advisory Committee; Pulmonary-Allergy Drugs Advisory Committee, Renewal

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; renewal of advisory committee.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the renewal of the Pulmonary-Allergy Drugs Advisory Committee by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Pulmonary-Allergy Drugs Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until May 30, 2018.

**DATES:** Authority for the Pulmonary-Allergy Drugs Advisory Committee will expire on May 30, 2016, unless the Commissioner formally determines that renewal is in the public interest.

**FOR FURTHER INFORMATION CONTACT:** Cindy Hong, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, *PADAC@fda.hhs.gov*.

**SUPPLEMENTARY INFORMATION:** Issued in 41 CFR 102–3.65 and approval by the Department of Health and Human Services issued in 45 CFR part 11 and by the General Services Administration, FDA is announcing the renewal of the Pulmonary-Allergy Drugs Advisory Committee. The committee is a discretionary Federal advisory committee established to provide advice to the Commissioner. The Pulmonary-Allergy Drugs Advisory Committee advises the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective drugs for human use and, as required, any other product for which the Food and Drug Administration has regulatory responsibility. The Committee reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of pulmonary disease and diseases with allergic and/or immunologic mechanisms and makes appropriate recommendations to the Commissioner of Food and Drugs.

The Committee shall consist of a core of 11 voting members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of pulmonary medicine, allergy, clinical immunology, and epidemiology or statistics. Members will be invited to serve for overlapping terms of up to four years. Almost all non-Federal members of this committee serve as Special Government Employees. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee may include one non-voting member who is identified with industry interests.

Further information regarding the most recent charter and other information can be found at *http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/Pulmonary-AllergyDrugsAdvisoryCommittee/ucm107567.htm* or by contacting the Designated Federal Officer (see **FOR FURTHER INFORMATION CONTACT**). Since no change has been made to the committee name or description of duties, no amendment will be made to 21 CFR 14.100.

This document is issued under the Federal Advisory Committee Act (5 U.S.C. app.). For general information related to FDA advisory committees, please visit us at *http://www.fda.gov/AdvisoryCommittees/default.htm*.