

Dated: November 12, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2013-27503 Filed 11-15-13; 8:45 am]

BILLING CODE 4160-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2013-N-1119]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Food Canning Establishment Registration, Process Filing, and Recordkeeping for Acidified Foods and Thermally Processed Low-Acid Foods in Hermetically Sealed Containers; Extension of Comment Period

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

**ACTION:** Notice; extension of comment period.

**SUMMARY:** The Food and Drug Administration (FDA or we) is extending the comment period for the information collection entitled “Food Canning Establishment Registration, Process Filing, and Recordkeeping for Acidified Foods and Thermally Processed Low-Acid Foods in Hermetically Sealed Containers” that appeared in the *Federal Register* of September 18, 2013 (78 FR 57391). In the notice requesting comment on the proposed information collection, we requested comments on the information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA). We are taking this action in response to a request for an extension to allow interested persons additional time to submit comments on the proposed information collection.

**DATES:** FDA is extending the comment period on the proposed information collection. Submit either electronic or written comments by February 18, 2014.

**ADDRESSES:** Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the 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, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In the *Federal Register* of September 18, 2013 (78 FR 57391), FDA published a notice with a 60-day comment period to request comment on a proposed collection of information related to “Food Canning Establishment Registration, Process Filing, and Recordkeeping for Acidified Foods and Thermally Processed Low-Acid Foods in Hermetically Sealed Containers.” Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval.

We have received a request to extend the comment period for the proposed collection of information. The request noted that we intend to issue a draft guidance document further explaining the forms that are the subject of the collection of information and requested that the comment period for the proposed collection of information be extended to match the comment period that will be announced in a future notice requesting comments on such a draft guidance document. The requestor expected that a likely comment period for the draft guidance would be 60 days.

We have considered the request and are extending the comment period for the information collection for 90 days, until February 18, 2014. We believe that a 90-day extension allows adequate time for interested persons to submit comments without significantly delaying our submission of the proposed collection of information to OMB for review under the PRA. We are not granting the specific request to extend the comment period to match the date when we publish a notice of availability for a related draft guidance because we cannot say with certainty when that notice will publish. However, we expect to issue that notice in a timely manner such that we would

announce a comment period until approximately February 18, 2014. In addition, we note that comments are welcome on guidance documents at any time (21 CFR 10.115(g)(5)).

##### II. Request for Comments

Interested persons may submit either electronic comments regarding this document 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 will be posted to the docket at <http://www.regulations.gov>.

Dated: November 13, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2013-N-0878]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Premarket Notification for a New Dietary Ingredient

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or we) 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.

**DATES:** Fax written comments on the collection of information by December 18, 2013.

**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](mailto:oira_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0330. 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, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, [PRAStaff@fda.hhs.gov](mailto: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.

**Premarket Notification for a New Dietary Ingredient (NDI)—21 CFR 190.6 (OMB Control Number 0910-0330)—Extension**

Section 413(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 350b(a)) provides that at least 75 days before the introduction or delivery for introduction into interstate commerce of a dietary supplement that contains an NDI, a manufacturer or distributor of dietary supplements or of an NDI is to submit to us (as delegate for the Secretary of Health and Human Services) information upon which the manufacturer or distributor has based its conclusion that a dietary supplement containing an NDI will reasonably be expected to be safe. Part 190 (21 CFR part 190) implements these statutory provisions. Section 190.6(a) requires each manufacturer or distributor of a dietary supplement containing an NDI, or of an NDI, to submit to the Office of Nutrition, Labeling, and Dietary Supplements notification of the basis for their conclusion that said supplement or ingredient will reasonably be expected to be safe. Section 190.6(b) requires that the notification include the following: (1) The complete name and address of the manufacturer or distributor, (2) the name of the NDI, (3) a description of the dietary supplements that contain the NDI, and (4) the history of use or other evidence of safety establishing that the dietary ingredient will reasonably be expected to be safe.

The notification requirements described previously are designed to

enable us to monitor the introduction into the food supply of NDIs and dietary supplements that contain NDIs, in order to protect consumers from the introduction of unsafe dietary supplements into interstate commerce. We use the information collected under these regulations to help ensure that a manufacturer or distributor of a dietary supplement containing an NDI is in full compliance with the FD&C Act. We are currently developing an electronic means for submitting this information.

*Description of Respondents:* The respondents to this collection of information are firms in the dietary supplement industry, including dietary supplement and dietary ingredient manufacturers, packagers and re-packagers, holders, labelers and re-labelers, distributors, warehouses, exporters, and importers.

In the **Federal Register** of August 26, 2013 (78 FR 52773), FDA published a 60-day notice requesting public comment on the proposed collection of information; two comments were received with one containing multiple comments. Some comments were outside the scope of the four collection of information topics being solicited and therefore will not be discussed in this document.

One comment suggested providing drop-down menus to facilitate data entry. FDA appreciates this suggestion and will continue to consider various configurations for submitting information in electronic form that are most effective and efficient for respondents. Another comment stated that FDA’s estimate of 20 hours per notification is not accurate. The comment indicated that 40 to 60 hours were required to extract and summarize relevant information from the firm’s files, and that an additional 20 to 40 hours was needed to format the information to meet NDI requirements. FDA deliberated over this comment, but believes that collecting and compiling

data under applicable regulatory requirements for the premarket notification program places a minimal burden on respondents. As noted both in our August 26, 2013, notice and in this document, § 190.6(a) requires each manufacturer or distributor of an NDI, or dietary supplement containing an NDI, to submit notification of the basis for their conclusion that the supplement or ingredient will reasonably be expected to be safe. Because we are requesting only that information that the manufacturer or distributor should have already developed, we believe that 20 hours per submission is an appropriate burden estimate.

Both comments note that in the **Federal Register** of July 5, 2011 (76 FR 39111), FDA issued a draft guidance entitled “Dietary Supplements: New Dietary Ingredient Notifications and Related Issues” (available at <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/DietarySupplements/ucm257563.htm>) and suggested that FDA underestimated the reporting burden of the notification procedures under § 190.6 because we failed to take into account the provisions of the draft guidance. FDA considered this response but submits that the notification procedure requirements set forth in its regulations at § 190.6 remain unchanged. The collection of information in this instant analysis is exclusive of the draft guidance and pertains only to the subject regulations. However, as stated in the notice of availability for the draft guidance, FDA does intend to publish a 60-day notice inviting comment on the information collection burden associated with that document and will carefully evaluate all comments it receives.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

| 21 CFR section | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|----------------|-----------------------|------------------------------------|------------------------|-----------------------------|-------------|
| 190.6          | 55                    | 1                                  | 55                     | 20                          | 1,100       |

<sup>1</sup> 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 data to meet the requirements of the premarket notification program because we are requesting only that information that the manufacturer or distributor should already have developed to satisfy itself that a dietary supplement

containing an NDI is in full compliance with the FD&C Act. In the past, commenters argued that our burden estimate is too low. Section 190.6(a) requires each manufacturer or distributor of a dietary supplement containing an NDI, or of an NDI, to submit notification of the basis for their

conclusion that said supplement or ingredient will reasonably be expected to be safe. Section 190.6 requests simply the extraction and summarization of the safety data that should have already been developed by the manufacturer or distributor. Thus, we estimate that extracting and summarizing the relevant

information from the company's files, and presenting it in a format that will meet the requirements of section 413 of the FD&C Act will require a burden of approximately 20 hours of work per submission.

We estimate that 55 respondents will submit one premarket notification each and that it will take a respondent 20 hours to prepare the notification, for a total of 1,100 hours. The estimated number of premarket notifications and hours per response is an average based on our experience with notifications received during the last 3 years and information from firms that have submitted recent premarket notifications.

Dated: November 13, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2013-27536 Filed 11-15-13; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Office of the Director, National Institutes of Health; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Recombinant DNA Advisory Committee.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

*Name of Committee:* Recombinant DNA Advisory Committee.

*Date:* December 4-5, 2013.

*Time:* December 04, 2013, 12:30 p.m. to 5:45 p.m.

*Agenda:* The NIH Recombinant DNA Advisory Committee (RAC) will review and discuss selected human gene transfer protocols and related data management activities. Please check the meeting agenda at OBA Meetings Page (available at the following URL: [http://oba.od.nih.gov/rdna\\_rac/rac\\_meetings.html](http://oba.od.nih.gov/rdna_rac/rac_meetings.html)) for more information.

*Place:* National Institutes of Health, Rockledge II, Conference Room 9100, 6701 Rockledge Drive, Bethesda, MD 20892.

*Time:* December 05, 2013, 8:30 a.m. to 12:45 p.m.

*Agenda:* The NIH Recombinant DNA Advisory Committee (RAC) will review and discuss selected human gene transfer protocols and related data management activities. Please check the meeting agenda at OBA Meetings Page (available at the

following URL: [http://oba.od.nih.gov/rdna\\_rac/rac\\_meetings.html](http://oba.od.nih.gov/rdna_rac/rac_meetings.html)) for more information.

*Place:* National Institutes of Health, Rockledge II, Conference Room 9100, 6701 Rockledge Drive, Bethesda, MD 20892.

*Contact Person:* Chezelle George, Office of Biotechnology Activities, Office of Science Policy/OD, National Institutes of Health, 6705 Rockledge Drive, Room 750, Bethesda, MD 20892, 301-496-9838, [georgec@od.nih.gov](mailto:georgec@od.nih.gov).

Information is also available on the Institute's/Center's home page: <http://oba.od.nih.gov/rdna/rdna.html>, where an agenda and any additional information for the meeting will be posted when available.

OMB's "Mandatory Information Requirements for Federal Assistance Program Announcements" (45 FR 39592, June 11, 1980) requires a statement concerning the official government programs contained in the Catalog of Federal Domestic Assistance. Normally NIH lists in its announcements the number and title of affected individual programs for the guidance of the public. Because the guidance in this notice covers virtually every NIH and Federal research program in which DNA recombinant molecule techniques could be used, it has been determined not to be cost effective or in the public interest to attempt to list these programs. Such a list would likely require several additional pages. In addition, NIH could not be certain that every Federal program would be included as many Federal agencies, as well as private organizations, both national and international, have elected to follow the NIH Guidelines. In lieu of the individual program listing, NIH invites readers to direct questions to the information address above about whether individual programs listed in the Catalog of Federal Domestic Assistance are affected.

(Catalogue of Federal Domestic Assistance Program Nos. 93.14, Intramural Research Training Award; 93.22, Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds; 93.232, Loan Repayment Program for Research Generally; 93.39, Academic Research Enhancement Award; 93.936, NIH Acquired Immunodeficiency Syndrome Research Loan Repayment Program; 93.187, Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds, National Institutes of Health, HHS)

Dated: November 12, 2013.

**Carolyn A. Baum,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2013-27455 Filed 11-15-13; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Performance Review Board Members

Title 5, U.S.C. Section 4314(c)(4) of the Civil Service Reform Act of 1978, Public Law 95-454, requires that the appointment of Performance Review Board Members be published in the **Federal Register**.

The following persons may be named to serve on the Performance Review Boards or Panels, which oversee the evaluation of performance appraisals of Senior Executive Service members of the Department of Health and Human Services.

| LAST NAME             | FIRST NAME |
|-----------------------|------------|
| ETZINGER .....        | MICHAEL    |
| CLARK .....           | WESTLEY    |
| HENDRIKSSON .....     | MARLA      |
| DEL VECCHIO .....     | PAOLO      |
| ENOMOTO .....         | KANA       |
| DELPHIN-RIITMON ..... | MIRIAM     |
| HARDING .....         | FRANCES    |
| DELANY .....          | PETER      |
| BEADLE .....          | MIRTHA     |
| KADE .....            | DARYL      |
| POWER .....           | KATHRYN    |
| BENOR .....           | DAVID      |
| FLEMING .....         | MARY       |

**Michael Etzinger,**

*Executive Officer and Director, Office of Management, Technology and Operations.*

**Janine Denis Cook,**

*Chemist, Division of Workplace Programs, Center for Substance Abuse Prevention, Substance Abuse and Mental Health Services Administration.*

[FR Doc. 2013-27423 Filed 11-15-13; 8:45 am]

**BILLING CODE 4151-17-P**

## DEPARTMENT OF HOMELAND SECURITY

### Federal Emergency Management Agency

[Docket ID: FEMA-2013-0047; OMB No. 1660-NEW]

#### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Federal Emergency Management Agency, DHS.

**ACTION:** Notice.

**SUMMARY:** The Federal Emergency Management Agency, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on a new information collection. In accordance with the Paperwork Reduction Act of 1995, this notice seeks comments concerning the Salesforce Customer Relationship Management System.

**DATES:** Comments must be submitted on or before January 17, 2014.

**ADDRESSES:** To avoid duplicate submissions to the docket, please use only one of the following means to submit comments: