

**LeRoy A. Richardson,**

*Chief, Information Collection Review Office,  
Office of Scientific Integrity, Office of the  
Associate Director for Science, Office of the  
Director, Centers for Disease Control and  
Prevention.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Performance Review Board Members

**AGENCY:** Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** The Centers for Disease Control and Prevention (CDC) located within the Department of Health and Human Services (HHS) is publishing the names of the Performance Review Board Members who are reviewing performance for Fiscal Year 2013.

**FOR FURTHER INFORMATION CONTACT:** Sharon O'Brien, Deputy Director, Executive and Scientific Resources Office, Human Capital and Resources Management Office, Centers for Disease Control and Prevention, 4770 Buford Highway NE., Mailstop K-15, Atlanta, Georgia 30341, Telephone (770) 488-1781.

**SUPPLEMENTARY INFORMATION:** Title 5, U.S.C. 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 will serve on the CDC Performance Review Boards or Panels, which will oversee the evaluation of performance appraisals of Senior Executive Service members for the Fiscal Year 2013 review period:

Christine Branche, Co-Chair  
James Seligman, Co-Chair  
Barbara Bowman  
Janet Collins  
Hazel Dean  
Jane Gentleman  
Joseph Henderson  
Jennifer Parker  
Tanja Popovic  
Steve Redd  
Tom Sinks  
Kevin Smagh

Dated: November 8, 2013.

#### Stacey Hoffman,

*Acting Director, Division of Executive  
Secretariat, Centers for Disease Control and  
Prevention.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2013-N-1394]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry on Special Protocol Assessment

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection in the guidance for industry on special protocol assessment.

**DATES:** Submit either electronic or written comments on the collection of information by January 17, 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, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** 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. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

#### Guidance for Industry on Special Protocol Assessment—(OMB Control Number 0910-0470)—Extension

The "Guidance for Industry on Special Protocol Assessment" describes Agency procedures to evaluate issues related to the adequacy (e.g., design, conduct, analysis) of certain proposed studies. The guidance describes procedures for sponsors to request special protocol assessment and for the Agency to act on such requests. The guidance provides information on how the Agency interprets and applies provisions of the Food and Drug Administration Modernization Act of 1997 and the specific Prescription Drug User Fee Act of 1992 (PDUFA) goals for special protocol assessment associated with the development and review of PDUFA products. The guidance describes the following two collections of information: (1) The submission of a notice of intent to request special protocol assessment of a carcinogenicity protocol and (2) the submission of a request for special protocol assessment.

#### Notification for a Carcinogenicity Protocol

As described in the guidance, a sponsor interested in Agency assessment of a carcinogenicity protocol should notify the appropriate division in FDA's Center for Drug Evaluation and Research (CDER) or the Center for Biologics Evaluation and Research (CBER) of an intent to request special protocol assessment at least 30 days

prior to submitting the request. With such notification, the sponsor should submit relevant background information so that the Agency may review reference material related to carcinogenicity protocol design prior to receiving the carcinogenicity protocol.

#### *Request for Special Protocol Assessment*

The guidance asks that a request for special protocol assessment be submitted as an amendment to the investigational new drug application (IND) for the underlying product and that it be submitted to the Agency in triplicate with Form FDA 1571 attached. The guidance also suggests that the sponsor submit the cover letter to a request for special protocol assessment via facsimile to the appropriate division in CDER or CBER. Agency regulations (21 CFR 312.23(d)) state that information provided to the Agency as part of an IND is to be submitted in triplicate and with the appropriate cover form, Form FDA 1571. An IND is submitted to FDA under existing regulations in part 312 (21 CFR part 312), which specifies the information that manufacturers must submit so that FDA may properly evaluate the safety and effectiveness of investigational drugs and biological products. The information collection requirements resulting from the preparation and submission of an IND under part 312 have been estimated by FDA and the reporting and recordkeeping burden has been approved by OMB under OMB control number 0910-0014.

FDA suggests that the cover letter to the request for special protocol assessment be submitted via fax to the appropriate division in CDER or CBER to enable Agency staff to prepare for the arrival of the protocol for assessment. The Agency recommends that a request for special protocol assessment be submitted as an amendment to an IND for two reasons: (1) To ensure that each

request is kept in the administrative file with the entire IND and (2) to ensure that pertinent information about the request is entered into the appropriate tracking databases. Use of the information in the Agency's tracking databases enables the appropriate Agency official to monitor progress on the evaluation of the protocol and to ensure that appropriate steps will be taken in a timely manner.

The guidance recommends that the following information should be submitted to the appropriate Center with each request for special protocol assessment so that the Center may quickly and efficiently respond to the request:

- Questions to the Agency concerning specific issues regarding the protocol; and
- All data, assumptions, and information needed to permit an adequate evaluation of the protocol, including: (1) The role of the study in the overall development of the drug; (2) information supporting the proposed trial, including power calculations, the choice of study endpoints, and other critical design features; (3) regulatory outcomes that could be supported by the results of the study; (4) final labeling that could be supported by the results of the study; and (5) for a stability protocol, product characterization and relevant manufacturing data.

*Description of Respondents:* A sponsor, applicant, or manufacturer of a drug or biologic product regulated by the Agency under the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act (42 U.S.C. 262) who requests special protocol assessment.

*Burden Estimate:* Table 1 of this document provides an estimate of the annual reporting burden for notifications for a carcinogenicity protocol and requests for a special protocol assessment.

*Notification for a Carcinogenicity Protocol.* Based on the number of notifications for carcinogenicity protocols and the number of carcinogenicity protocols currently submitted to CDER and CBER, CDER estimates that it will receive approximately 50 notifications of an intent to request special protocol assessment of a carcinogenicity protocol per year from approximately 23 sponsors. CBER estimates that it will receive approximately one notification of an intent to request special protocol assessment of a carcinogenicity protocol per year from approximately one sponsor. The hours per response, which is the estimated number of hours that a sponsor would spend preparing the notification and background information to be submitted in accordance with the guidance, is estimated to be approximately 8 hours.

*Requests for Special Protocol Assessment.* Based on the number of requests for special protocol assessment currently submitted to CDER and CBER, CDER estimates that it will receive approximately 300 requests for special protocol assessment per year from approximately 145 sponsors. CBER estimates that it will receive approximately 14 requests from approximately 11 sponsors. The hours per response is the estimated number of hours that a respondent would spend preparing the information to be submitted with a request for special protocol assessment, including the time it takes to gather and copy questions to be posed to the Agency regarding the protocol and data, assumptions, and information needed to permit an adequate evaluation of the protocol. Based on the Agency's experience with these submissions, FDA estimates approximately 15 hours on average would be needed per response.

FDA estimates the burden of this collection as follows:

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

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Notification for carcinogenicity protocols .....	24	2.1	51	8	408
Requests for special protocol assessment .....	156	2	314	15	4,710
Total .....					5,118

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: November 12, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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

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## 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.