

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.

**Authority:** 22 U.S. Code 7104 and 22 U.S. Code 7105(c)(4).

**Mary B. Jones,**  
ACF/OPRE Certifying Officer.

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2019-N-2778]

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Threshold of Regulation for Substances Used in Food-Contact Articles**

**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 6, 2019.

**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 0910-0298. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, *PRASStaff@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.

**Threshold of Regulation for Substances Used in Food-Contact Articles—21 CFR 170.39**

*OMB Control Number 0910-0298—Extension*

Under section 409(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 348(a)), the use of a food additive is deemed unsafe unless one of the following is applicable: (1) It conforms to an exemption for investigational use under section 409(j) of the FD&C Act; (2) it conforms to the terms of a regulation prescribing its use; or (3) in the case of a food additive that meets the definition of a food-contact substance in section 409(h)(6) of the FD&C Act, there is either a regulation authorizing its use in accordance with section 409(a)(3)(A) or an effective notification in accordance with section 409(a)(3)(B).

The regulations in § 170.39 (21 CFR 170.39) established a process that provides the manufacturer with an opportunity to demonstrate that the likelihood or extent of migration to food of a substance used in a food-contact article is so trivial that the use need not be the subject of a food additive listing regulation or an effective notification.

The Agency has established two thresholds for the regulation of substances used in food-contact articles. The first exempts those substances used in food-contact articles where the resulting dietary concentration would be at or below 0.5 part per billion. The second exempts regulated direct food additives for use in food-contact articles where the resulting dietary exposure is 1 percent or less of the acceptable daily intake for these substances.

To determine whether the intended use of a substance in a food-contact article meets the threshold criteria, certain information specified in § 170.39(c) must be submitted to FDA. This information includes the following components: (1) The chemical composition of the substance for which the request is made; (2) detailed information on the conditions of use of the substance; (3) a clear statement of the basis for the request for exemption from regulation as a food additive; (4) data that will enable FDA to estimate the daily dietary concentration resulting from the proposed use of the substance; (5) results of a literature search for toxicological data on the substance and its impurities; and (6) information on the environmental impact that would result from the proposed use. We use this information to determine whether the food-contact substance meets the threshold criteria.

*Description of Respondents:* Respondents to this information collection are individual manufacturers and suppliers of substances used in food-contact articles (*i.e.*, food packaging and food processing equipment) or of the articles themselves.

In the **Federal Register** of June 21, 2019 (84 FR 29209), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

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

21 CFR 170.39	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Threshold of regulation for substances used in food-contact articles .....	7	1	7	48	336

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

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments. We estimate that approximately seven requests per year

will be submitted under the threshold of regulation exemption process of § 170.39, for a total of 336 hours. In the **Federal Register** of June 21, 2019, we estimated four requests per year. In

reconsideration of the two to three requests that were received but did not become effective, we retain our previous estimate of seven requests per year, with

four of those requests becoming effective.

The threshold of regulation process offers one advantage over the premarket notification process for food-contact substances established by section 409(h) of FD&C Act (OMB control number 0910-0495) in that the use of a substance exempted by FDA is not limited to only the manufacturer or supplier who submitted the request for an exemption. Other manufacturers or suppliers may use exempted substances in food-contact articles as long as the conditions of use (e.g., use levels, temperature, type of food contacted, etc.) are those for which the exemption was issued. As a result, the overall burden on both Agency and the regulated industry would be significantly less in that other manufacturers and suppliers would not have to prepare, and we would not have to review, similar submissions for identical components of food-contact articles used under identical conditions. Manufacturers and other interested persons can easily access an up-to-date list of exempted substances, which is on display at FDA's Dockets Management Staff and on the internet at <https://www.fda.gov/food/packaging-food-contact-substances-fcs/threshold-regulation-exemptions-substances-used-food-contact-articles>. Having the list of exempted substances publicly available decreases the likelihood that a company would submit a food additive petition or a notification for the same type of food-contact application of a substance for which the Agency has previously granted an exemption from the food additive listing regulation requirement.

Dated: October 23, 2019.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2019-N-2312]

#### Request for Nominations From Industry Organizations Interested in Participating in the Selection Process for Nonvoting Industry Representatives and Request for Nominations for Nonvoting Industry Representatives on the Allergenic Products Advisory Committee

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is requesting that any industry organizations interested in participating in the selection of a nonvoting industry representative to serve on the Allergenic Products Advisory Committee (APAC) for the Center for Biologics Evaluation and Research notify FDA in writing. FDA is also requesting nominations for a nonvoting industry representative(s) to serve on the APAC. A nominee may either be self-nominated or nominated by an organization to serve as a nonvoting industry representative. Nominations will be accepted for current vacancies effective with this notice.

**DATES:** Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests must send a letter stating that interest to FDA by December 6, 2019 (see sections I and II of this document for further details). Concurrently, nomination materials for prospective candidates should be sent to FDA by December 6, 2019.

**ADDRESSES:** All statements of interest from industry organizations interested in participating in the selection process of nonvoting industry representative nominations should be sent via email to Prabhakara Atreya (see **FOR FURTHER INFORMATION CONTACT**). All nominations for nonvoting industry representatives must be submitted electronically by accessing the FDA Advisory Committee Membership Nomination Portal: <https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm>. Information about becoming a member of an FDA advisory committee can also be obtained by visiting FDA's website at: <http://www.fda.gov/AdvisoryCommittees/default.htm>.

**FOR FURTHER INFORMATION CONTACT:**

Prabhakara Atreya, Division of Scientific Advisors and Consultants, Center for Biologics Evaluation and Research, 10903 New Hampshire Ave., Bldg. 71, Rm. 6306, Silver Spring, MD 20993-0002, 240-402-8006, Fax: 301-595-1307, email: [Prabhakara.Atreya@fda.hhs.gov](mailto:Prabhakara.Atreya@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** The Agency intends to add a nonvoting industry representative(s) to the following advisory committee:

#### I. Allergenic Products Advisory Committee

The APAC reviews and evaluates data concerning the safety, effectiveness, and adequacy of labeling of marketed and investigational allergenic biological products or materials that are

administered to humans for the diagnosis, prevention, or treatment of allergies and allergic diseases, and makes appropriate recommendations to the Commissioner of Food and Drugs (the Commissioner) of its findings regarding the affirmation or revocation of biological product licenses; on the safety, effectiveness, and labeling of the products; on clinical and laboratory studies of such products; on amendments or revisions to regulations governing the manufacture, testing, and licensing of allergenic biological products; and on the quality and relevance of FDA's research programs which provide the scientific support for regulating these agents.

#### II. Selection Procedure

Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests should send a letter via email stating that interest to the FDA contact (see **FOR FURTHER INFORMATION CONTACT**) within 30 days of publication of this document (see **DATES**). Within the subsequent 30 days, FDA will send a notification to each organization that has expressed an interest, attaching a complete list of all such organizations; and a list of all nominees along with their current resumes. The letter will also state that it is the responsibility of the interested organizations to confer with one another and to select a candidate, within 60 days after the receipt of the FDA letter, to serve as the nonvoting member to represent industry interests for the APAC. The interested organizations are not bound by the list of nominees in selecting a candidate. However, if no individual is selected within 60 days, the Commissioner will select the nonvoting member to represent industry interests.

#### III. Application Procedure

Individuals may self-nominate, and/or an organization may nominate one or more individuals to serve as a nonvoting industry representative. Contact information, a current curriculum vitae, and the name of the committee of interest should be sent to the FDA Advisory Committee Membership Nomination Portal (see **ADDRESSES**) within 30 days of publication of this document (see **DATES**). FDA will forward all nominations to the organizations expressing interest in participating in the selection process for the committee. (Persons who nominate themselves as nonvoting industry representatives will not participate in the selection process).

FDA seeks to include the views of women and men, members of all racial