

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN¹

| Activity | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|-----------------------|------------------------------------|------------------------|-----------------------------|-------------|
| Meeting Requests | | | | | |
| Combining and Sending Meeting Request Letters for Manufacturers, Importers, and Researchers | 67 | 1 | 67 | 10 | 670 |
| Meeting Information Packages | | | | | |
| Combining and Submitting Meeting Information Packages for Manufacturers, Importers, and Researchers | 67 | 1 | 67 | 18 | 1,206 |
| Total | | | | | 1,876 |

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

FDA's estimate of the number of respondents for meeting requests in Table 1 of this document is based on the number of meeting requests to be received over the next 3 years.

In the next three years of this collection, FDA estimates that 67 pre-application meetings will be requested. The number is not expected to change, as the public is more experienced in submitting applications for substantial equivalence, requests for non-substantial equivalence, etc.

Thus, FDA estimates the number of manufacturers, importers, researchers, and investigators who are expected to submit meeting requests in Table 1 of this document to be 67 (50 year 1 requests + 100 year 2 requests + 50 year 3 requests divided by 3). The hours per response, which is the estimated number of hours that a respondent would spend preparing the information recommended by this guidance to be submitted with a meeting request is estimated to be approximately 10 hours each, and the total burden hours are 670 hours (10 hours preparation/ mailing times 67 average respondents per year). Based on FDA's experience, the Agency expects it will take respondents this amount of time to prepare, gather, copy, and submit brief statements about the product and a description of the purpose and details of the meeting.

FDA's estimate of the number of respondents for compiling meeting information packages in Table 1 of this document is based on 67 respondents each preparing copies of their information package and submitting them to FDA, for a total of 1,206 hours annually. The hours per response, which is the estimated number of hours that a respondent would spend preparing the information package as recommended by the guidance, is estimated to be approximately 18 hours per information package. Based on FDA's experience, the Agency expects

that it will take respondents 1,206 hours of time (67 respondents times 18 hours) to gather, copy, and submit brief statements about the product, a description of the details of the anticipated meeting, and data and information that generally would already have been generated for the planned research and/or product development.

The total number of burden hours for this collection of information is 1,876 hours (67 hours to prepare and submit meeting requests and 1,206 hours to prepare and submit information packages).

Dated: September 11, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-23332 Filed 9-16-15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0021]

Agency Information Collection Activities; Proposed Collection; Comment Request; Substances Generally Recognized as Safe; Notification Procedure

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) 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 provisions of the Notification Procedure for Substances Generally Recognized as Safe (GRAS).

DATES: Submit either electronic or written comments on the collection of information by November 16, 2015.

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, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, PRAStaff@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, we are publishing this notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, we invite 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 our 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.

Substances Generally Recognized as Safe: Notification Procedure—21 CFR 170.36 and 570.36

(OMB Control Number 0910–0342)—
Extension

Section 409 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 348) establishes a premarket approval requirement for “food additives”;

section 201(s) of the FD&C Act (21 U.S.C. 321(s)) provides an exclusion to the definition of “food additive” and thus from the premarket approval requirement, for uses of substances that are GRAS by qualified experts. In the **Federal Register** of April 17, 1997 (62 FR 18938), we published a proposed rule that would establish a voluntary procedure whereby manufacturers would notify us about a view of a particular use (or uses) of a substance is not subject to the statutory premarket approval requirements based on a determination that such use is GRAS. Under an interim policy announced in the proposed rule, we invited manufacturers to submit notices of their independent determinations for review under the framework of the proposed rule during the period between issuance of the proposal and any final rule based on the proposal. The proposed regulations (proposed 21 CFR 170.36 and 21 CFR 570.36) provide a standard format for the voluntary submission of a notice.

To assist respondents in submissions to our Center for Food Safety and Applied Nutrition (CFSAN), we developed Form FDA 3667 entitled “Generally Recognized as Safe Notice.”

The form, and elements prepared as attachments to the form, may be submitted in electronic format via the Electronic Submission Gateway (ESG), or may be submitted in paper format, or as electronic files on physical media with paper signature page. While we do not expect Form FDA 3667 to reduce reporting time for respondents, use of the form helps to expedite our review of the information being submitted. For submissions to our Center for Veterinary Medicine (CVM), respondents may continue to send GRAS notices in letter format to the Agency, as instructed in our **Federal Register** notice of June 4, 2010 (75 FR 31800).

Presently, we have committed to issuing a final rule regarding “Substances Generally Recognized as Safe” in 2016, as part of a settlement agreement with the Center for Food Safety, which filed a lawsuit in 2014 seeking to vacate our 1997 proposed rule.

Description of Respondents: The respondents to this collection of information are manufacturers of substances used in food and feed.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

| 21 CFR part | FDA Form No. ² | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|----------------------|-----------------------------|-----------------------|------------------------------------|------------------------|-----------------------------|-------------|
| 170.36 (CFSAN) | FDA 3667 ³ | 40 | 1 | 40 | 150 | 6,000 |
| 570.36 (CVM) | N/A | 20 | 1 | 20 | 150 | 3,000 |
| Total | | | | | | 9,000 |

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

² Only CFSAN uses Form FDA 3667.

³ Form FDA 3667 may be submitted electronically via the ESG.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN ¹

| 21 CFR part | Number of recordkeepers | Number of records per recordkeeper | Total annual records | Average burden per recordkeeping | Total hours |
|----------------------------|-------------------------|------------------------------------|----------------------|----------------------------------|-------------|
| 170.36(c)(v) (CFSAN) | 40 | 1 | 40 | 15 | 600 |
| 570.36(c)(v) (CVM) | 20 | 1 | 20 | 15 | 300 |
| Total | | | | | 900 |

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

For purposes of this extension request, we are retaining our 2012 estimates. The PRA analysis for the GRAS final rule will take into account any changes to the GRAS notification procedure as set forth in the final rule and we will revise the collection accordingly.

Dated: September 11, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-23334 Filed 9-16-15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-0001]

Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on November 19, 2015, from 8 a.m. to 1 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993-0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

Contact Person: Lauren D. Tesh, 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, FAX: 301-847-8533, ODAC@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously

announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at <http://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: Information will be presented to gauge investigator interest in exploring potential pediatric development plans for two products in various stages of development for adult cancer indications. The subcommittee will consider and discuss issues concerning diseases to be studied, patient populations to be included, and possible study designs in the development of these products for pediatric use. The discussion will also provide information to the Agency pertinent to the formulation of written requests for pediatric studies, if appropriate. The products under consideration are: (1) ABT-414, application submitted by AbbVie, Inc., and (2) Lenvatinib, application submitted by Eisai, Inc.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the subcommittee. Written submissions may be made to the contact person on or before November 4, 2015. Oral presentations from the public will be scheduled between approximately 9:05 a.m. to 9:35 a.m., and 11:30 a.m. to 12 noon. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before October 27, 2015. Time allotted for each presentation may be limited. If the number of registrants

requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by October 28, 2015.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Lauren D. Tesh at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: September 14, 2015.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2015-23366 Filed 9-16-15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Alliance for Innovation on Maternal and Child Health Cooperative Agreement

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice of Single-Case Deviation from Competition Requirement for the Alliance for Innovation on Maternal and Child Health Cooperative Agreement at the Association of State and Territorial Health Officials, Grant Number UC4MC28036.

SUMMARY: HRSA announces the award of a program expansion supplement in the amount of \$100,000 for the Alliance for Innovation on Maternal and Child Health (AIM) cooperative agreement. The purpose of the AIM cooperative agreement, as stated in the funding