

sometimes been sent for the wrong reasons.

In addition to content and format recommendations for each type of DHCP letter, the guidance also includes advice on consulting with FDA to develop a DHCP letter, when to send a letter, what type of letter to send, and conducting an assessment of the letter's impact.

Based on a review of FDA's Document Archiving, Reporting and Regulatory Tracking System for 2012 to 2015, we

identified DHCP letters that were sent and the identity of each sponsor sending out a DHCP letter for each year. We estimate that we will receive approximately 25 DHCP Letters annually from approximately 18 application holders. FDA professionals familiar with DHCP letters and with the recommendations in the guidance estimate that it should take an application holder approximately 100

hours to prepare and send DHCP letters in accordance with the guidance.

In the **Federal Register** of March 10, 2016 (81 FR 12734), we published a 60-day notice requesting public comment on the proposed extension of this collection of information. No comments were received.

FDA estimates the annual reporting burden of this collection of information 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 (hours)	Total hours
Annual average .....	18	1.4	25	100	2,500

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

Dated: October 17, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2016-N-0001]

**Request for Nominations for Voting Members on a Public Advisory Committee; Food Advisory Committee**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is requesting nominations for voting members to serve on the Food Advisory Committee (the Committee), Office of Regulations, Policy, and Social Sciences, Center for Food Safety and Applied Nutrition.

FDA seeks to include the views of women and men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees and, therefore, encourages nominations of appropriately qualified candidates from these groups.

**DATES:** Nominations received on or before December 20, 2016, will be given first consideration for membership on the Food Advisory Committee. Nominations received after December 20, 2016, will be considered for nomination to the committee as later vacancies occur.

**ADDRESSES:** All nominations for membership should be sent electronically by logging into the FDA

Advisory Committee Membership Nomination Portal: <https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm> or by mail to Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, Silver Spring, MD 20993-0002.

**FOR FURTHER INFORMATION CONTACT:** *Regarding all nomination questions for membership, the primary contact is:* Karen Strambler, 5001 Campus Drive, Rm. 1C-008, College Park, MD 20740, email: [karen.strambler@fda.hhs.gov](mailto:karen.strambler@fda.hhs.gov), 240-402-2589, Fax: 301-436-2367.

Information about becoming a member on an FDA advisory committee can also be obtained by visiting FDA's Web site by using the following link: <http://www.fda.gov/AdvisoryCommittees/default.htm>.

**SUPPLEMENTARY INFORMATION:** FDA is requesting nomination for voting members on the Committee.

**I. General Description of the Committee Duties**

The Committee reviews and evaluates emerging food safety, nutrition, and other food- or cosmetic-related health issues that FDA considers of primary importance for its food and cosmetics programs. The Committee may be charged with reviewing and evaluating available data and making recommendations on matters such as those relating to: (1) Broad scientific and technical food- or cosmetic-related issues, (2) the safety of food ingredients and new foods, (3) labeling of foods and cosmetics, (4) nutrient needs and nutritional adequacy, and (5) safe exposure limits for food contaminants. The Committee may also be asked to provide advice and make

recommendations on ways of communicating to the public the potential risks associated with these issues and on approaches that might be considered for addressing the issues.

**II. Criteria for Voting Members**

The Committee consists of a core of 15 voting members including the Chair. Members and the Chair are selected by the Commissioner of Food and Drugs (the Commissioner) designee from among authorities knowledgeable in the fields of physical sciences, biological and life sciences, food science, risk assessment, nutrition, food technology, molecular biology, epidemiology and other relevant scientific and technical disciplines. Members will be invited to serve for overlapping terms of up to 4 years. Almost all non-Federal members of this Committee serve as Special Government Employees. The core of voting members may include two technically qualified member(s), selected by the Commissioner or designee, who are identified with consumer interests and are recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee may include two non-voting member(s) who are identified with industry interests.

**III. Nomination Procedures**

Any interested person may nominate one or more qualified individuals for membership on the advisory committee. Self-nominations are also accepted. Nominations must include a current, complete résumé or curriculum vitae for each nominee, including current business address and/or home address, telephone number, and email address if available. Nominations must also

specify the advisory committee for which the nominee recommended. Nominations must also acknowledge that the nominee is aware of the nomination unless self-nominated. FDA will ask potential candidates to provide detailed information concerning such matters related to financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of conflicts of interest.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: October 18, 2016.

**Janice M. Soreth,**

*Acting Associate Commissioner, Special Medical Programs.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-N-0600]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Animal Drug User Fee Cover Sheet

**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 requirements of the Animal Drug User Fee cover sheet.

**DATES:** Submit either electronic or written comments on the collection of information by December 20, 2016.

**ADDRESSES:** You may submit comments as follows:

#### *Electronic Submissions*

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically,

including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### *Written/Paper Submissions*

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

*Instructions:* All submissions received must include the Docket No. FDA-2010-N-0600 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Animal Drug User Fee Cover Sheet." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the

claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, [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