

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2016-N-0628; FDA-2012-N-0306; FDA-2002-N-0323; FDA-2012-N-0427; FDA-2012-N-0536; FDA-2012-N-0560; FDA-2015-N-3662; FDA-2012-N-0976; FDA-2013-N-0297; FDA-2012-N-1203; FDA-2011-D-0893; FDA-2014-N-0189; FDA-2012-N-1210]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North, 11601 Landsdown St., North Bethesda, MD 20852, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections recently approved by OMB

under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB control No.	Date approval expires
Reporting Associated with New Animal Drug Applications	0910-0032	8/31/2019
Administrative Detention and Banned Medical Devices	0910-0114	8/31/2019
Registration of Food Facilities	0910-0502	8/31/2019
Inspection by Accredited Persons Program Under the Medical Device User Fee and Modernization Act of 2002	0910-0510	8/31/2019
Medical Device User Fee Cover Sheet—FDA Form 3601	0910-0511	8/31/2019
Guidance on Informed Consent for in Vitro Diagnostic Studies Using Leftover Human Specimens That Are Not Individually Identifiable	0910-0582	8/31/2019
Guidance for Reagents for Detection of Specific Novel Influenza A Viruses	0910-0584	8/31/2019
Guidance: Emergency Use Authorization of Medical Products	0910-0595	8/31/2019
Prevention of <i>Salmonella</i> Enteritidis in Shell Eggs During Production—Recordkeeping and Registration Provisions	0910-0660	8/31/2019
Information to Accompany Humanitarian Device Exemption Applications and Annual Distribution Number Reporting Requirements	0910-0661	8/31/2019
Guidance for Center for Devices and Radiological Health Appeals Processes	0910-0738	8/31/2019
Deeming Tobacco Products To Be Subject to the FD&C Act	0910-0768	8/31/2019
Food Labeling: Revision of the Nutrition Facts Label and Supplement Facts Label	0910-0813	7/31/2019

Dated: September 6, 2016.
Leslie Kux,
Associate Commissioner for Policy.
 [FR Doc. 2016-21877 Filed 9-9-16; 8:45 am]
BILLING CODE 4164-01-P

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; Tobacco Products Scientific 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 Tobacco Products Scientific

Advisory Committee, Office of Science, Center for Tobacco Products.

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 November 14, 2016 will be given first consideration for membership on the Tobacco Products Scientific Advisory Committee. Nominations received after November 14, 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 Nomination Portal: <http://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:* Caryn Cohen, Office of Science, Center for Tobacco Products, Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993-0002, 1-877-287-1373 (choose Option 5), TPSAC@fda.hhs.gov.

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 nominations for voting members on the Tobacco Products Scientific Advisory Committee.

I. General Description of the Committee Duties

The Tobacco Products Scientific Advisory Committee (the Committee)

advises the Commissioner of Food and Drugs (the Commissioner) or designee in discharging responsibilities related to the regulation of tobacco products. The Committee reviews and evaluates safety, dependence, and health issues relating to tobacco products and provides appropriate advice, information, and recommendations to the Commissioner.

II. Criteria for Voting Members

The Committee consists of 12 members including the Chair. Members and the Chair are selected by the Commissioner or designee from among individuals knowledgeable in the fields of medicine, medical ethics, science, or technology involving the manufacture, evaluation, or use of tobacco products. Almost all non-Federal members of this committee serve as Special Government Employees. The Committee includes nine technically qualified voting members, selected by the Commissioner or designee. The nine voting members include seven members who are physicians, dentists, scientists, or health care professionals practicing in the area of oncology, pulmonology, cardiology, toxicology, pharmacology, addiction, or any other relevant specialty. The nine voting members also include one member who is an officer or employee of a State or local government or of the Federal Government, and one member who is a representative of the general public. Members will be invited to serve for terms of up to 4 years.

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 is 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: September 6, 2016.

Janice M. Soreth,

Acting Associate Commissioner, Special Medical Programs.

[FR Doc. 2016-21819 Filed 9-9-16; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-D-2565]

510(k) Third Party Review Program; Draft Guidance for Industry, Food and Drug Administration Staff, and Third Party Review Organizations; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled “510(k) Third Party Review Program.” This draft guidance provides a comprehensive look into FDA’s current thinking regarding the 510(k) Third Party (TP) Review Program authorized under section 523 of the Federal Food, Drug, and Cosmetic Act (FD&C Act). In an effort to encourage harmonization, this guidance proposes to refer to, for the purpose of the TP Review Program, where appropriate and consistent with the FD&C Act and other applicable laws and regulations, the elements from the International Medical Device Regulators Forum’s regulatory assessment program called the Medical Device Single Audit Program. In addition, the Food and Drug Administration Safety and Innovation Act (FDASIA) requires FDA to establish and publish in the **Federal Register** criteria to reaccredit and deny reaccreditation of TP Review Organizations. Those criteria, including others, are described in this draft guidance. This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by January 10, 2017. Submit written or electronic comments on the collection of information by November 14, 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-2016-D-2565 for the draft guidance entitled “510(k) Third Party Review Program.” 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