

Patients who are interested in presenting comments as part of the initial panel discussions will be asked to indicate in their registration which topic(s) they wish to address. These patients also must send to PatientFocused@fda.hhs.gov a brief summary of responses to the topic questions by March 20, 2017. Panelists will be notified of their selection approximately 7 days before the public meeting. We will try to accommodate all patients and patient stakeholders who wish to speak, either through the panel discussion or audience participation; however, the duration of comments may be limited by time constraints.

Transcripts: Please be advised that as soon as a transcript of the public meeting is available, it will be accessible at <https://www.regulations.gov>. It may be viewed at the Division of Dockets Management (see **ADDRESSES**). A link to the transcript will also be available on the Internet at <http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm527587.htm>.

Dated: December 9, 2016.
Leslie Kux,
Associate Commissioner for Policy.
 [FR Doc. 2016-29998 Filed 12-13-16; 8:45 am]
BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2013-N-0375; FDA-2013-N-0370; FDA-2013-N-0134; FDA-2009-N-0511; FDA-1997-N-0020; FDA-2011-N-0902; FDA-2013-N-0662; FDA-2013-N-0450; FDA-2012-N-0477; FDA-2013-N-0519]

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, 10A63, 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 |
|--|-----------------|-----------------------|
| Agreement for Shipments of Devices for Sterilization | 0910-0131 | 9/30/2019 |
| Export of Medical Devices—Foreign Letters of Approval | 0910-0264 | 9/30/2019 |
| Mammography Facilities, Standards, and Lay Summaries for Patients | 0910-0309 | 9/30/2019 |
| Medicated Fee Mill License Application | 0910-0337 | 9/30/2019 |
| Substances Generally Recognized as Safe: Notification Procedure | 0910-0342 | 9/30/2019 |
| Prescription Drug Product Labeling; Medication Guide Requirements | 0910-0393 | 9/30/2019 |
| Applications for FDA Approval to Market a New Drug: Patent Submission and Listing Requirements and Application of 30-month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug is Invalid or Will Not be Infringed | 0910-0513 | 9/30/2016 |
| Substances Prohibited from Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed | 0910-0339 | 10/31/2019 |
| Investigational Device Exemptions Reports and Records—21 CFR 812 | 0910-0078 | 11/30/2019 |
| Guidance for Industry on How to Submit Information in Electronic Format to the Center for Veterinary Medicine Using the FDA Electronic Submission Gateway | 0910-0454 | 11/30/2019 |

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-4119]

Food Safety Modernization Act Third-Party Certification Program User Fee Rate for Fiscal Year 2017

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the fiscal year (FY) 2017 fee rate for accreditation bodies applying to be recognized in the third-party certification program that is authorized by the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the FDA Food Safety Modernization Act (FSMA).

FOR FURTHER INFORMATION CONTACT: Sylvia Kim, Office of Foods and Veterinary Medicine, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 3212, Silver Spring, MD 20993, 301-796-7599.

DATES: This fee is effective January 13, 2017, and will remain in effect through September 30, 2017.

SUPPLEMENTARY INFORMATION:

I. Background

Section 307 of FSMA, Accreditation of Third-Party Auditors, amends the FD&C Act to create a new provision, section 808, under the same name. Section 808 of the FD&C Act (21 U.S.C. 384d) directs us to establish a new program for accreditation of third-party certification bodies¹ conducting food safety audits and issuing food and facility certifications to eligible foreign entities (including registered foreign

¹ For the reasons explained in the third-party certification final rule (80 FR74570 at 74578-74579, November 27, 2015), and for consistency with the implementing regulations for the third-party certification program in 21 CFR parts 1, 11, and 16, this notice uses the term “third-party certification body” rather than the term “third-party auditor” used in section 808(a)(3) of the FD&C Act.