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.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Food and Drug Administration

For Industry/UserFees/PrescriptionDrugUserFee/
http://www.fda.gov/

For Industry/UserFees/PrescriptionDrugUserFee/
ucm527587.htm.

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, 10003 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.

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. 364d) directs us to establish a new program for accreditation of third-party certification bodies conducting food safety audits and issuing food and facility certifications to eligible foreign entities (including registered foreign

Table 1—List of Information Collections Approved by OMB

<table>
<thead>
<tr>
<th>Title of collection</th>
<th>OMB control No.</th>
<th>Date approval expires</th>
</tr>
</thead>
<tbody>
<tr>
<td>Agreement for Shipments of Devices for Sterilization</td>
<td>0910–0131</td>
<td>9/30/2019</td>
</tr>
<tr>
<td>Export of Medical Devices—Foreign Letters of Approval</td>
<td>0910–0264</td>
<td>9/30/2019</td>
</tr>
<tr>
<td>Mammography Facilities, Standards, and Lay Summaries for Patients</td>
<td>0910–0309</td>
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<tr>
<td>Medicated Fee Mill License Application</td>
<td>0910–0337</td>
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<tr>
<td>Prescription Drug Product Labeling; Medication Guide Requirements</td>
<td>0910–0393</td>
<td>9/30/2019</td>
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<tr>
<td>Substances Prohibited from Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed</td>
<td>0910–0339</td>
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<tr>
<td>Investigational Device Exemptions Reports and Records—21 CFR 812</td>
<td>0910–0078</td>
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<tr>
<td>Guidance for Industry on How to Submit Information in Electronic Format to the Center for Veterinary Medicine Using the FDA Electronic Submission Gateway</td>
<td>0910–0454</td>
<td>11/30/2019</td>
</tr>
</tbody>
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SUPPLEMENTARY INFORMATION:

I. Background

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