moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

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/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: June 6, 2016.
Jill Hartzler Warner,
Associate Commissioner for Special Medical Programs.

[FR Doc. 2016–13709 Filed 6–9–16; 8:45 am]
BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Food and Drug Administration

[Docket No. FDA–2009–N–0511]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medicated Feed Mill License Application

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by July 11, 2016.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to oira_submission@OMB.eop.gov. All comments should be identified with the OMB control number 0910–0337. Also include the FDA 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: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Medicated Feed Mill License Application—21 CFR Part 515—OMB Control Number 0910–0337—Revision

Feed manufacturers that seek to manufacture feed using Category II, Type A medicated articles or manufacture certain liquid and free-choice feed, using Category I, Type A medicated articles that must follow proprietary formulas or specifications are required to obtain a facility license under section 512 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360b). Our regulations in part 515 (21 CFR part 515) establish the procedures associated with applying for a facility license. We require that a manufacturer seeking a facility license submit a completed medicated feed mill license application using Form FDA 3448 (21 CFR 515.10(b)). We use the information submitted to establish that the applicant has made the certifications required by section 512 of the FD&C Act, to register the mill, and to schedule a pre-approval inspection. We have made minor editorial revisions to Form FDA 3448, including the addition of a dedicated field for the submitter’s email address in the contact information section. We estimate that the revisions will not change the amount of time necessary to complete the form.

We require the submission of a supplemental medicated feed mill license application for a change in facility ownership or a change in facility address (§ 515.11(b)). If a licensed facility is no longer manufacturing medicated animal feed under § 515.23, a manufacturer may request voluntary revocation of a medicated feed mill license. An applicant also has the right to file a request for hearing under § 515.30(c) to give reasons why a medicated feed mill license should not be refused or revoked.

In the Federal Register of March 9, 2016 (81 FR 12509), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received one comment, which was not responsive to the comment request.

We estimate the burden of this collection of information as follows:
These estimates are based on our experience with medicated feed mill license applications. We estimate that we will receive 20 medicated feed mill license applications, 40 supplemental applications, 40 requests for voluntary revocation, and that these submissions will take approximately 15 minutes per response, as shown in table 1, rows 1 through 3. We estimate that preparing a request for a hearing under §515.30(c) takes approximately 4 hours, as shown in table 1, row 4. In table 2, we estimate that 890 licensees will keep the records required by 21 CFR 510.305 expending a total of 27 hours annually.

Dated: June 6, 2016.

Leslie Kux,
Associate Commissioner for Policy.
[FR Doc. 2016–13790 Filed 6–9–16; 8:45 am]
BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

[Docket No. FDA–2016–D–1264]

Dissemination of Patient-Specific Information From Devices by Device Manufacturers; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled “Dissemination of Patient-Specific Information from Devices by Device Manufacturers.” The FDA developed this draft guidance to facilitate the appropriate and responsible dissemination of patient-specific information recorded, stored, processed, retrieved, and/or derived from medical devices from manufacturers to patients. This draft guidance provides recommendations to industry, healthcare providers, and FDA staff about the mechanisms and considerations for device manufacturers sharing such information with patients. 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 of 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 August 9, 2016.

ADRESSES: 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.”

Table 1—Estimated Annual Reporting Burden

<table>
<thead>
<tr>
<th>21 CFR section and activity</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Total annual responses</th>
<th>Average burden per response</th>
<th>Total hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medicated Feed Mill License Application using Form FDA 3448 (515.10(b))</td>
<td>20</td>
<td>1</td>
<td>20</td>
<td>0.25 (15 minutes)</td>
<td>5</td>
</tr>
<tr>
<td>Supplemental Feed Mill License Application using Form FDA 3448 (515.11(b))</td>
<td>40</td>
<td>1</td>
<td>40</td>
<td>0.25 (15 minutes)</td>
<td>10</td>
</tr>
<tr>
<td>Voluntary Revocation of Medicated Feed Mill License. (515.23)</td>
<td>40</td>
<td>1</td>
<td>40</td>
<td>0.25 (15 minutes)</td>
<td>10</td>
</tr>
<tr>
<td>Filing a Request for a Hearing on Medicated Feed Mill License (515.30(c))</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td><strong>29</strong></td>
</tr>
</tbody>
</table>

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

Table 2—Estimated Annual Recordkeeping Burden

<table>
<thead>
<tr>
<th>21 CFR section and activity</th>
<th>Number of recordkeepers</th>
<th>Number of records per recordkeeper</th>
<th>Total annual records</th>
<th>Average burden per recordkeeping</th>
<th>Total hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maintenance of Records for Approved Labeling for Each “Type B” and “Type C” Feed (510.305).</td>
<td>890</td>
<td>1</td>
<td>890</td>
<td>0.03 (2 minutes)</td>
<td>27</td>
</tr>
</tbody>
</table>

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