TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN 1

<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>Total</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>29</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 1

<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.

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.

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.”
Section I. Background

Increasingly, patients seek to play an active role in their own healthcare. FDA believes that manufacturers providing patients with accurate, useable information about their healthcare (including the medical products they use and patient-specific information these products generate) will improve healthcare by empowering patients to participate fully with their healthcare providers in making sound medical decisions. For purposes of this guidance, patient-specific information is defined as any information unique to an individual patient or unique to that patient’s treatment or diagnosis that may be recorded, stored, processed, retrieved, and/or derived from a medical device. This information may include, but is not limited to, recorded patient data, device usage/output statistics, healthcare provider inputs, incidence of alarms, and/or records of device malfunctions or failures.

FDA developed this draft guidance to convey FDA’s policy regarding the dissemination of patient-specific information recorded, stored, processed, retrieved, and/or derived from a medical device and provided by the manufacturer to the patient who is either treated or diagnosed with that specific device. This draft guidance document also outlines considerations for the form in which this information is communicated to help to ensure clarity of content and appropriate context.

Manufacturers may share patient-specific information (recorded, stored, processed, retrieved, and/or derived from a medical device, consistent with the intended use of that medical device) with patients either on their own initiative or at the patient’s request, without obtaining additional premarket review before doing so. Any labeling, as that term is defined in section 201(m) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), that is provided to the patient by the manufacturer is subject to applicable requirements in the FD&C Act and FDA regulations.

Section II. Significance of Guidance

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance when finalized will represent the current thinking of FDA on “Dissemination of Patient-Specific Information from Devices by Device Manufacturers.” It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

Section III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the Internet. A search capability for all FDA developed this draft guidance to convey FDA’s policy regarding the dissemination of patient-specific information from Devices by Device Manufacturers may share patient-specific information (recorded, stored, processed, retrieved, and/or derived from a medical device) with patients either on their own initiative or at the patient’s request, without obtaining additional premarket review before doing so. Any labeling, as that term is defined in section 201(m) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), that is provided to the patient by the manufacturer is subject to applicable requirements in the FD&C Act and FDA regulations.

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Section III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at http://www.fda.gov/medicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm. Guidance documents are also available at http://www.regulations.gov. Persons unable to download an electronic copy of “Dissemination of Patient-Specific Information from Devices by Device Manufacturers” may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 1500067 to identify the guidance you are requesting.

Section IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations and guidance. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR parts 801 and 809, regarding device labeling, are approved under OMB control number 0910–0485.

Dated: June 6, 2016.

Leslie Kux,
Associate Commissioner for Policy.

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