Since the last OMB approval, our estimated annual reporting burden for the information collection reflects an increase due to an increase in the number of submissions we have received.

Dated: July 11, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–15283 Filed 7–17–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–4428]

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 August 19, 2019.

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: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *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—Extension

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 (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 (§ 515.10(b) (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 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) (21 CFR 515.11(b))). If a licensed facility is no longer manufacturing medicated animal feed under § 515.23 (21 CFR 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) (21 CFR 515.30(c)) to give reasons why a medicated feed mill license should not be refused or revoked.

In the **Federal Register** of December 26, 2018 (83 FR 66280), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section and activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Medicated Feed Mill License Application using Form FDA 3448 (515.10(b)).	14	1	14	0.25 (15 minutes)	4
Supplemental Feed Mill License Application using Form FDA 3448 (515.11(b)).	54	1	54	0.25 (15 minutes)	14
Voluntary Revocation of Medicated Feed Mill License (515.23).	29	1	29	0.25 (15 minutes)	7
Filing a Request for a Hearing on Medicated Feed Mill License (515.30(c)).	1	1	1	4	4
Total					29

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section and activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Maintenance of Records for Approved Labeling for Each ''Type B'' and ''Type C'' Feed (510.305).	837	1	837	0.03 (2 minutes)	25

[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 14 medicated feed mill license applications, 54 supplemental applications, 29 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 837 licensees will keep the records required by 21 CFR 510.305, expending a total of 25 hours annually.

Our estimated burden for the information collection reflects an overall decrease of 2 hours and a corresponding decrease of 56 responses/records. We attribute this adjustment to a net decrease in the number of submissions we received over the last few years.

Dated: July 12, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–15284 Filed 7–17–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0893]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Center for Devices and Radiological Health Appeals Processes

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 August 19, 2019.

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 0910–0738. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *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.

Center for Devices and Radiological Health Appeals Processes

OMB Control Number 0910–0738—Extension

The guidance document entitled ''Guidance for Industry and Food and Drug Administration Staff; Center for Devices and Radiological Health Appeals Processes'' [1] describes the processes available to outside stakeholders to request additional review of decisions or actions by Center for Devices and Radiological Health (CDRH) employees. FDA is seeking approval for the reporting burden associated with requests for additional review of decisions and actions by CDRH employees as described in the guidance.

Individuals outside of FDA who disagree with a decision or action taken by CDRH and wish to have it reviewed or reconsidered have several processes for resolution from which to choose, including requests for supervisory review of an action, petitions, and hearings. Of these, by far the most commonly used is a request for supervisory review under § 10.75 (21 CFR 10.75) (''10.75 appeal''). Section 517A of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360g–1), added by section 603 of the Food and Drug Administration Safety and Innovation Act, includes requirements pertaining to the process and timelines for 10.75 appeals of ''significant decisions'' regarding 510(k) premarket notifications, applications for premarket approvals (PMAs), and applications for investigational device exemptions (IDEs).

A request for review under § 10.75 should be based on the information that was already present in the administrative file at the time of the decision that is being reviewed as provided in § 10.75(d). Section 517A of the FD&C Act refers to significant decisions regarding the information in the administrative file for premarket notification (section 510(k) of the FD&C Act (21 U.S.C. 360(k))), PMA (section 515 (21 U.S.C. 360e)), and IDE (section 520(g) (21 U.S.C. 360j(g))) submissions that is collected under existing regulations that specify the information manufacturers must submit so that FDA may properly evaluate the safety and effectiveness of medical devices. The information collections associated with these regulations are currently approved by the OMB as follows: The collections of information in 21 CFR part 807, subpart E (premarket notification) have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 814 (premarket approval) have been approved under OMB control number 0910–0231; and the collections of information in 21 CFR part 812 (investigational device exemption) have been approved under OMB control number 0910–0078.

While CDRH already possesses in the administrative file the information that would form the basis of a decision on a matter under appeal, the submission of particular information regarding the request itself and the data and information relied on by the requestor in the appeal would facilitate timely resolution of the decision under review. The guidance describes the collection of information not expressly specified under existing regulations such as the submission of the request for review, minor clarifications as part of the request, and supporting information.

In the **Federal Register** of March 8, 2019 (84 FR 8530), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

[1] *https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm284670.pdf.*