Estimated Total Annual Burden Hours: 1,600

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: Sec. 413. [8 U.S.C. 1523]

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2019–15274 Filed 7–17–19; 8:45 am]

BILLING CODE 4184–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0976]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance: Emergency Use Authorization of Medical Products and Related Authorities

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 0910–0595. 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.

Guidance: Emergency Use Authorization of Medical Products and Related Authorities

OMB Control Number 0910–0595—Extension

The guidance describes the Agency's policies applicable to the authorization of the emergency use of certain medical products under sections 564, 564A, and 564B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360bbb–3, 360bbb–3a, and 360bbb–3b), as amended or added by the Project BioShield Act of 2004 (Pub. L. 108–276), the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (Pub. L. 113–5), 21st Century Cures Act (Pub. L. 114–255), and Public Law 115–92 (2017). The FD&C Act permits the FDA Commissioner (the Commissioner) to authorize the use of unapproved medical products or unapproved uses of approved medical products during an emergency declared under section 564 of the FD&C Act. The data to support issuance of an emergency use authorization (EUA) must demonstrate that, based on the totality of the scientific evidence available to the Commissioner, including data from adequate and well-controlled clinical trials (if available), it is reasonable to believe that the product may be effective in diagnosing, treating, or preventing a serious or life-threatening disease or condition (21 U.S.C. 360bbb–3(c)). Although the exact type and amount of data needed to support an EUA may vary depending on the nature of the declared emergency and the nature of the candidate product, FDA recommends that a request for consideration for an EUA include scientific evidence evaluating the product's safety and effectiveness, including the adverse event profile for diagnosis, treatment, or prevention of the serious or life-threatening disease or condition, as well as data and other information on safety, effectiveness, risks and benefits, and (to the extent available) alternatives.

Under section 564 of the FD&C Act, the Commissioner may establish conditions on the authorization. Section 564(e) requires the Commissioner (to the extent practicable given the circumstances of the emergency) to establish certain conditions on an authorization that the Commissioner finds necessary or appropriate to protect the public health and permits the Commissioner to establish other conditions that he or she finds necessary or appropriate to protect the public health. Conditions authorized by section 564(e) of the FD&C Act include, for example: Requirements for information dissemination to healthcare providers or authorized dispensers and product recipients; adverse event monitoring and reporting; data collection and analysis; recordkeeping and records access; restrictions on product advertising, distribution, and administration; and limitations on good manufacturing practices requirements. Some conditions, the statute specifies, are mandatory to the extent practicable for authorizations of unapproved products and discretionary for authorizations of unapproved uses of approved products. Moreover, some conditions may apply to manufacturers of an EUA product, while other conditions may apply to any person who carries out any activity for which the authorization is issued. Section 564 of the FD&C Act also gives the Commissioner authority to establish other conditions on an authorization that he or she finds to be necessary or appropriate to protect the public health. Additionally, sections 564A and 564B established streamlined mechanisms to facilitate preparedness and response activities involving certain FDA-approved products without requiring FDA to issue an EUA, including expiration date extension authority.

For purposes of estimating the annual burden of reporting (table 1), FDA has established four categories of respondents: (1) Those who file a request for FDA to issue an EUA or a substantive amendment to an EUA that has previously been issued, assuming that a requisite declaration under section 564 of the FD&C Act has been made and criteria for issuance have been met; (2) those who submit a request for FDA to review information/data (*i.e.,* a pre-EUA package) for a candidate EUA product or a substantive amendment to an existing pre-EUA package for preparedness purposes; (3) manufacturers who carry out an activity related to an unapproved EUA product (*e.g.,* administering product, disseminating information) who must

report to FDA regarding such activity; and (4) public health authorities (*e.g.,* State, local) who carry out an activity (*e.g.,* administering product, disseminating information) related to an unapproved EUA product who must report to FDA regarding such activity or who submit to FDA an expiration date extension request for an approved product.

In some cases, manufacturers directly submit EUA requests. Often a Federal Government entity (*e.g.,* Centers for Disease Control and Prevention, Department of Defense) requests that FDA issue an EUA and submits pre-EUA packages for FDA to review. In many of these cases, manufacturer respondents inform these requests and submissions, which are the activities that form the basis of the estimated reporting burdens. However, in some cases the Federal Government is the sole respondent; manufacturers do not inform these requests or submissions. FDA estimates minimal burden when the Federal Government performs the relevant activities. In addition to variability based on whether there is an active manufacturer respondent, other factors also inject significant variability in estimates for annual reporting burdens. A second factor is the type of product. For example, FDA estimates greater burden for novel therapeutics than for certain unapproved uses of approved products. A third significant factor that injects variability is the type of submission. For example, FDA estimates greater burden for ''original'' EUA and pre-EUA submissions than for amendments to them, and FDA estimates minimal burden to issue an EUA when there is a previously reviewed pre-EUA package or investigational application. For purposes of estimating the reporting burden, FDA has calculated the anticipated burden on manufacturers based on the anticipated types of responses (*i.e.,* estimated manufacturer input), types of product, and types of submission that comprise the described reporting activities.

For purposes of estimating the annual burden of recordkeeping, FDA has also calculated the anticipated burden on manufacturers and public health officials associated with administration of unapproved products authorized for emergency use, recognizing that the Federal Government will perform much of the recordkeeping related to administration of such products (table 2). FDA is not calculating any recordkeeping burden for public health authorities who may need to submit expiration date extension requests, as these entities already maintain records for the products that they stockpile, which would include records of any expiration date request or extension.

The guidance refers to previously approved collections of information. These collections are subject to review by the OMB under the PRA. These collections have been approved as follows: Adverse experience reporting for biological products is approved under OMB control number 0910–0308; adverse drug experience reporting is approved under OMB control number 0910–0230; adverse device experience reporting is approved under OMB control number 0910–0471; investigational new drug (IND) application regulations are approved under OMB control number 0910–0014 and investigational device exemption (IDE) reporting is approved under OMB control number 0910–0078; current good manufacturing practices for finished pharmaceuticals are approved under OMB control number 0910–0139, and for devices under OMB control number 0910–0073; applications for marketing a new drug are approved under OMB control number 0910–0001, and for biological products under OMB control number 0910–0338. Any additional burden imposed by this proposed collection would be minimal.

In the **Federal Register** of April 4, 2019 (84 FR 13299), FDA published a 60-day notice requesting public comment on the proposed collection of information. Although one comment was received, it was not responsive to the four collection of information topics solicited.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Type of respondent	No. of respondents	No. of responses per respondent	Total annual responses	Average burden per response (hours)	Total hours
Requests to Issue an EUA or a Substantive Amendment to an Existing EUA	12	2.39	29	45	1,305
FDA Review of a Pre-EUA Package or an Amendment Thereto	32	1.79	57	34	1,938
Manufacturers of an Unapproved EUA Product	12	5.8	70	2	140
Public Health Authorities; Unapproved EUA Product	30	3	90	2	180
Public Health Authorities; Request for Expiration Date Extension	1	1	1	2	2
Total					3,565

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Type of respondent	No. of recordkeepers	No. of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Manufacturers of an Unapproved EUA Product	12	2	24	25	600
Public Health Authorities; Unapproved EUA Product	30	3	90	3	270
Total					870

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

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.