

women and/or would benefit from sex- and gender-related analyses.

Dated: July 6, 2020.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

[FR Doc. 2020–14878 Filed 7–9–20; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2017–N–1066]

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Annual Reporting for Custom Device Exemption**

**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:** Submit written comments (including recommendations) on the collection of information by August 10, 2020.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting “Currently under Review—Open for Public Comments” or by using the search function. The OMB control number for this information

collection is 0910–0767. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Ila S. Mizrahi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, [PRAStaff@fda.hhs.gov](mailto: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.

**Annual Reporting for Custom Device Exemption**

*OMB Control Number 0910–0767—Extension*

The custom device exemption is set forth at section 520(b)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360j(b)(2)(B)). A custom device is in a narrow category of device that, by virtue of the rarity of the patient’s medical condition or physician’s special need the device is designed to treat, it would be impractical for the device to comply with premarket review regulations and performance standards.

The Food and Drug Administration Safety and Innovation Act (FDASIA) implemented changes to the custom device exemption contained in section 520(b) of the FD&C Act. The new provision amended the existing custom device exemption and introduced new concepts and procedures for custom devices, such as:

- Devices created or modified to comply with the order of an individual physician or dentist;

- the potential for multiple units of a device type (limited to no more than five units per year) qualifying for the custom device exemption; and

- annual reporting requirements by the manufacturer to FDA about devices manufactured and distributed under section 520(b) of the FD&C Act.

Under FDASIA, “devices” that qualify for the custom device exemption contained in section 520(b) of the FD&C Act were clarified to include no more than “five units per year of a particular device type” that otherwise meet all the requirements necessary to qualify for the custom device exemption.

In the **Federal Register** of September 24, 2014 (79 FR 57112), FDA announced the availability of the guidance entitled “Custom Device Exemption.” FDA has developed this document to provide guidance to industry and FDA staff about implementation of the custom device exemption contained in the FD&C Act. The intent of the guidance is to define terms used in the custom device exemption, explain how to interpret the “five units per year of a particular device type” language contained in the FD&C Act, describe information that FDA proposes manufacturers should submit in the custom device annual report, and provide recommendations on how to submit an annual report for devices distributed under the custom device exemption.

In the **Federal Register** of February 21, 2020 (85 FR 10175), we 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 <sup>1</sup>

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Annual reporting for custom devices .....	34	1	34	40	1,360

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

Our estimated burden for the information collection reflects an overall increase of 40 hours and a corresponding increase of one response/record. We attribute this adjustment to an increase in the number of submissions we received over the last few years.

Dated: July 6, 2020.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2010-N-0601]

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Current Good Manufacturing Practice Regulations for Medicated Feeds**

**AGENCY:** Food and Drug Administration, Health and Human Services (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:** Submit written comments (including recommendations) on the collection of information by August 10, 2020.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information

collection by selecting “Currently under Review—Open for Public Comments” or by using the search function. The OMB control number for this information collection is 0910-0152. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Ila S. Mizrahi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St. North Bethesda, MD 20852, 301-796-7726, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@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.

**Current Good Manufacturing Practice Regulations for Medicated Feeds—21 CFR part 225**

*OMB Control Number 0910-0152—Extension*

Under section 501 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 351), FDA has the statutory authority to issue current good manufacturing practice (cGMP) regulations for drugs, including medicated feeds. Medicated feeds are administered to animals for the prevention, cure, mitigation, or treatment of disease, or growth promotion and feed efficiency. Statutory requirements for cGMPs have been codified under part 225 (21 CFR part 225). Medicated feeds that are not manufactured in accordance with these regulations are considered adulterated under section 501(a)(2)(B) of the FD&C Act. Under part 225, a manufacturer is required to establish, maintain, and retain records for a medicated feed, including records to document procedures required during the

manufacturing process to assure that proper quality control is maintained. Such records would, for example, contain information concerning receipt and inventory of drug components, batch production, laboratory assay results (*i.e.*, batch and stability testing), labels, and product distribution.

This information is needed so that FDA can monitor drug usage and possible misformulation of medicated feeds to investigate violative drug residues in products from treated animals and to investigate product defects when a drug is recalled. In addition, FDA will use the cGMP criteria in part 225 to determine whether or not the systems and procedures used by manufacturers of medicated feeds are adequate to assure that their feeds meet the requirements of the FD&C Act as to safety, and also that they meet their claimed identity, strength, quality, and purity, as required by section 501(a)(2)(B) of the FD&C Act.

A license is required when the manufacturer of a medicated feed involves the use of a drug or drugs that FDA has determined requires more control because of the need for a withdrawal period before slaughter or because of carcinogenic concerns. Conversely, a license is not required, and the recordkeeping requirements are less demanding for those medicated feeds for which FDA has determined that the drugs used in their manufacture need less control. Respondents to this collection of information are commercial feed mills and mixer/feeders.

In the **Federal Register** of March 4, 2020 (85 FR 12790), we 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 RECORDKEEPING BURDEN (REGISTERED LICENSED COMMERCIAL FEED MILLS) <sup>1</sup>

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
225.42(b)(5) through (8) requires records of receipt, storage, and inventory control of medicated feeds.	825	260	214,500	1 .....	214,500
225.58(c) and (d) requires records of the results of periodic assays for medicated feeds that are in accord with label specifications and also those medicated feeds not within documented permissible assay limits.	825	45	37,125	0.50 (30 minutes)	18,562.50
225.80(b)(2) requires that verified medicated feed label(s) be kept for 1 year.	825	1,600	1,320,000	0.12 (7 minutes) ..	158,400
225.102(b)(1) through (5), requires records of Master Record Files and production records for medicated feeds.	825	7,800	6,435,000	0.08 (5 minutes) ..	514,800
225.110(b)(1) and (2) requires maintenance of distribution records for medicated feeds.	825	7,800	6,435,000	0.02 (1 minute) ....	128,700