TABLE 4—ESTIMATED ANNUAL RECORDKEEPING BURDEN (NONREGISTERED UNLICENSED MIXER/FEEDERS) [1]—Continued

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeper	Total hours
225.180 requires identification, storage, and inventory control of labeling in a manner that prevents label mixups and assures that correct labels are used for medicated feeds.	3,400	32	108,800	0.12 (7 minutes) ..	13,056
225.202 requires records of formulation, production, and distribution of medicated feeds.	3,400	260	884,000	0.33 (20 minutes)	291,720
Total					331,976

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

Our estimated burden for the information collection reflects a decrease of 65,265.20 hours. We attribute this adjustment to a decrease in the number of respondents for Registered Licensed Commercial Feed Mills. Medicated Feed Mill licensing is voluntary. Firms may withdraw if they go out of business or if they change the source of the drug and a license is not required.

Dated: July 2, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–14797 Filed 7–9–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0598]

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

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 0910–0154. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, 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.*

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 Type A Medicated Articles, 21 CFR part 226

OMB Control Number 0910–0154—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 Type A medicated articles. A Type A medicated article is a feed product containing a concentrated drug diluted with a feed carrier substance. A Type A medicated article is intended solely for use in the manufacture of another Type A medicated article or a Type B or Type C medicated feed. Medicated feeds are administered to animals for the prevention, cure, mitigation, or treatment of disease or for growth promotion and feed efficiency.

Statutory requirements for cGMPs for Type A medicated articles have been codified in part 226 (21 CFR part 226). Type A medicated articles 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 226, a manufacturer is required to establish, maintain, and retain records for Type A medicated articles, including records to document procedures required under 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), and product distribution.

The required records are used by both the respondents and FDA. The records are used by manufacturers of Type A medicated articles to verify that appropriate control measures have been maintained, or that appropriate corrective actions were taken if the control measures were not maintained. Such verification activities are essential to ensure that the cGMP system is working as planned. We review the records during the conduct of periodic plant inspections. This information is needed so that we can monitor drug usage and possible misformulation of Type A medicated articles. The information could also prove useful to us in investigating product defects when a drug is recalled. In addition, we will use the cGMP criteria in part 226 to determine whether or not the systems used by manufacturers of Type A medicated articles are adequate to ensure that their medicated articles meet the requirements of the FD&C Act as to safety and also meet the article's claimed identity, strength, quality, and purity, as required by section 501(a)(2)(B) of the FD&C Act.

In the **Federal Register** of February 21, 2020 (85 FR 10170), 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 [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
226.42; requires records be prepared and maintained for 2 years with respect to components (drug and nondrug) used in the manufacture of the medicated premixes.	65	260	16,900	0.75 (45 minutes).	12,675
226.58; requires recordkeeping for establishment of laboratory controls to ensure that adequate specifications and test procedures for the drug components and Type A medicated articles conform to appropriate standards of identity, strength, quality, and purity.	65	260	16,900	1.75	29,575
226.80; requires maintenance of records for packaging and labeling of Type A medicated articles.	65	260	16,900	0.75 (45 minutes).	12,675
226.102; requires maintenance of master-formula and batch-production records for Type A medicated articles.	65	260	16,900	1.75	29,575
226.110; requires maintenance of distribution records (for 2 years) for each shipment of Type A medicated articles for recall purposes.	65	260	16,900	0.25 (15 minutes).	4,225
226.115; requires maintenance of complaint files for Type A medicated articles for 2 years.	65	10	650	0.5 (30 minutes).	325
Total	.....	.....	.....	.....	89,050

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

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: July 2, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–14796 Filed 7–9–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Notice of Purchased/Referred Care Delivery Area Redesignation for the Northwestern Band of the Shoshone Nation

AGENCY: Indian Health Service, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: This Notice advises the public that the Indian Health Service (IHS) proposes to expand the geographic boundaries of the Purchased/Referred Care Delivery Area (PRCDA) for the Northwestern Band of the Shoshone Nation (NWBSN) in the State of Utah to include the Utah counties of Box Elder, Davis, Salt Lake, and Weber. The current PRCDA for the NWBSN is Box Elder County in the State of Utah. Tribal members residing on the Fort Hall Indian Reservation are provided health services through the IHS direct care facility in Fort Hall, Idaho, or by Purchased/Referred Care (PRC) referrals to private providers. NWBSN members residing outside of the PRCDA are eligible for direct care services, however, they are not eligible for PRC services. The sole purpose of this expansion would be to authorize additional Tribal members and beneficiaries to receive PRC services.

DATES: Comments must be submitted August 10, 2020.

ADDRESSES: In commenting, please refer to FR Number 2020–14760. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a Comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Evonne Bennett, Acting Director, Division of Regulatory and Policy Coordination, Indian Health Service, 5600 Fishers Lane, Mail Stop: 09E70, Rockville, Maryland 20857. Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the above address.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to the address above.

If you intend to deliver your comments to the Rockville address, please call telephone number (301) 443–1116 in advance to schedule your arrival with a staff member.

FOR FURTHER INFORMATION CONTACT: CDR John Rael, Director, Office of Resource Access and Partnerships, Indian Health Service, 5600 Fishers Lane, Mail Stop: 10E85C, Rockville, Maryland 20857. Telephone 301/443–0969 (This is not a toll free number).

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment.

Background: The IHS provides services under regulations in effect as of September 15, 1987, and republished at 42 CFR part 136, subparts A–C. Subpart C defines a Contract Health Service Delivery Area (CHSDA), now referred to as a PRCDA, as the geographic area within which PRC will be made available by the IHS to members of an identified Indian community who reside in the PRCDA. Residence within a PRCDA by a person who is within the scope of the Indian health program, as set forth in 42 CFR 136.12, creates no legal entitlement to PRC but only potential eligibility for services. Services needed, but not available at an IHS/Tribal facility, are provided under the PRC program depending on the availability of funds, the person's relative medical priority, and the actual availability and accessibility of alternate resources in accordance with the regulations.

The regulations at 42 CFR part 136, subpart C, provide that, unless otherwise designated, a PRCDA shall consist of a county which includes all