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 [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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	No. of Respondents	No. 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.

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