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, 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: Rachel Showalter, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 240-994-7399, 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

This information collection supports the implementation of FDA statutory and regulatory requirements that govern current good manufacturing practice (cGMP) for Type A medicated articles. A Type A medicated article is an animal 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. Section 501 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 351), governs current cGMP for drugs, including Type A medicated articles, and these statutory requirements are codified in part 226 (21 CFR part 226).

Manufacturers are 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 under part 226. Type A medicated articles, which are not manufactured in accordance with these regulations, are considered adulterated under section 501(a)(2)(B) of the FD&C Act (21 U.S.C. 351(a)(2)(B)).

Description of Respondents: The respondents to this information collection are manufacturers of Type A medicated articles.

In the *Federal Register* of January 31, 2023 (88 FR 6281), 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 Recordkeeping Burden[1]

21 CFR Part; Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response[2]	Total Hours

226.42, 226.58, 226.80, 226.102, 226.110, and 226.115; Recordkeeping and maintenance of records for components used in the manufacture of the medicated premixes, laboratory controls, packaging and labeling, master formula and batch-production, distribution records and complaint files.	65	1,370	89,050	~ 1 hour	89,050

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

The burden we attribute to recordkeeping activities associated with the provisions in 21 CFR part 226 are assumed to be distributed among the individual elements and averaged among respondents. 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: June 7, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023-12512 Filed: 6/9/2023 8:45 am; Publication Date: 6/12/2023]