

United States Food and Drug Administration

Current Good Manufacturing Practice Regulations for Type A Medicated Articles

OMB Control No. 0910-0154

SUPPORTING STATEMENT

Terms of Clearance: None.

Part A: Justification:

1. Circumstances Making the Collection of Information Necessary

This information collection supports the implementation of Food and Drug Administration (FDA, us or we) 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 (the 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)).

We therefore request OMB extension of OMB approval for the information collection requirements contained in 21 CFR part 226, as discussed in this supporting statement.

2. Purpose and Use of the Information Collection

The required records are used by both the respondents and the 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 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.

3. Use of Improved Information Technology and Burden Reduction

The regulation does not specifically prescribe the use of automated, electronic, mechanical, or other technological techniques or other forms of information technology as necessary for use by firms. Companies are free to use whatever forms of information technology may best assist them in retaining the appropriate records and making them available to regulatory officials. We estimate that about ninety percent (90%) of respondents will keep some of the required records electronically in the next 3 years.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection.

5. Impact on Small Businesses or Other Small Entities

Our best estimate is that approximately 65 firms are involved in the manufacturing of Type A medicated articles. We estimate that 75 percent of these 65 firms, or 49 respondents, are small businesses, and we have kept their particular needs in mind during the development of these regulations. The recordkeeping is no more burdensome for small businesses than for large. The requirements are the minimum requirements for CGMPs. We aid small businesses in complying with our requirements through our Regional Small Business Representatives and through the scientific and administrative staffs within the agency. We have provided a Small Business Guide on our website at <https://www.fda.gov/animal-veterinary/resources-you/cvm-small-business-assistance>.

6. Consequences of Collecting the Information Less Frequently

Under a CGMP system, the frequency of data collection by each manufacturer would occur periodically during Type A medicated article manufacturing operations, but that frequency of observation and recording would vary considerably for different manufacturers and different Type A medicated articles. Less frequent recordkeeping would reduce or nullify the effectiveness of the regulation to provide assurance to both the Type A medicated article manufacturer and FDA that the Type A medicated article meets standards for safety and meets the claimed identity, strength, quality, and purity standards. We do not collect CGMP records as a routine matter. Records remain on file at each Type A medicated article manufacturing facility. We would examine the records during a periodic inspection or during an investigation.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances associated with this information collection.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

FDA published a 60-day notice for public comment in the *Federal Register* of January 31, 2023 (88 FR 6281). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

There are no incentives, payments or gifts associated with this information collection.

10. Assurance of Confidentiality Provided to Respondents

In preparing this Supporting Statement, we consulted with our Privacy Office to ensure appropriate handling of information collected.

This (ICR) collects personally identifiable information (PII). PII is collected in the context of the individuals’ professional capacity and the FDA-related work they perform for their employer (e.g., point of contact at a regulated entity). The PII submitted is name, email address, and phone number. While it has been determined that FDA does not use name or any other personal identifier to retrieve records from the information collected, information collected is maintained in a Privacy Act system of records as described in HHS/FDA System of Records Notice (SORN) 09-10-0002 for Regulated Industry Employee Enforcement Records. Through appropriate form and webpage design, FDA limited submission fields and minimized the PII collected to protect the privacy of the individuals.

Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9)). FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information.

11. Justification for Sensitive Questions

The collection of information does not involve sensitive questions.

12. Estimates of Annualized Burden Hours and Cost

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

12a. Annualized Hour Burden Estimate

Table 1.--Estimated Annual Recordkeeping Burden

21 CFR Part; Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response ¹	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 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.

12b. Annualized Cost Burden Estimate

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Records Clerk ¹	89,050	\$30.24	\$2,692,872

¹May 2022 National Industry-Specific Occupational Employment and Wage Estimates, Bureau of Labor Statistics and including 30% for benefits (<https://www.bls.gov/oes/current/oes434199.htm>)

13. Estimates of Other Total Annual Costs to Respondents/Recordkeepers or Capital Costs

There are no capital, start-up, operating or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

We estimate the cost to the Federal government to be \$38,669.40. This estimate is based on the salary of an FTE at the GS-12/Step 5 level in the locality pay area of Washington-Baltimore-Arlington, DC-MD-VA-WV-PA in 2023 (\$51.15/hour x 36 hours per inspection x 21 inspections = \$38,669.40).

15. Explanation for Program Changes or Adjustments*

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

16. Plans for Tabulation and Publication and Project Time Schedule

This information collected will not be published or tabulated.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

The OMB expiration date will be displayed.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.