United States Food and Drug Administration

Current Good Manufacturing Practice Regulations for Type A Medicated Articles
OMB Control No. 0910-0154

SUPPORTING STATEMENT

Part A: Justification:

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA, Agency, us or we) regulations. Under section 501 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), 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 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). 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 ensure 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.

We therefore request OMB extension of OMB approval of 0910-0154 found in 21 CFR part 226; Current Good Manufacturing Practice Regulations for Type A Medicated Articles, 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 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.

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. There is no duplication of effort in this area. Data collected by each manufacturer is site specific. In addition, no duplication of Federal regulations concerning medicated feed manufacturing is likely because of the clear Congressional authorization in section 501(a)(2)(B) of the FD&C Act that FDA promulgate regulations for drugs, including Type A medicated articles, as opposed to the U.S. Department of Agriculture.

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/industry.

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 collection of information.

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 February 21, 2020 (85 FR 10170). 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 information collection request (ICR) collects personally identifiable information (PII). PII is collected in the context of the individuals' professional capacity. The PII collected as part of inspections includes name, address, email address, phone number and fax number.

FDA further determined that although PII is collected the collection is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Act do not apply. Specifically, FDA does not use name or any other personal identifier to retrieve records from the information collected. FDA also minimized the PII to be collected to protect the privacy of the individuals.

Company records describing manufacturing procedures, which may be consulted during a facility inspection, and CGMP records that we may copy or take possession of often contain trade secret and confidential commercial information. Confidential commercial information is protected from disclosure under the Freedom of Information Act (FOIA) under sections 552(a) and (b) (5 U.S.C. 552(a) and (b)), by section 301(j) of the FD&C Act, and by part 20 of our regulations (21 CFR part 20).

11. Justification for Sensitive Questions

The collection of information does not involve sensitive questions.

12. Estimates of Annualized Burden Hours and Cost

12a. Annualized Hour Burden Estimate

FDA estimates the burden of this collection as follows:

Table 1. --Estimated Annual Reporting Burden

21 CFR Section	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
226.42; requires records be prepared and maintained for two years with respect to components (drug and non-drug), used in the manufacture of the medicated premixes.	65	260	16,000	.75 (45 minutes)	12,675
226.58; requires recordkeeping for establishment of laboratory controls to ensure that	65	260	16,000	1.75 (1 hour, 45 minutes)	29,575

adequate specifications and test procedures for the drug components and Type A medicated articles conform to appropriate standards of identity, strength, quality and purity.					
226.80; requires maintenance of records for packaging and labeling of Type A medicated articles.	65	260	16,900	.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 (1 hour, 45 minutes)	29,575
226.110; requires maintenance of distribution records (2 years), for each shipment of Type A medicated articles for recall purposes.	65	260	16,900	.025 (15 minutes)	4,225
226.115; requires maintenance of complaint files for Type A medicated articles for two years.	65	10	650	.5 (30 minutes)	325
Total					89,050

12b. Annualized Cost Burden Estimate

21 CFR Part Form No. Activity Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Records clerk[1]	89,050	$25.86	$2,302,833

[1]May 2019 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 $35,441.28. 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 in 2020 ($46.88/hour x 36 hours per inspection x 21 inspections = $35,441.28).

15. Explanation for Program Changes or Adjustments

No adjustments or program changes are reported. The decrease in annual number of responses is due to the way the ICR was entered into ROCIS--five ICs were decreased to one.

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.