FOOD AND DRUG ADMINISTRATION

Current Good Manufacturing Practice Regulations for Type A Medicated Articles,
21 CFR Part 226

OMB Control No. 0910-0154

SUPPORTING STATEMENT

Terms of Clearance: None.

A. Justification

1. Circumstances Making the Collection of Information Necessary

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 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.

We request extension of OMB approval of the information collection provisions in the following citations:

21 CFR 226.42 - Recordkeeping - Requirement that records be prepared and maintained for two years with respect to components (drug and non-drug), used in the manufacture of the medicated premixes.

21 CFR 226.58 – Recordkeeping - Specifies recordkeeping requirements 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.

21 CFR 226.80 - Recordkeeping- Requires maintenance of records for packaging and labeling of Type A medicated articles.

21 CFR 226-102- Recordkeeping - Requirement for maintenance of master-formula and batch production records for Type A medicated articles.

21 CFR 226.110 - Recordkeeping - Requirement for maintenance of distribution records (2 years), for each shipment of Type A medicated articles for recall purposes.

21 CFR 226.115 - Recordkeeping - Requirement for maintenance of complaint files for Type A medicated articles for two years.

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 assure 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 three years.

4. Efforts to Identify Duplication and Use of Similar Information

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 manufacture of Type A medicated articles. We estimate that 75% 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 http://www.fda.gov/oc/industry/.

6. Consequences of Collecting the Information Less Frequently

Data collection occurs occasionally. 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

In accordance with 5 CFR 1320.8(d), on October 17, 2016, FDA published in the Federal Register (81 FR 71513) a 60-day notice soliciting public comment. No comments were received.

Additionally, there is ongoing communication with two organizations representing the industry: the Animal Health Institute, Alexandria, VA and the American Feed Industry Association, Arlington, VA.

9. Explanation of Any Payment or Gift to Respondents

This collection of information does not provide for payment or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

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

This information collection does not involve questions that are of a personally sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

12 a. 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	16,900	.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 (1 hour, 45 minutes)	29,575
226.80; requires maintenance of records for packaging and labeling of Type A medicated articles.	65	260	16,900	.75 (45 minutes)	12,675

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
226.102; 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

We based our estimate of the time required for record preparation and maintenance on our communications with industry. We derived additional information needed to calculate the total burden hours (i.e., manufacturing sites, number of Type A medicated articles being manufactured, etc.) from our records and experience.

12 b. Annualized Cost Burden Estimate

Type of Respondent	Total Burden Hours	Hourly Wage Rate[1]	Total Respondent Costs
Records Clerk	89,050	$18.64	$1,659,892

[1] May 2015 National Industry-Specific Occupational Employment and Wage Estimates, US Department of Labor, Bureau of Labor Statistics, Information and Record Clerks 43-4199(https://www.bls.gov/oes/current/oes434199.htm)

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/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 that the average hourly wage for respondents is equivalent to a GS-12-5 level in the locality pay area of Washington-Baltimore in 2016, approximately $42.08/hour. Increasing this wage by 30% to account for overhead costs ($12.62), FDA estimates the average hourly cost to respondents to be $54.70/hour. Based upon 21 inspections per year and 36 hours per inspection, the cost to the Federal Government is $41,353.20 (21 inspections x 36 hours/inspection x $54.70 = $41,353.20).

15. Explanation for Program Changes or Adjustments

The burden has not changed from the burden shown in the current inventory.

16. Plans for Tabulation and Publication and Project Time Schedule

There is no intent on the part of the Federal Government to publish this data, nor is any general statistical analysis by the Federal Government anticipated.

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.