OMB 0910-0152
SUPPORTING STATEMENT
THE CURRENT GOOD MANUFACTURING PRACTICE FOR
MEDICATED FEEDS

A. JUSTIFICATION

Abstract

1. Circumstances Making the Collection of Information Necessary.

The Federal Food, Drug, and Cosmetic Act (the act) under the Drug Amendments of 1962 provides authorization to establish current good manufacturing practice regulations (CGMPs) for drugs, including medicated feeds. Medicated feeds which are not manufactured under conforming methods or in conforming facilities are deemed to be adulterated under section 501(a)(2)(B) of the act. Regulations concerning current good manufacturing practices in the manufacture of medicated feeds (21 CFR Part 225), were initially established May 11, 1965. The current regulations were published March 3, 1986.

The specific citations within 21 CFR Part 225 regarding recordkeeping requirements for which we request OMB approval are as follows:

Commercial Feed Mills - Registered License holders.

21 CFR 225.42(b) (5) through (b) (8) - Recordkeeping - Specifies recordkeeping requirements for procedures for the receipt, storage and inventory control of medicated feeds.

21 CFR 225.58(c) and (d) - Recordkeeping - Specifies recordkeeping requirements for the results of periodic assays for medicated feeds that are in accord with label specifications and also those medicated feeds not within documented permissible assay limits.

21 CFR 225.80 (b) (2) - Recordkeeping - Requirement that verified medicated feed label (s) be kept for one year.

21 CFR 225.102 (b) (1) through (b) (5) - Recordkeeping - Specifies recordkeeping requirements for master record files and production records for medicated feeds.

21 CFR 225.110(b1) and (b) (2) - Recordkeeping - Specifies recordkeeping requirements for maintenance of distribution records for medicated feeds.

21 CFR 225.115 (b) (1) and (b) (2) - Recordkeeping - Specifies recordkeeping requirements for maintenance of complaint files by the medicated feed manufacturer.

Mixer - Feeders - Registered license holders

21 CFR 225.42(b) (5) through (b) (8) - Recordkeeping - Specifies recordkeeping requirements for procedures for receipt, storage and inventory control of medicated feeds.

21 CFR 225.58 (c) and (d) - Recordkeeping - Specifies recordkeeping requirements for the results or periodic assays of medicated feeds that are in accord with label specifications and also those medicated feeds not within documented permissible assay limits.

21 CFR 225.80 (b) (2) - Recordkeeping - Requirement that verified medicated feed label(s) be kept for one year.

21 CFR 225.102 (b) (1) through (b) (5) - Recordkeeping - Specifies recordkeeping requirements for master record files and production records for medicated feeds...

Commercial Feed Mills - Non registered license holders

21 CFR 225.142 - Recordkeeping - Specifies recordkeeping requirements for adequate recordkeeping procedures for identification, storage and inventory control (receipt and use) of Type a medicated articles and Type B medicated feeds.

21 CFR 225.158 - Recordkeeping - Specifies recordkeeping requirements when the results of laboratory assays of drug components indicate that the medicated feed is not in accord with the permissible assay limits.

21 CFR- 225.180 - Recordkeeping - Specifies recordkeeping requirements for identification , storage and inventory control of labeling in a manner that prevent label mix-ups and assures that correct labels are used for medicated feeds.

21 CFR 225.202 - Recordkeeping - Specifies recordkeeping requirements for retention of formula production and distribution records.

Mixer-Feeders - Non registered license holders

21 CFR 225.142 - Recordkeeping - Specifies recordkeeping requirements for adequate recordkeeping procedures for identification, storage and inventory control (receipt and use), of Type a medicated articles and Type B medicated feeds.

21 CFR 225.158 - Recordkeeping - Specifies recordkeeping requirements when the results of laboratory assays of drug components indicate that the medicated feed is not in accord with the permissible assay limits.

21 CFR- 225.180 - Recordkeeping - Specifies recordkeeping requirements for identification , storage and inventory control of labeling in a manner that prevent label mix-ups and assures

that correct labels are used for medicated feeds.

21 CFR 225.202 - Recordkeeping - Specifies recordkeeping requirements for retention of formula production and distribution records.

2. Purpose and Use of the Information Collection

Medicated animal feeds are produced using Type a medicated articles and various feed ingredients such as ground corn. These feeds contain animal drugs intended for prevention, cure, mitigation, or treatment of disease (therapeutic use), or intended to affect the structure or function of the animal (growth promotion and feed efficiency). Compliance with cGMP`s provides some assurance that medicated feeds will be safe and effective for their labeled conditions of use and that edible products from treated animals will be free of unsafe drug residues. The recordkeeping and retention requirements are intended as a drug accountability system consisting of records of receipt, batch production, daily drug inventory, distribution, and compliant files.

Facilities manufacturing certain medicated feeds using Type A medicated articles are required to register as drug manufacturers under section 510 of the act; as such, these firms are subject to FDA inspection every two years. Recordkeeping and retention requirements provide documented evidence of compliance with current good manufacturing practices. The remaining medicated feed manufacturers, while not required to register with FDA, are required to be in compliance with a less stringent set of current good manufacturing practice requirements. These facilities are subject to occasional inspection by FDA, generally for cause.

The kind of records required by 21 CFR Part 225 is those normally maintained by an efficient feed manufacturing facility to monitor its own functions and drug accountability. Drug inventory control is necessary so that the firms and Agency investigators can monitor drug usage and possible over-or-under formulation of medicated feeds. In addition, such information is reviewed by the Agency in the course of follow-up investigations of drug residues in edible products of treated animals.

3. Use of Information Technology and Burden Reduction

The industry is increasingly turning to the use of automated production facilities. The use of computer generated records is acceptable for the purposes of recordkeeping for FDA inspections. However, currently 0% of records for this information collection are submitted electronically.

4. Efforts to Identify Duplication and Use of Similar Information

Each manufacturer is responsible for the labeling and recordkeeping for the products they manufacture. No duplication would, therefore, occur. There are no similar records that could

substitute for those required by these regulations.

5. Impact on Small Businesses or Other Small Entities

The same information is requested from large and small firms and is the minimal amount needed. Headquarters and field personnel provide direct assistance and advice to small businesses in dealing with the requirements through the FDA Office of Small Manufacturers Assistance.

By feed mill size, most respondents (to the USDA study referenced below) in 2004 had feed mills that produced from 1,000 to 9,999 tons per year. Only 56 feed mills had production of over 100,000 tons per year, yet they produced 53 percent of the total.[1]

6. Consequences of Collecting the Information Less Frequently

This information is reported annually. If this information was not reported, FDA would not have access to information necessary for determining risk to the public health, of a potential contamination problem concerning medicated feeds.

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

There are no special circumstances that occur when collecting this information.

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

No comments were received in response to the Federal Register Notice of November 29, 2010 (75 FR 73101).

9. Explanation of Any Payment or Gift to Respondents

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

10. Assurance of Confidentiality Provided to Respondents

All confidential information will be kept confidential in accordance with 18 U.S.C. 1905 and 21 U.S.C.331 (j), as well as section 301(j) of the Act.

11. Justification for Sensitive Questions

These regulations do not contain questions pertaining to sex behavior, attitude, religious beliefs, or any other matters that are commonly considered private or sensitive in nature.

12. Estimates of Annualized Burden Hours and Costs

1 "Feed Mill Operations of Agricultural Cooperatives," U.S. Department of Agriculture Research Report #207, September 2005

12a. Annualized Hour Burden Estimate

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Recordkeeping Burden (Registered Licensed Commercial Feed Mills)					
21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
225.42(b)(5) trough (b)(8)	1,004	260	261,040	1	261,040
225.58(c) and (d)	1,004	45	45,180	30/60	22,590
225.80(b)(2)	1,004	1,600	1,606,400	7/60	192,768
225.102(b)(1)	1,004	7,800	7,831,200	5/60	626,496
225.110(b)(1) and (b)(2)	1,004	7,800	7,831,200	.015	117,468
225.115(b)(1) and (b)(2)	1,004	5	5020	7/60	602
Total					1,220,964

Table 2--Estimated Annual Recordkeeping Burden (Registered Licensed Mixer-Feeders)					
21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
225.42(b)(5) trough (b)(8)	100	260	26,000	9/60	3,900
225.58(c) and (d)	100	36	3,600	30/60	1,800
225.80(b)(2)	100	48	4,800	7/60	576
225.102(b)(1)	100	260	26,000	24/60	10,400
Total					16,676

Table 3--Estimated Annual Recordkeeping Burden (Nonregistered Unlicensed Commercial Feed Mills)					
21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
225.142	8,000	4	32,000	1	32,000
225.158	8,000	1	8,000	4	32,000
225.180	8,000	96	768,000	7/60	92,160
225.202	8,000	260	2,080,000	39/60	1,352,000
Total					1,508,160

Table 4--Estimated Annual Recordkeeping Burden (Nonregistered Unlicensed Mixer-Feeders)

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
225.142	45,000	4	180,000	1	180,000
225.158	45,000	1	45,000	4	180,000
225.180	45,000	32	1,440,000	7/60	172,000
225.202	45,000	260	11,700,000	20/60	3,861,000
Total					4,393,000

The burden hours for this collection of information were derived as follows:

There are approximately 54,000 feed manufacturers that must comply with current good manufacturing practice (cGMP's) regulations for medicated feeds when manufacturing medicated animal feed. Licensed manufacturers, those manufacturing a medicated feeds using a drug which FDA has determined requires more control because of the need for a withdrawal period before slaughter or carcinogenic concerns, are required to comply with the more stringent cGMP's. Those firms not required to be licensed must comply with the less demanding cGMP's. Of the medicated feed manufacturers, it is estimated that 1,104 are license holders (1,004 are commercial feed mills and 100 are mixer-feeders or on-farm operations). The remainder of the feed manufacturers (i.e., 53,000) consists of non-license holders (8,000 are commercial feed mills and 45,000 are mixer-feeder operations).

The estimate of the times required for record preparation and maintenance is based on agency communications with industry. Other information needed to finally calculate the total burden hours (i.e., number of recordkeepers, number of medicated feeds being manufactured, etc.) is derived from agency records and experience.

[1]

12b. Annualized Cost Burden Estimate

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Feed Mill Worker	7,138,800	$10.00[2]	$71,388,000

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

There are no other costs.

14. Annualized Cost to the Federal Government

2 Bureau of Labor Statistics, National Industry-Specific Occupation Employment and Wage Estimates, May 2009.

It is estimated that an FDA inspector spends approximately one hour reviewing various types of required records during an inspection. Approximately 680 inspections are conducted annually. These inspections, conducted by a GS-12-05 employee earning approximately $40.66 an hour resulted in an estimated annual cost of $27,649 (680 x $40.66).

15. Explanation for Program Changes or Adjustments.

There has been a decrease in the number of licensed feed manufacturers of medicated feeds who are required to comply with the Food and Drug Administration's (FDA) regulations.

Therefore the adjusted annual hour burden decreased from 7,206,902 hours to 7,138,800, a decrease of 68,102 hours. The annual number of responses decreased from 34,931,951 to 33,893,440, a decrease of 1,038,511.

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 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.