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

A. JUSTIFICATION

1. Circumstances Which Make Information Collection 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

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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. How, by Whom, and the Purpose for Collecting this Information.

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 are 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 Technology to Reduce the Burden on the Public.

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.

4. Identification and Use of Duplicate 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. FDA’s Efforts to Reduce Burden on Small Business.

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.

6. Impact of not Collecting this Information or Collecting Information Less Frequently

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. Explain Any Circumstances That Occur When Collecting this Information.

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

8. Identification of Outside FDA Sources.

No comments were received in response to the Federal Register Notice of August 16, 2007 (72 FR 46089).

9. Payments or Gifts Offered to Respondents

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

10. Method of Assuring Respondent Confidentiality.

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. Use of 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. Burden Hours and Costs Associated with this Information Collection.

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

There are approximately 54,160 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 54,160 manufacturers, it is estimated that 1,160 are license holders (1,060 are commercial feed mills and 100 are mixer-feeders or on-farm operations). The remainder of the 54,160 (i.e., 53,000) consists of non-license holders (8,000 are commercial feed mills and 45,000 are mixer-feeder operations).

A breakout of the recordkeeping requirements for each class of facility are as follows:

Table 1.--Estimated Annual Recordkeeping Burden (Registered Licensed Commercial Feed Mills)\1\

21 CFR Section	No. of Recordkeepers	Annual Frequency per Record-keeper	Total Annual Records	Hours per Recordkeeper	Total Hours
225.42(b)(5) through (b)(8)	1,060	260	275,600	1	275,600
225.58(c) and (d)	1,060	45	47,700	.5	23,850
225.80(b)(2)	1,060	1,600	1,696,000	.12	203,520
225.102(b)(1)	1,060	7,800	8,268,000	.08	661,440
225.110(b)(1) and (b)(2)	1,060	7,800	8,268,000	.015	124,020
225.115(b)(1) and (b)(2)	1,060	5	5,300	.12	636
Total					1,289,066

\1\ There are no capital or operating and maintenance costs associated with this collection of information.

Table 2.--Estimated Annual Recordkeeping Burden (Registered Licensed Mixer-Feeders)\1\

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
225.42(b)(5) through (b)(8)	100	260	26,000	.15	3,900
225.58(c) and (d)	100	36	3,600	.5	1,800
225.80(b)(2)	100	48	4,800	.12	576
225.102(b)(1) through (b)(5)	100	260	26,000	.4	10,400
TOTAL				16,676	

\1\ There are no capital costs or operating and maintenance costs associated with this collection of information.

Table 3.--Estimated Annual Recordkeeping Burden (Nonregistered Unlicensed Commercial Feed Mills)\1\

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	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	.12	92,160
225.202	8,000	260	2,080,000	.65	1,352,000
TOTAL					1,508,160

\1\ There are no capital costs or operating and maintenance costs associated with this collection of information.

Table 4.--Estimated Annual Recordkeeping Burden (Nonregistered Unlicensed Mixer-Feeders)\1\

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	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	.12	172,000
225.202	45,000	260	11,700,000	.33	3,861,000
TOTAL					4,393,000

\1\ There are no capital costs or operating and maintenance costs associated with this collection of information.

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.

Cost to the Respondents

The cost to the respondents is estimated to be $72,069,020. This cost estimate is based on an average hourly wage of $10.00, ($10.00 x 7,206,902).

13. Annual Cost Estimate to Respondents.

This collection of information does not result in a cost burden beyond the hour burden to respondents.

14. Annual Cost Estimate to FDA.

It has been estimated that an FDA inspector spends approximately one hour reviewing various types of required records during an inspection. Six hundred eighty-four inspections were conducted by FDA personnel in 2003. These inspections, conducted by a GS-12-05 employee earning approximately $36.00 an hour resulted in an estimated annual cost of $24,624 (684 x $36).

15. Changes from Previous Approval.

There has been a slight decrease in the burden to feed manufacturers that must comply with current good manufacturing regulations for medicated feeds. The adjusted burden has decreased from 7,315,661 hours to 7,206,902, a decrease of 108,759 hours.

16. Publishing the Results of this Information Collection.

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.