SUPPORTING STATEMENT
CURRENT GOOD MANUFACTURING PRACTICE FOR TYPE A MEDICATED ARTICLES - 21 CFR PART 226
OMB 0910-0154

A. JUSTIFICATION

1. Circumstances Which Make this Information Collection Necessary.

The Federal Food, Drug, and Cosmetic Act (the act), authorizes establishment by FDA of current good manufacturing practice regulations (CGMPs), for drugs, including Type A medicated articles which are intended for use in the manufacture of medicated complete animal feeds. Type A medicated articles are feed products containing a concentrated drug diluted with a feed carrier substance(s). Current good manufacturing practices regulations in the manufacture of medicated premixes were established November 1, 1967. The Title "Medicated Premix", was changed to 'Type A Medicated Article as of March 1, 1986. Type A medicated articles which are not manufactured in accordance with CGMPs are deemed to be adulterated under section 501 (a)(2)(B) of the Act.

The collection of information requirements within 21 CFR Part 226 for which OMB approval is being requested are summarized below:

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 Article(s) 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 Article(s).

21 CFR 226-102- Recordkeeping - Requirement for maintenance of master-formula and batch production records for Type A Medicated Article(s).

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

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

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

Records retention required by 21 CFR Part 226 are those normally maintained by an efficient drug manufacturing facility to monitor its own functions and drug accountability. Drug inventory control is necessary to monitor drug usage and possible under-or-over-formulation of Type A medicated articles. Production and distribution records are essential in the investigation of product defects, particularly when a drug recall is indicated.

3. Use of Technology to Reduce the Burden on the Public.

The kind of information required by these regulations may be met by the type of records normally on hand and those introduced by the use of computer technology. Computers have been introduced to maintain control over the total manufacturing process,. Most firms now use computerized forms to maintain procedures and provide analytical information. With computer assisted equipment, many areas of recordkeeping are handled routinely and without error. The FDA has developed guides to assure that computerized operations are validated and properly run.

4. Identification and Use of Duplicate Information.

Data collected is site specific, so there is no duplication of efforts. There are no other regulations that require collection of the same data.

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 Manufacture Assistance.

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

The information required under these regulations must be developed for each batch of Type A medicated article manufactured. There is no time schedule for information collection. The frequency is set by the manufacturer's production schedule.

7. Explain any Special Circumstances that Occur When Collecting this Information.

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

8. Identification of Outside FDA Sources.

This regulation was subject to public comment under the Administrative Procedures Act and public comments were addressed as part of the public rulemaking process. No changes have been made in the regulatory requirements and no comments were submitted in response to the 60 day Federal Register notice of August 16, 2007 (72 FR 46087). Additionally, there is continuous communication with two organizations representing the industry i.e., the Animal

Health Institute, Alexandria, VA and the American Feed Industry Association, Arlington, VA.

9. Payments or Gifts Offered to Respondents

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

10. Method of Assuring Respondent Confidentiality.

Confidentiality of information will be safeguarded within the provisions of FDA's public information regulations in 21 CFR Part 20.

11. Use of Sensitive Questions.

This information collection does not involve 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

Under the act, all manufacturers of Type A medicated articles are required to register. Because these firms may also be registered as manufacturers of animal drugs (pharmaceutical dosage forms) or animal feeds, an accurate complete count is difficult. Our best estimate is that approximately 115 firms are involved in the manufacture of Type A medicated articles. All manufacturers are required to keep records to document procedures required under the manufacturing process to assure that proper quality control is maintained. Time spent on records under the regulations related to the manufacturing operation are estimated as follows:

Estimated Annual Recordkeeping Burden 1

21 CFR Section	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
226.42	115	260	29,000	0.75	22,425
226.58	115	260	29,000	1.75	52,325
226.80	115	260	29,000	0.75	22,425
226.102	115	260	24,000	1.75	52,325
226.110	115	260	29,000	0.25	7,475
226.115	115	10	1,150	0.5	575
					157,550

Total					

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

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

Cost to Respondents

The cost of record keeping to respondents is 157,550 hours times $14.31 per hour (hourly wage) equals $2,254,540.

13. Annual Cost Estimate to Respondents.

There are no additional annual cost burdens beyond the burden hours for record keeping to respondents above.

Annual Cost Estimate to FDA.

FDA professional staff spends approximately 36 hours per inspection in the observation of facilities, operations and records. Investigational cost was computed on the basis of a GS 12-05 investigator making $36 per hour (2007 hourly wage). Based upon 21 inspections per year, the cost to the government is 21 inspections x 36 hours/inspection x $36 = $27,216.

15. Explanation for Program Changes or Adjustments

The hourly burden has remained the same since the last renewal at 157,550 hours.

16 Publishing the Results of this Information Collection

This section is not applicable since the information collected is site dependent and not sent to a central point for compilation for statistical purposes.