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

## A. JUSTIFICATION

### Abstract

### 1. Circumstances Making 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 is 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. Purpose and Use of the Information Collection

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 Improved Technology and Burden Reduction**

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. However, to date, 0% of records are submitted electronically under this information collection.

**4. Efforts to Identify Duplication and Use of Similar 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. 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 Manufacture Assistance.

**6. Consequences of Collecting the 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. 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**

In accordance with 5 CFR 1320.8(d), on November 26, 2010 (75 FR 72827), a 60-day notice for public comment (Attachment 1) was published in the Federal Register. No comments were received.

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. Explanation of Any Payments or Gift Offered to Respondents**

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

**10. Assurance of Confidentiality to Respondents**

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

**11. Justification for 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. Estimates of Annualized Burden Hours and Costs**

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. The time spent on the records under the regulations related to the manufacturing operation is estimated as follows:

12a. Annualized Hour Burden Estimate

Estimated Annual Recordkeeping Burden

| 21 CFR Section | No. of Recordkeepers | Annual Frequency per Recordkeeping | Total Annual Records | Hours per Record | Total Hours |
|---|---|---|---|---|---|
| 226.42 | 115 | 260 | 29,900 | 0.75 | 22,425 |
| 226.58 | 115 | 260 | 29,900 | 1.75 | 52,325 |
| 226.80 | 115 | 260 | 29,900 | 0.75 | 22,425 |
| 226.102 | 115 | 260 | 29,900 | 1.75 | 52,325 |
| 226.110 | 115 | 260 | 29,900 | 0.25 | 7,475 |
| 226.115 | 115 | 10 | 1,150 | 0.5 | 575 |
| Total | | | | | 157,550 |

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.

12b. Annualized Cost Burden Estimate

| Type of Respondent | Total Burden Hours | Hourly Wage Rate[1] | Total Respondent Costs |
|---|---|---|---|
| Clerical worker | 157, 550 | $14.31[1] | $2,254,540 |

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

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

**Annualized Cost to the Federal Government**

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 $40.66 per hour (2011 hourly wage). Based upon 21 inspections per year, the cost to the government is 21 inspections x 36 hours/inspection x $40.66 = $30,739.

## 15. Explanation for Program Changes or Adjustments

The decrease (-931,500) that appears in the "Due to Adjustment in Agency Discretion" column was due to an inadvertent error 3 years ago. Some how the number of responses was entered as 1,082,150, this was incorrect. The correct total is 150,650.

**16. Plans for Tabulation and Publication and Project Time Schedule**

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

**17. Reasons Display of OMB Expiration Date is Inappropriate**

Display is not inappropriate.

**18. Exceptions to Certification for Paperwork Reduction Act Submissions**

There are no exceptions to the certification.

1 Based on agency communications with industry.