Supporting Statement

Veterinary Feed Directive

0910-0363

A. Justification

1. Circumstances Making the Information Collection Necessary

With the passage of the Animal Drug Availability Act (ADAA) the Congress enacted legislation establishing a new class of restricted feed use drugs, veterinary feed directive (VFD) drugs, which may be distributed and use of VFD drugs are similar to those for prescription drugs regulated under section 503(f) of the act, the implementing VFD regulation (21 CFR 558.6) is tailored to the unique circumstances relating to the distribution of medicated feeds. The VFD regulation ensures the protection of public health while enabling animal producers to obtain and use needed drugs as efficiently and cost-effectively as possible.

We request OMB approval for information collection required by the following citations:

21 CFR 514.1(b)(9- Reporting --- Requires submission of a VFD form as a part of the new animal drug application for each VFD drug.

21 CFR 558.6(a)(3-5) – Reporting --- Requires production of a VFD with specific information.

21 CFR 558.6(c)(1-4) – Recordkeeping --- Requires maintenance of VFD records two years after the date of issuance.

21 CFR 558.6(d)(1)(i, ii, iii) – Reporting --- Requires notification to the FDA by the distributor upon first engaging in distribution.

21 CFR 558.6(d)(1)(iv) – Reporting --- Requires a change of address notification when applicable.

21 CFR 558.6(d)(2)- Reporting --- Allows a distributor, in lieu of a VFD order, to ship VFD feed if the consignee furnishes an acknowledgement letter affirming that it will only distribute feed bearing or containing a VFD drug to an animal producer who holds a valid VFD or to another distributor who furnishes an acknowledgement letter.

21 CFR 558.6(e)(1-3)- Recordkeeping --- Requires the distributor to keep records of receipt and distribution of all medicated animal feeds containing VFD drugs.

2. Purpose and Use of the Information

A VFD drug is limited to use under a valid veterinary-client-patient relationship where the veterinarian assumes the responsibility for safe and effective use of a VFD drug and the client has agreed to follow the instructions of the veterinarian.

Control of certain antimicrobials is critical to reducing unnecessary use of such drugs in animals and to slowing or preventing the development of bacteria resistance to antimicrobial drugs. Safety concerns relating to difficulty of diagnosis of disease conditions, high toxicity, or other reasons, may also require that the use of an animal drug in animal feed be limited to use by order and under the supervision of a licensed veterinarian.

Although statutory controls on the distribution and use of VFD drugs are similar to those for prescription drugs regulated under section 503(f) of the act, the implementing VFD regulations are tailored to the unique circumstances relating to the distribution of animal feeds containing a VFD drug. The information collected by FDA staff will help assure compliance with the VFD regulation and provide assurance that the 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.

3. Use of Information Technology and Burden Reduction

The industry is increasingly turning to the use of automated production facilities. The use of information technology is acceptable for the purposes of recordkeeping for FDA inspections.

4. Efforts to Identify Duplication and Use of Similar Information

Each veterinarian and manufacturer/distributor is responsible for his/her own recordkeeping. Further, there are no other regulations that would require the submission or retention of this material. Therefore, duplication would not occur.

5. Impact on Small Business or Other Small Entities

The proposed collection of information carries the same burden, per VFD, for small or large firms. The regulation should not have a significant effect on small business, as the cost of the additional veterinary service and paperwork burden is minimal and constitutes an insignificant percentage of revenue of the affected firms.

6. Consequences of Collecting the Information Less Frequently

All reporting and recordkeeping are one time events associated with issuance of a VFD for the recordkeeping burden.

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

All of the reporting requirements are consistent with 5 CFR 1320.5.

8. Efforts to Obtain Comments on the Information Collection Before Submission to OMB.

On June 5, 2008, FDA published in the **Federal Register** a 60-day notice (73 FR 32029) Requesting comments on this information collection. No comments were received.

9. Explanation of Any Payment or Gift to Respondent

There were no payments or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondent

Information will be kept confidential in accordance with 18 USC 1905 and 21 USC 3310.

11. Justification for Sensitive Questions

This information collection does not contain questions pertaining to sexual behavior, attitude, religious beliefs, or any other matter commonly considered private or of a sensitive nature.

12. Estimates of Hour Burden

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

Table 1. - Estimated Annual Reporting Burden

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
558.6(a)(3) through (a)(5)	15,000	25	375,000	.25	93,750
558.6(d)(1)(i) through (d)(1)(iii)	300	1	300	.25	75
558.6(d)(1)(iv)	20	1	20	.25	5
558.6(d)(2)	1,000	5	5000	.25	1,250
514.1(b)(9)	1	1	1	3.00	3
Total	16,321				95,083

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

Table 2.-Estimated Annual Recordkeeping Burden

21 CFR Section	No. of Record-keepers	Annual Frequency per Record-keeping	Total Annual Records	Hours per Record	Total Hours
558.6(c)(1) through (c)(4)	112,500	10	1,125,000	.0167	18,788
558.6(e)(1) through (e)(4)	5,000	75	375,000	.0167	6,263
Total	117,500				25,051

[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 communication with industry and agency records and experience.

13. Estimate of Other Total Cost Burden to Respondents and Recordkeepers

The collection of information would not result in a cost burden beyond the hour burden to respondents cited above.

14. Annualized Cost to the Federal Government

Based on agency estimates of 10 minutes for a GS-7 employee to process the notification, total cost per year are estimated to be $4,800.00

15. Explanation of Program Changes and Adjustments

We have adjusted the number of respondents under 558.6(d)(i) through (d)(iii) from 1500 to 300 due to our experience with the VFD distributions and our database information. The reporting burden Table I reflects those changes.

16. Plans for tabulation and Publication and Project Time Schedule

Information is not to be published for statistical use.