

SUPPORTING STATEMENT

VETERINARY FEED DIRECTIVE - NPRM

A. JUSTIFICATION

1. Circumstances Making the Information Collection Necessary

With the passage of 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 without involving State pharmacy laws. Although 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 would be tailored to the unique circumstances relating to the distribution of medicated feeds. This proposal would ensure 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:

21CFR 514.1(b)(9) **Reporting**

Requires submission of a VFD in a specific format as a part of the new animal drug application for each VFD drug.

21CFR 558. 6(a)(3-5) **Reporting**

Requires production of a VFD with specific information.

21CFR 558.6(c)(1) **Recordkeeping**

Requires maintenance of VFD records two years after the date of issuance.

21CFR 558.6 (d)(1)(i) through (d)(1) (iii) **Reporting**

Requires notification to the FDA by the distributor upon first engaging in distribution.

21CFR 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.

21CFR 558.6(e)(ii) **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 the 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 bacterial 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 animal 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 some 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 residues.

3. Use of Information Technology and Burden Reduction

The industry is increasingly turning to the use of automated production facilities. The use of automated printouts 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. Duplication would, therefore, 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 recordkeeper's benefit.

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.

To a large extent, the amendment to the statute, which included reporting and paperwork collection, was crafted by the Coalition for Animal Health (a group that represents veterinarians, animal producers and the feed industry). In addition, we consulted with several segments of the industry to obtain concurrence with the projected recordkeeping statistics.

9. Explanation of Any Payment or Gift to Respondent

There are 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 331(j), as well as section 301 (j) of the Act.

11. Justification for Sensitive Questions

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

12. Estimates of Hour Burden Including Annualized Hourly Costs

21 CFR	# of Respondents	Annual Frequency of Response	Total Annual Responses	Hours per Response	Total Hours	Capital Costs
558.6(a)(3-5)	15,000	25	375,000	0.25	93,750	\$12,250.00
558.6(d)(1)(i-iii)	5,000	1	5,000	0.25	1,250	
558.6(d)(1)(iv)	100	1	100	0.25	25	
558.6(d)(2)	5,000	1	5,000	0.25	1,250	
514.1(b)(9)	1	1	1			
Total hours/cost	25,101				96,275	\$12,250.00

1 There are no operating or maintenance cost associated with this collection of information

Estimated Annual Recordkeeping Burden

21CFR	# of Recordkeepers	Annual Frequency of Recordkeepers	Total Annual Records	Hours per Record	Total Hours	Capital Costs
558.6 (c)(1)	112,500	10	1,125,000	.0167	18,788	\$37,500.00
558.6(e)(ii)	5,000	75	375,000	.0167	6,263	
Total Hours/Cost					25,051	\$37,500.00

1 There are no operating and maintenance cost associated with this collection of information

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's burden to respondents cited above

14. Annualized Cost to the Federal Government

Based on agency estimates of 10 minutes for a GS-7 government employee to process the notification, total costs in the first year are estimated at about \$11,000.00.

15. Explanation of Program Changes or Adjustments

This is a new collection. Thus, there are no changes or adjustments to previous burden estimates.

16. Plans for Tabulation and Publication and Project Time Schedule

Information is not to be published for statistical use.