Veterinary Feed Directive
OMB Control No. 0910-0363
Supporting Statement

A. Justification

1. Circumstances Making the Collection of Information Necessary

In 1996, the Animal Drug Availability Act (ADAA) (Public Law 104–250) was enacted to facilitate the approval and marketing of new animal drugs and medicated feeds. Among other things, the ADAA created a new regulatory category for certain new animal drugs called veterinary feed directive drugs (or VFD drugs). VFD drugs are new animal drugs intended for use in or on animal feed which are limited to use under the professional supervision of a licensed veterinarian in the course of the veterinarian's professional practice. The VFD regulation was tailored to the unique circumstances relating to the use of certain medicated feeds. All distributors of medicated feed containing VFD drugs must notify FDA of their intent to distribute such feed, and records must be maintained of the distribution and feeding (under the professional supervision of a licensed veterinarian) of all medicated feeds containing VFD drugs. The VFD regulation ensures the protection of the public health while enabling animal producers to obtain and use needed drugs as efficiently and cost effectively as possible.

On December 12, 2013, FDA published a proposed rule in the Federal Register (78 FR 75515) intended to improve the efficiency of FDA's VFD program. The provisions included in the proposed rule were based on stakeholder input received in response to solicitations for public comment, including an advanced notice of proposed rulemaking on March 29, 2010 (75 FR 15387), and draft text of proposed amendments to the current VFD regulations on April 13, 2012 (77 FR 22247). FDA is now finalizing the rule and thereby revising the information collection provisions by lowering the recordkeeping burden without compromising human or animal safety, by providing greater deference and flexibility to the veterinary profession for licensing and veterinary practice requirements, and by ensuring continued access to Category I Type A medicated articles by unlicensed feed mills.

We are specifically requesting approval for the following provisions, noting that there has been some renumbering of the codified regulations:

Reporting

21 CFR 558.6(c)(4); requires notification to the FDA by the distributor upon first engaging in distribution of VFD feeds.

Reporting

21 CFR 558.6(c)(6); requires a change of address notification by a distributor when applicable.

Recordkeeping

21 CFR 558.6(c); requires maintenance of VFD records for two years after the date of issuance by all parties (i.e., veterinarians, distributors, and producers).

Recordkeeping

21 CFR 558.6(e); requires the distributor to keep records of receipt and distribution of all medicated animal feeds containing VFD drugs.

3rd Party Disclosure

21 CFR 558.6(b)(7); issuance of a VFD by veterinarian with specific information.

3rd Party Disclosure

21 CFR 558.6(c)(8); generation of acknowledgement letter.

This information collection is not related to the American Recovery and Reinvestment Act of 2009.

2. Purpose and Use of the Information

A VFD drug is limited to use under the professional supervision of a licensed veterinarian, wherein 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. The implementing VFD regulations are tailored to the unique circumstances relating to the distribution and use 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.

Entities affected are from the private sector: veterinarians, distributors, and animal food producers, who are private businesses, will be affected by this information collection.

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. Currently about 50% (half) of submissions are electronic, however, we expect this number to increase.

4. Efforts to Identify Duplication and Use of Similar Information

Each veterinarian, client, and manufacturer/distributor of VFD feed 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.

The agency estimates that 100% of respondents are private sector businesses.

6. Consequences of Collecting the Information Less Frequently

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

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. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A proposed rule revising the VFD regulations was published in the Federal Register on December 12, 2013 (78 FR 75515). FDA received some feedback suggesting that the current VFD process was overly burdensome. In response to this concern, FDA began exploring ways to improve the VFD program's efficiency including the ability of respondents to retain and submit VFD forms electronically without the requirement to also send the original paper form. Other comments to the rulemaking fell outside the scope of the PRA, but are addressed in the agency's preamble to the final rule.

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 is 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 Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

The table below presents what the agency believes is a one-time burden resulting from the final rule. We believe that this burden reflects what the respective respondents may expend in order to determine which actions are necessary to comply with the regulations. We believe the total burden reflected in this table will be realized upon implementation of the final rule.

One-time Burden to Review Rule

Applicable Burden; Respondent	Estimated No. of Respondents	Estimated Time for Review	Total One-time Burden
Reporting; VFD Feed Distributers	1,376	4	5,504
Recordkeeping; Food Animal Veterinarian	3,050	1	3,050
Recordkeeping; Clients (Producers)	10,000	0.5	5,000
3rd Party Disclosure; VFD Drug Sponsors (General and Operations Managers)	3	6	18
Total	14,429		13,572

The following tables are included in the Paperwork Analysis section of the final rule. The analysis explains in detail how the revisions to the burden hours and costs were calculated. Burden hours and costs were derived from the agency's Final Regulatory Impact Analysis (FRIA) supporting the final rule.

Table 1 – Estimated Annual Reporting Burden[1]

21 CFR Section; Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Avg. Burden per Response	Total Hours
558.6(c)(4); a distributor must notify FDA prior to the first time it distributes a VFD drug.	300	1	300	.125	37.5
558.6(c)(6); a distributor must notify FDA within 30 days of any change in ownership, business name, or business address.	20	1	20	.125	2.5
Total					40

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

Table 2 – Estimated Annual Recordkeeping Burden[1]

21 CFR Section; Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Avg. Burden per Recordkeeping	Total Hours
558.6(c)(1) through (c)(4); filing of VFD copies by veterinarians and producers.	13,050	114.9	1,500,000	.0167	25,050
558.6(e)(1) through (e)(4); filing of VFD copies by distributors only.	1,376	545.1	750,000	.0167	12,525
Total	14,426		2,250,000		37,575

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

Table 3.—Estimated Annual 3rd Party Disclosure[1]

21 CFR Section; Activity	No. of Disclosures per Respondent	No. of Disclosures per Respondent	Total Annual Disclosures	Avg. Burden per Disclosure	Total Hours
558.6(b)(7);veterinarian issues VFD	3,050	246	750,000	0.125	93,750
558.6(c)(8); acknowledgement letter generation[3]	1,000	5	5,000	0.125	625
TOTAL					94,375

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

12b. Annualized Cost Burden Estimate

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
VFD Feed Distributors	13,230	$71.00	$939,330
Clients (Producers)	12,525	$31.00	$388,275
Drug Sponsors	3	$83.00	$249
Veterinarian	106,275	$84.00	$8,927,100
TOTAL	132,033		$10,254,954

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

The following cost table is based on the agency's FRIA for the final rule.

Table 4 – Annualized Cost Burden Estimate

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Cost
One-Time Cost Burden			
VFD Feed Distributors – Review of Final Rule	5,504	$96.00	$529,000
Veterinarians –Review of Final Rule	3,050	$84.00	$255,000
Clients – Review of Final Rule	5,000	$49.00	$244,000
Sponsors – Review of Final Rule	18	$140.00	$2,500
Total One-time Cost Burden	13,572		$1,030,500

Annual Cost Burden			
VFD Feed Distributors (Reporting)	40	$96.00	$384
VFD Feed Distributors (Recordkeeping, Third-party Disclosure)	13,150	$77.00	$1,012,550
Veterinarians (Recordkeeping, Third-Party Disclosure)	106,275	$84.00	$8,927,100
Clients (Recordkeeping)	12,525	$49.00	$613,725
Total Annual Cost Burden	131,990		$10,553,759
TOTAL	145,562		$11,584,259

For Feed Distributors, FDA estimates review of the final rule and notifications to FDA to be completed by personnel at the general and operations manager level. The NAICS code 311100--Animal Food Manufacturing, reports the hourly compensation (including the 100% increase for total overhead costs) at about $96 per hour. FDA estimates other information collection tasks (recordkeeping and issuance of acknowledgement letters) to be completed by personnel at the industrial production manager level, at a total compensation rate (including all overhead costs) of about $77 per hour.

FDA estimates that there are about 3,050 veterinarians that exclusively treat food-producing animals. We use the AVMA 2010 median veterinarian hourly compensation rate of about $39, and adjust it to include the additional 100% for total overhead costs, as well as adjust it to 2013 dollars. The result is an estimated compensation rate of about $84 per hour.

For sponsors of the VFD drugs that FDA has approved, FDA estimates information collection tasks to be completed by personnel at the general and operations manager level. The hourly pay for general and operations managers at firms in the North American Industrial Classification System (NAICS) code 325400--Pharmaceutical and Medicine Manufacturing, is about $70. When adjusted for total overhead costs at 100 percent, the resulting total compensation is about $140 per hour.

For animal food producers (clients), FDA uses the Bureau of Labor Statistics' Occupation Employment and Wage data that reports the median wage of a first-line supervisor of farming, fishery, and forestry workers (adjusted for total overhead costs at 100% of labor costs)) of about $49 per hour.

We estimate that the capital costs for recordkeeping as a result of the final rule will be reduced from $180,000 (storing paper copies of all VFDs in file cabinets for 2 years) to $90,000 (one-half of VFDs stored as paper copies in 150 file cabinets for 2 years), and an annual cost savings of $19,600 for one-half of the industry filing VFDs electronically for 2 years.

14. Annualized Cost to the Federal Government

FDA estimates that the review and other administrative costs associated with a labeling supplement submitted by a VFD drug sponsor would require 3 hours. Based on the Fiscal Year 2010 appropriation for the Center for Veterinary Medicine at FDA, the average annual cost of one of these employees is $213,000, including the cost of all overhead support of that full time employee. This equates to an hourly wage of about $102. We have adjusted this wage to about $108 per hour in 2013 dollars. The total review and filing effort for FDA employees for the 6 VFD drug labeling supplements that are expected to be submitted would be 18 hours, with a total cost of about $1,900.

15. Explanation of Program Changes and Adjustments

The estimated burden for this information collection has been revised to reflect the agency's finalization of its rulemaking for the VFD program, including the one-time burden imposed upon implementation of the rule as well as the recurring burden associated with ongoing regulatory compliance. This results in an immediate increase in the number of annual responses by **769,428** and an increase in burden hours of **13,530**; however, the agency believes that, upon implementation of the final rule and realization of the one-time burden, this final rule will result in an overall decrease in annual burden.

Also, upon reexamining this collection, we removed the reporting burden found in 21 CFR 514.1(b)(9) (requiring submission of a VFD form by drug sponsors as a part of the new animal drug application) because this is accounted for under OMB Control No. 0910-0032 (New Animal Drug Applications).

16. Plans for tabulation and Publication and Project Time Schedule

Information is not to be published for statistical use.

17. Reason Display of OMB Expiration Date Is Inappropriate

There is no reason not to display the OMB expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.