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

A. Justification

1. Circumstances Making the Collection of Information Necessary

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).

While the VFD final rule will revise the information collection and will contain new provisions to make the VFD process more efficient and cost effective, the agency is seeking to extend its current approval authority under OMB Control No. 0920-0363 before its expiration on December 31, 2014. Specifically, we are requesting approval for the following provisions:

Reporting

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

3rd Party Disclosure

21 CFR 558.6(a)(3-5): Requires production of a VFD by the veterinarian with specific information.

Recordkeeping

21 CFR 558.6(c)(1-4): Requires maintenance of VFD records for two years after the date of issuance by all parties (i.e., veterinarians, distributors, and producers).

Reporting

21 CFR 558.6(d)(1)(i, ii, iii): Requires notification to the FDA by the distributor upon first engaging in distribution of VFD feeds.

Reporting

21 CFR 558.6(d)(1)(iv): Requires a change of address notification by a distributor when applicable.

3rd Party Disclosure

21 CFR 558.6(d)(2): Allows a distributor, in lieu of a VFD order, to ship VFD feed if the consignee furnishes an acknowledgement letter affirming that he/she 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.

Recordkeeping

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

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.

(2) 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. Approximately 50% of submissions are electronic.

4. Efforts to Identify Duplication and Use of Similar Information

Each veterinarian, manufacturer/distributor of VFD feed, and producer 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 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. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), FDA published a 60-day paperwork renewal notice in the Federal Register of September 25, 2014 (79 FR 57558). One comment was received, however it did not respond to any of the information collection elements solicited and therefore is not discussed in this document.

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

FDA estimates the burden for this information collection as follows:

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(d)(1)(i) through (d)(1)(iii); a distributor must notify FDA prior to the first time it distributes a VFD drug.	300	1	300	.25	75
558.6(d)(1)(iv); a distributor must notify FDA within 30 days of any change in ownership, business name, or business address.	20	1	20	.25	5
514.1(b)(9); sponsor submits 3 copies of VFD with new drug application	1	1	1	3	3
Total					83

[1] There are no capital costs or 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[2]	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[3]	.0167	12,525
Total	14,426		2,250,000		37,575

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

[2] The same recordkeeping requirement for distributors is listed in two separate sections of the codified; therefore, we have listed distributors separately (in reference to 558.6(e)(1) through (e)(4)) in order to avoid double counting their recordkeeping requirement.

[3] Distributors may receive an acknowledgement letter in lieu of a VFD when consigning VFD feed to another distributor (please see Table 3. below). Such letters, like VFDs, are also subject to a 2-year record retention requirement. Thus, the recordkeeping burden for acknowledgement letters is included as a subset of the VFD recordkeeping burden.

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(a)(3)-(a)(5); veterinarian issues VFD	3,050	246	750,000	0.125	93,750
558.6(d)(2); acknowledgement letter generation[3]	1,000[2]	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.

[2] 1,000 VFD distributors (of the 1,376 total distributors) times 5 disclosures per distributor equals 5,000 annual acknowledgement letters times 0.125 hours equals 625 hours annually.

[3] Distributors may receive an acknowledgement letter in lieu of a VFD when consigning VFD feed to another distributor (please see Table 3. below). Such letters, like VFDs, are also subject to a 2-year record retention requirement. Thus, the recordkeeping burden for acknowledgement letters is included as a subset of the VFD recordkeeping burden.

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

14. Annualized Cost to the Federal Government

Based on an agency estimate of 10 minutes for a GS-12/Step 1 employee to process each notification, then multiplied by 300 notifications per year (50 hours), and then multiplied by $35.88 per hour, we believe the cost to the Federal government to be $1,794.

15. Explanation of Program Changes and Adjustments

The estimated burden for this information collection has been revised to reflect an update in the number of veterinarians, producers, and distributors, and to reflect 2 VFD drugs currently approved. The result is an overall increase in the annual number of responses by **369,800** and an increase in burden hours of **11,899**.

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.