U.S. Food and Drug Administration
Veterinary Feed Directive

OMB Control No. 0910-0363

SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

   This information collection supports Food and Drug Administration (FDA, we or us) regulations. Section 504 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 354) establishes a regulatory category for certain new animal drugs called veterinary feed directive (VFD) drugs. Our VFD regulation is set forth at 21 CFR 558.6. 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. 21 CFR 558.3(b)(6). An animal feed containing a VFD drug or a combination VFD drug may be fed to animals only by or upon a lawful VFD issued by a licensed veterinarian (21 CFR 558.6(a)(1)). Veterinarians issue three copies of the VFD: One for their own records, one for their client (food animal producer), and one to the client's VFD feed distributor (21 CFR 558.6(a)(4) and 558.6(b)(8)–(9)). The VFD includes information about the number and species of animals to receive feed containing one or more of the VFD drugs (21 CFR 558.6(b)(3)), along with other information required under 21 CFR 558.6. All distributors of medicated feed containing VFD drugs must notify us of their intent to distribute such feed, and must maintain records of the receipt and distribution of all medicated feeds containing VFD drugs.

   We therefore request OMB approval of the information collection provisions found in 21 CFR 558.6: Veterinary Feed Directive, and discussed in this supporting statement.

2. Purpose and Use of the Information Collection

   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. The VFD regulation is tailored to the unique circumstances relating to the distribution and use of animal feeds containing a VFD drug. We use the information collected to assess compliance with the VFD regulation. The required recordkeeping and third party disclosures 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.

   Respondents are from the private sector (for-profit businesses), and include food animal producers, veterinarians, feed mills, and sponsors.

3. Use of Improved 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

   FDA is the only Agency that requires this information. The required information is not available from any other source.
5. Impact on Small Businesses or Other Small Entities

   The proposed collection of information carries the same burden, per VFD, for small or large firms. There is no exemption from the requirements of the regulation for small businesses. The agency estimates that 100% of respondents are small businesses. FDA aids small businesses in complying with its requirements through the Agency's Regional Small Business Representatives and through the scientific and administrative staffs within the Agency. FDA also provides a Small Business Guide on the Agency's website at http://www.fda.gov/oc/industry/.
6. Consequences of Collecting the Information Less Frequently

   Data collection occurs occasionally. All reporting and recordkeeping requirements are one-time events associated with issuance of a VFD.
7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

   There are no special circumstances associated with this collection of 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), we published a 60-day notice for public comment in the *Federal Register* of January 17, 2018 (83 FR 2456). No comments were received.
9. Explanation of Any Payment or Gift to Respondents

   We do not provide any payments or gifts to respondents.
10. Assurance of Confidentiality Provided to Respondents

    We expect that notifications submitted by VFD drug sponsors may contain trade secret and commercial confidential information. As a result, all files are maintained in a secured area. Confidentiality of the information submitted under these reporting requirements is protected. Only information that is releasable under the agency's regulations in 21 CFR part 20 would be released to the public. This information is also safeguarded by section 301(j) of the FD&C Act and would be protected from disclosure under the Freedom of Information Act (FOIA) under sections 552(a) and (b) (5 U.S.C. 552(a) and (b)).
11. Justification for Sensitive Questions

This information collection does not involve questions that are of a personally sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

We are retaining the estimates used in our analysis of the information collection provisions in the final rule entitled "Veterinary Feed Directive," published in the *Federal Register* of June 3, 2015 (80 FR 31708, at 31728) and approved by OMB.

A. Reporting Requirements
Description of Respondents: VFD Feed Distributors, VFD Drug Sponsors.
A distributor of animal feed containing a VFD drug must notify us prior to the first time it distributes the VFD feed (21 CFR 558.6(c)(5)). This notification is required one time per distributor and must include the information set forth in 21 CFR 558.6(c)(5). In addition, a distributor must notify us within 30 days of any change in ownership, business name, or business address (21 CFR 558.6(c)(6)). Additional reporting burdens for current VFD drug sponsors are approved under OMB control numbers 0910–0032 (New Animal Drug Applications) and 0910–0669 (Abbreviated New Animal Drug Applications).

Table 1.--Estimated Annual Reporting Burden[1]

21 CFR Section, Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
558.6(c)(5) requires a distributor to notify us prior to the first time it distributes a VFD feed	300	1	300	.125 (7 minutes)	37.5
558.6(c)(6) requires a distributor to notify us within 30 days of any change in ownership, business name, or business address	20	1	20	.125 (7 minutes)	2.5
Total					40

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

B. Recordkeeping Requirements
Description of Respondents: VFD Feed Distributors, Food Animal Veterinarians, and Clients (Food Animal Producers).
As stated previously, veterinarians issue three copies of the VFD: One for their own records, one for their client, and one to the client's VFD feed distributor. All involved parties (the veterinarian, the distributor, and the client) must retain a copy of the VFD for 2 years (21 CFR 558.6(a)(4)). In addition, VFD feed distributors must also keep receipt and distribution records of VFD feeds they manufacture and make them available for

inspection by us for 2 years (21 CFR 558.6(c)(3)). If a distributor manufactures the VFD feed, the distributor must also keep VFD manufacturing records for 1 year in accordance with part 225 and such records must be made available for inspection and copying by FDA upon request (§ 558.6(c)(4)). These record requirements are currently approved under OMB control number 0910–0152, Current Good Manufacturing Practice Regulations for Medicated Feed. Distributors may distribute VFD to another distributor only if the originating distributor first obtains a written acknowledgement letter. Such letters, like VFDs, are also subject to a 2-year record retention requirement. (21 CFR 558.6(c)(8).)

Table 2.--Estimated Annual Recordkeeping Burden[1]					
21 CFR Section; Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
558.6(a)(4); required recordkeeping by veterinarians and producers.	13,050	114.9	1,500,000	.0167 (1 minute)	25,050
558.6(a)(4), (c)(3), (c)(4), and (c)(8); required recordkeeping by distributors.	1,376	545.1	750,000	.0167 (1 minute)	12,525
Total					37,575

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

C. Third-Party Disclosure Requirements

Description of Respondents: VFD Drug Sponsors, Food Animal Veterinarians, VFD Feed Distributors, and Clients (Food Animal Producers).

Our regulation requires that veterinarians include the information specified at 21 CFR 558.6(b)(3) through (b)(5) on the VFD. Additional requirements relating to the VFD are specified at 21 CFR 558.6(b)(7) through (b)(9). A distributor may only distribute a VFD feed to another distributor for further distribution if the originating distributor (consignor) first obtains a written acknowledgement letter from the receiving distributor (consignee) before the feed is shipped (21 CFR 558.6(c)(8)).

Table 3. – Estimated Annual Third-Party Disclosure Burden[1]					
21 CFR Section; Activity	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours
558.6(b)(3)-(b)(5) and (b)(7)-(b)(9); required disclosures when a veterinarian issues a VFD.	3,050	246	750,000	.125 (7 minutes)	93,750
558.6(c)(8); required disclosure (acknowledgement letter) from one distributor to another.	1,000	5	5,000	.125 (7 minutes)	625
Total					94,375

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

The VFD regulation also contains several labeling provisions that are exempt from OMB review and approval under the PRA because they are a "public disclosure of information

originally supplied by the Federal government to the recipient for the purpose of disclosure to the public" (5 CFR 1320.3(c)(2)) and therefore do not constitute a "collection of information" under the PRA (44 U.S.C. 3501, et seq.). All labeling and advertising for VFD drugs, combination VFD drugs, and feeds containing VFD drugs or combination VFD drugs must prominently and conspicuously display the following cautionary statement: "Caution: Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian" (21 CFR 558.6(a)(6)). In addition, the veterinarian must ensure that the following statement is included on the VFD (21 CFR 558.6(b)(3)(xiii)), "Use of feed containing this veterinary feed directive (VFD) drug in a manner other than as directed on the labeling (extralabel use) is not permitted."

The veterinarian may restrict VFD authorization to only include the VFD drug(s) cited on the VFD or such authorization may be expanded to allow the use of the cited VFD drug(s) along with one or more over-the-counter animal drugs in an approved, conditionally approved, or indexed combination VFD drug (21 CFR 558.6(b)(6)). The veterinarian must affirm his or her intent regarding combination VFD drugs by including one of the following statements on the VFD:

1. "This VFD only authorizes the use of the VFD drug(s) cited in this order and is not intended to authorize the use of such drug(s) in combination with any other animal drugs" (21 CFR 558.6(b)(6)(i)).
2. "This VFD authorizes the use of the VFD drug(s) cited in this order in the following FDA-approved, conditionally approved, or indexed combination(s) in medicated feed that contains the VFD drug(s) as a component." [List specific approved, conditionally approved, or indexed combination medicated feeds following this statement.] (21 CFR 558.6(b)(6)(ii)).
3. "This VFD authorizes the use of the VFD drug(s) cited in this order in any FDA-approved, conditionally approved, or indexed combination(s) in medicated feed that contains the VFD drug(s) as a component." (21 CFR 558.6(b)(6)(iii)).

These labeling statements are not subject to review by OMB because, as stated previously, they are a "public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public" (5 CFR 1320.3(c)(2)) and therefore do not constitute a "collection of information" under the PRA (44 U.S.C. 3501, et seq.).

The one-time burdens included in our analysis of the June 3, 2015, final rule (80 FR 31708, at 31729-31732) are not included in the estimate provided in this information collection request. Our estimate of the annual recurring burden for this information collection has not changed since the last OMB approval.

12b. Annualized Cost Burden Estimate

Table 4.--Annualized Cost Burden Estimate

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Cost

VFD Feed Distributors (Reporting)	40	$77.00	$3,080
VFD Feed Distributors (Recordkeeping, Third-party Disclosure)	13,150	$69.00	$907,350
Veterinarians (Recordkeeping, Third-Party Disclosure)	106,275	$64.00	$6,801,600
Clients (Recordkeeping)	12,525	$31.00	$388,275
TOTAL	131,990		$8,100,305

For Feed Distributors, FDA estimates notifications to FDA to be completed by personnel at the general and operations manager level. 2017 Bureau of Labor Statistics' Occupation Employment and Wage data reports the median wage of about (including a 30% increase for benefits) at about $77.00 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 benefits) of about $69.00 per hour.

FDA estimates that there are about 3,050 veterinarians that exclusively treat food-producing animals. We use the 2017 Bureau of Labor Statistics' Occupation Employment and Wage data that reports the median wage of about $49, and adjust it to include the additional 30% for benefits. The result is an estimated compensation rate of about $64 per hour.

For clients (food animal producers), FDA uses the 2017 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 (including benefits) of about $31.00 per hour.

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

There are no capital, start-up, operating or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

We estimate the annualized cost to the Federal Government for the review and evaluation of notifications submitted by VFD drug sponsors to be $13,938. We estimate that we expend approximately 300 hours annually in the review of these submissions. We estimate the average hourly wage for personnel to review and evaluate a submission to be at the GS-13-1 level in the locality pay area of Washington-Baltimore in 2018,

approximately $46.46/hour. Thus, the estimated annualized cost to the Federal government is $13,938 (300 hours x $46.46/hour = $13,938).

15. Explanation for Program Changes or Adjustments

    This information collection reflects adjustments since last OMB approval. We believe cost burden previously attributed to rulemaking (0910-AG95) has been realized by respondents and therefore we have removed those costs accordingly. Similarly, and as discussed in the associated supporting statement, the rulemaking imposed one-time burden that has also been realized. As a result, the collection reflects a decrease of 14,438 annual hours and 13,573 hours.

16. Plans for Tabulation and Publication and Project Time Schedule

    Information is not to be published for statistical use.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

    We are not seeking approval to exempt display of the OMB approval date on any documents that are associated with this information collection.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

    There are no exceptions to the certification.