

United States Food and Drug Administration

Veterinary Feed Directive

OMB Control No. 0910-0363 -- EXTENSION

SUPPORTING STATEMENT

**Part A: Justification:**

1. Circumstances Making the Collection of Information Necessary

This information collection helps support implementation of FDA statutory and regulatory requirements. Section 504 of the Federal Food, Drug, and Cosmetic Act (the FD&C) (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. 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.

Distributors of medicated feed containing VFD drugs must notify FDA of their intent to distribute such feed via U.S. Postal mail, email, or fax and must maintain records of the receipt and distribution of all medicated feeds containing VFD drugs. 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. For third-party disclosures, FDA regulation requires that veterinarians include specific information on the VFD. A distributor may only distribute a VFD feed to another distributor for further distribution if the originating distributor (consignor) first obtains a written acknowledgment letter from the receiving distributor (consignee) before the feed is shipped.

We developed the guidance document “Guidance for Industry (GFI) #233 Veterinary Feed Directive Common Format Questions and Answers” (September 2016) (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-233-veterinary-feed-directive-common-format-questions-and-answers>) to provide guidance concerning the elements that must be included on the VFD and the elements that may be included on the VFD as described in 21 CFR 558.6. The guidance also provides examples that illustrate how a common VFD format might appear. Agency guidance documents are issued in accordance with our good guidance practice regulations in 21 CFR 10.115, which provide for public comment at any time.

We therefore request OMB approval of information collection requirements found in 21 CFR 558.6 as 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. We will use the information collected to assess compliance with the VFD regulation. The required reporting, 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.

*Description of Respondents:* Respondents to the information collection are VFD Feed Distributors, Food Animal Veterinarians, and Clients (Food Animal Producers).

### 3. Use of Improved Information Technology and Burden Reduction

Respondents may notify FDA of their intent to distribute medicated feed containing VFD drugs via U.S. Postal mail, email, or fax. Contact information can be found at <https://www.fda.gov/animal-veterinary/animal-food-feeds/medicated-feeds>.

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% of submissions are electronic (i.e., email), however, we expect this number to increase.

### 4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection.

### 5. Impact on Small Businesses or Other Small Entities

The information collection poses no undue burden on small entities. We estimate 80% of respondents are small businesses. FDA assists small businesses in complying with its regulatory requirements through Regional Small Business Representatives and through the scientific and administrative staffs within the agency. We also provide guidance on our website at <http://www.fda.gov/ForIndustry/SmallBusinessAssistance/default.htm>.

### 6. Consequences of Collecting the Information Less Frequently

The information collection schedule is consistent with statutory and regulatory requirements.

### 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

FDA published a 60-day notice for public comment in the *Federal Register* of 03/21/2024 (89 FR 20218). No comments were received.

### 9. Explanation of Any Payment or Gift to Respondents

There are no incentives, payments or gifts associated with this information collection.

### 10. Assurance of Confidentiality Provided to Respondents

In preparing this Supporting Statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected. Data will be kept private to the extent provided by law.

### *The Privacy Act of 1974*

This ICR collects personally identifiable information (PII). PII is collected in the context of the subject individuals' professional capacity and the FDA-related work they perform for their employer (e.g., point of contact at a regulated entity). The PII submitted includes point of contact name, business address, and point of contact signature. FDA determined that although PII is collected, the collection is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Act do not apply. Specifically, the contractor or FDA does not use name or any other personal identifier to retrieve records from the information collected. Through appropriate form and webpage design, FDA limited submission fields and minimized the PII collected to protect the privacy of the individuals.

### *Freedom of Information Act*

Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9)). FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information.

#### 11. Justification for Sensitive Questions

The collection of information does not involve sensitive questions.

#### 12. Estimates of Annualized Burden Hours and Cost

##### 12a. Annualized Hour Burden Estimate

Table 1. – Estimated Annual Reporting Burden<sup>1</sup>

21 CFR Part/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 FDA prior to the first time it distributes a VFD feed	112	1	112	0.12 (7 minutes)	13
558.6(c)(6) requires a distributor to notify FDA within 30 days of any change in ownership, business name, or business address	239	1	239	0.12 (7 minutes)	29
Total	351				42

<sup>1</sup>Totals may not sum due to rounding.

The number of respondents is based on the average number of notifications we have received over the past 3 years. 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 2.--Estimated Annual Recordkeeping Burden<sup>1</sup>

21 CFR Part/Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
558.6(a)(4), (c)(3), (4), and (8); requires recordkeeping by veterinarians, producers, and distributors to maintain their copy of the VFD Order, their receipt and distribution records, and their manufacturing records and acknowledgement letters, if applicable, for two years.	30,800	219.03	6,746,096	0.02 (1 minute)	134,922

<sup>1</sup>Totals may not sum due to rounding.

FDA’s guidance document, “GFI # 213 New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions with GFI #209,” (December 2013) (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-213-new-animal-drugs-and-new-animal-drug-combination-products-administered-or-medicated-feed>) describes a voluntary process wherein sponsors of new animal drugs used in and on animal feed and in water changed the marketing status of these drugs from over-the-counter to VFD. As a result of this voluntary process, which occurred in January 2017, the number of establishments distributing feeds containing VFD drugs increased, as well as the number of veterinarians issuing VFDs, and the number of food animal producers using VFD medicated feed. Thus, based on the current number of mixed practice veterinarians and the number of food animal veterinarians listed on the American Veterinary Medical Association’s website, we have increased the number of recordkeepers for veterinarians and producers.

Additionally, based on our program experience, we have decreased the number of records per recordkeeper, as we believe the previous numbers were too high. The burden we attribute to recordkeeping activities is assumed to be distributed among the individual elements and averaged among respondents.

In addition to the recordkeeping requirement under 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 21 CFR 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.”

While we have kept the number of distributors at 9,688, we have increased the number of recordkeepers for veterinarians and producers to 21,112 (9,688 + 21,112 = 30,800). Based on the current number of mixed practice veterinarians and the number of food animal veterinarians listed on the American Veterinary Medical Association’s website (3,934 + 3,606 = 7,540). We estimate 70% of those veterinarians would write VFDs (7,540 x 70% = 5,278). We estimate there are three producers per veterinarian (5,278 x 3 = 15,834) (5,278 + 15,834 = 21,112).

Table 3.--Estimated Annual Third-Party Disclosure Burden<sup>1</sup>

21 CFR Part/Activity	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours
558.6(b)(3)-(5) and (b)(7)-(9); requires veterinarians to disclose information on a VFD	5,278	40	211,120	0.12 (7 minutes)	25,334
558.6(c)(8); requires acknowledgment letter from one distributor to another	2,422	5	12,110	0.12 (7 minutes)	1,453
Total	7,700				26,787

<sup>1</sup>Totals may not sum due to rounding.

Based on program experience, we believe the original number of third-party disclosures estimate was too high and have decreased the number of disclosures per respondent.

The VFD regulation also contains several labeling provisions. These labeling statements 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)).

The total burden for this information collection is 161,751 hours.

## 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)	42	\$77.00	\$3,234
VFD Feed Distributors, Veterinarians, Clients (Recordkeeping, Third-party Disclosure)	161,709	\$63.58	\$10,281,458
TOTAL	161,751		\$10,284,692

For Feed Distributors, FDA estimates notifications to FDA to be completed by personnel at the general and operations manager level. In 2022, the Bureau of Labor Statistics' Occupation Employment and Wage data reported the mean wage of about (including a 30% increase for benefits) \$77.00 hour.

For Feed Distributors at the industrial production manager level, veterinarians that exclusively treat food-producing animals, and clients (food animal producers), using the 2022 Bureau of Labor Statistics' Occupation Employment and Wage data (including a 30% increase for benefits), FDA averaged the salary for all three occupations to determine the mean hourly wage of \$63.58.

## 13. Estimates of Other Total Annual Costs to Respondents/Recordkeepers or 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 \$13,482.00. We estimate that we spend approximately 300 hours annually in the review of these submissions. We estimate the average hourly wage for personnel to review and evaluate a submission at the 2024 OPM wage rates for a GS-11- Step 5 employee in the Washington-Baltimore-Arlington, DC-MD-VA-WV-PA area, to be approximately \$44.94/hour. Thus, the estimated annualized cost to the Federal government is \$13,482.00 (300 hours x \$44.94/hour = \$13,482.00).

## 15. Explanation for Program Changes or Adjustments

After a review of the information collection since our last request for OMB approval, we have adjusted our estimates based on our experience with the VFD regulations and updated data. As a result, the total burden for the information collection has decreased 39,387 hours since the last OMB approval.

## 16. Plans for Tabulation and Publication and Project Time Schedule

This information collected will not be published or tabulated.

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

FDA will display the OMB expiration date as required by 5 CFR 1320.8.

## 18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.