DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–0802]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Veterinary Feed Directive

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by July 17, 2024.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0363. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Rachel Showalter, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 240–994–7399, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Veterinary Feed Directive

OMB Control Number 0910–0363—Extension

This information collection helps support implementation of FDA statutory and regulatory requirements. Section 504 of the Federal Food, Drug, and Cosmetic Act (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 § 558.6 (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 § 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.

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.

In the **Federal Register** of March 21, 2024 (89 FR 20218), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

A. Reporting Requirements

Description of Respondents: VFD Feed Distributors.

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1] [2]

21 CFR part/activity	Number of respondents	Number 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

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] 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).

B. Recordkeeping Requirements

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1] [2]

21 CFR part/activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
558.6(a)(4) and (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 2 years.	30,800	219.03	6,746,096	0.02 (1 minute)	134,922

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] 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.''

C. Third-Party Disclosure Requirements

Description of Respondents: Food Animal Veterinarians, VFD Feed Distributors, and Clients.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1] [2]

21 CFR part/activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
558.6(b)(3)(v) and (b)(7)(ix); 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

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] 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.*).

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.

Dated: June 11, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–13299 Filed 6–14–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2000–D–0784]

International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products; Studies To Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Reproduction Testing (Revision 1); Draft Guidance for Industry; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA or Agency) is correcting a notice that appeared in the **Federal Register** on May 23, 2024. The