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]

BILLING CODE 4164–01–P

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

document announced the availability of a draft revised guidance for industry (GFI) #115 (VICH GL22) entitled ''Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Reproduction Testing (Revision 1).'' The document erroneously included incorrect contact information. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Li You, Center for Veterinary Medicine (HFV–153), Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855, 240–402–0828, *Li.You@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of May 23, 2024 (89 FR 45663), in FR Doc. 2024–11313, on page 45664, in the first column, correct the **FOR FURTHER INFORMATION CONTACT** section to read ''Li You, Center for Veterinary Medicine (HFV–153), Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855, 240–402–0828, *Li.You@fda.hhs.gov*.''

Dated: June 10, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–13224 Filed 6–14–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–4067]

Diabetic Foot Infections: Developing Drugs for Treatment; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled ''Diabetic Foot Infections: Developing Drugs for Treatment.'' The purpose of this guidance is to assist sponsors in the clinical development of drugs for the treatment of diabetic foot infections (DFI) without concomitant bone and joint involvement. This guidance finalizes and replaces the draft guidance of the same title issued on October 17, 2023.

DATES: The announcement of the guidance is published in the **Federal Register** on June 17, 2024.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2023–D–4067 for ''Diabetic Foot Infections: Developing Drugs for Treatment.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Mayurika Ghosh, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6219, Silver Spring, MD 20993; 301–796–4776.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Diabetic Foot Infections: Developing