The estimated burden for this information collection reflects an overall increase of 2,740 hours and 34 responses. The figures in the tables have been updated to reflect anticipated VQIP participation.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–22965 Filed 11–10–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–12280]

Agency Information Collection Activities; Proposed Collection; Comment Request; Veterinary Feed Directive

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the reporting, recordkeeping, and third-party disclosure burden associated with the veterinary feed directive regulations.

DATES: Either electronic or written comments on the collection of information must be submitted by January 11, 2027.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 11, 2027. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

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–2026–N–12280 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Veterinary Feed Directive.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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.

FOR FURTHER INFORMATION CONTACT: Kelly Covington, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 240–402–5661, *PRAStaff@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites

comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Veterinary Feed Directive—21 CFR 558.6

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 (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.

Additionally, we developed the guidance document ''GFI #120 Veterinary Feed Directive Regulation Questions and Answers (revised) (April 2024) Small Entity Compliance Guide'' (*https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-120-veterinary-feed-directive-regulation-questions-and-answers*) to aid industry in complying with the requirements of the 2015 VFD final rule.

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.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

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.	91	1	91	0.12 (7 minutes)	10.92
558.6(c)(6) requires a distributor to notify FDA within 30 days of any change in ownership, business name, or business address.	97	1	97	0.12 (7 minutes)	11.64
Total	188	.....	.....	.....	22.56

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

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), (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..	29,500	175.2	5,168,400	0.02 (1 minute)	103,368

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

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

21 CFR part/activity	Number of Record-keepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
558.6(b)(3)–(5) and (b)(7)–(9); requires veterinarians to disclose information on a VFD.	5,145	34	174,930	0.12 (7 minutes)	20,991.6
558.6(c)(8); requires acknowledgment letter from one distributor to another.	2,422	5	12,110	0.12 (7 minutes)	1,453
Total	7,567	.....	.....	.....	22,444.6

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

The numbers have been adjusted to reflect current (2024–2025) updated numbers. Since last reauthorization of the collection, the Center for Veterinary Medicine developed an internal database to more accurately capture VFD distributor requests for new distributors and changes to distributor information. A review of updated American Veterinary Medical Association information provided new numbers of licensed veterinarians and we continue to use the estimate of 70 percent will write VFDs. We also continue to see downward trends in the use of some VFD medicated feeds, and the numbers were reduced to reflect that trend.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–22964 Filed 11–10–26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Notice of Purchased/Referred Care Delivery Area Redesignation for the Kewa Pueblo

AGENCY: Indian Health Service, Department of Health and Human Services.

ACTION: Final notice.

SUMMARY: Notice is hereby given that the Indian Health Service (IHS) has decided to expand the geographic boundaries of the Purchased/Referred Care Delivery Area (PRCDA) for the Kewa Pueblo (''Kewa Pueblo'' or ''Tribe'') to include Bernalillo County, New Mexico. The final PRCDA includes Bernalillo, Sandoval, and Santa Fe Counties, New Mexico. This expansion will authorize additional Kewa Pueblo Tribal members and beneficiaries to receive Purchased/Referred Care (PRC) services.

DATES: This expansion is effective as of the date of publication of this notice.

ADDRESSES: This notice can be found at *https://www.federalregister.gov.* Written requests for information should be delivered to: CDR Tracy Sanchez, Acting Director, Office of Resource Access and Partnerships, Indian Health Service, 5600 Fishers Lane, Mail Stop 06SEH03, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: CDR Tracy Sanchez, Acting Director, Office of Resource Access and Partnerships by email at *Tracy.Sanchez@ihs.gov,* or by phone at (301) 443–0969 (This is not a toll-free number).

SUPPLEMENTARY INFORMATION: The IHS provides services under regulations in effect as of September 15, 1987, and republished at 42 CFR part 136, subparts A–C. Subpart C defines a Contract Health Service Delivery Area (CHSDA), now referred to as a PRCDA, as the geographic area within which PRC will be made available by the IHS to members of an identified Indian community who reside in the PRCDA. Residence within a PRCDA by a person who is within the scope of the Indian health program, as set forth in 42 CFR 136.12, creates no legal entitlement to PRC but only potential eligibility for services. Services needed, but not available at an IHS/Tribal facility, are provided under the PRC program depending on the availability of funds, the relative medical priority of the services to be provided, and the actual availability and accessibility of alternate resources in accordance with the regulations.

The regulations at 42 CFR part 136, subpart C, provide that, unless otherwise designated, a PRCDA shall consist of a county which includes all or part of a reservation and any county or counties which have a common boundary with the reservation. 42 CFR 136.22(a)(6). The regulations also provide that after Consultation with the Tribal governing body or bodies on those reservations included within the PRCDA, the Secretary may, from time to time, redesignate areas within the United States for inclusion in or exclusion from a PRCDA. 42 CFR 136.22(b). The regulations require that certain criteria must be considered before any redesignation is made. The criteria are as follows:

(1) The number of Indians residing in the area proposed to be so included or excluded;

(2) Whether the Tribal governing body has determined that Indians residing in the area near the reservation are socially and economically affiliated with the Tribe;

(3) The geographic proximity to the reservation of the area whose inclusion or exclusion is being considered; and

(4) The level of funding which would be available for the provision of PRC.

Additionally, the regulations require that any redesignation of a PRCDA be made in accordance with the procedures of the Administrative Procedure Act (5 U.S.C. 553). 42 CFR 136.22(c). In compliance with this requirement, the IHS published a notice of proposed redesignation and requested public comments on June 25, 2026 (91 FR 38449). The IHS did not receive any comments in response to the notice of proposed redesignation.

In support of this expansion, the IHS makes the following findings:

1. By expanding the PRCDA to include Bernalillo County, New Mexico, the Kewa Pueblo estimates that the Tribe's PRC eligible population would increase by an estimated 200 Tribal members.

2. As part of their expansion request, the Kewa Pueblo submitted a resolution from the Tribe's governing body. The resolution indicates that the requested expansion is intended to serve their members living in Bernalillo County, New Mexico. During Tribal Consultation, the Kewa Pueblo verified that those members are socially and economically affiliated with the Tribe.

3. Bernalillo County is approximately 30 miles from the Tribe's reservation. The requested expansion would form a contiguous area with the existing PRCDA. Tribal members of the Kewa Pueblo reside in the county proposed