DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–5603]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; New Animal Drug and Veterinary Master Files

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, 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 16, 2025.

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 0910–0032. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *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.

New Animal Drug Applications and Veterinary Master Files—21 CFR 514 and 558, and Section 571 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360ccc)

OMB Control Number 0910–0032—Extension

This information collection supports implementation of section 512 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360b), which governs new animal drugs. Agency regulations in 21 CFR part 514 (part 514) and associated regulations 21 CFR part 558, establish format and content requirements regarding new animal drug application (NADA) submissions, as well as provide for pre-application submissions, amended applications, and application supplements. This information collection also supports implementation of section 571 of the FD&C Act (21 U.S.C. 360ccc) regarding application for conditional approval of new animal drug (CNADA) submissions. As set forth in the FD&C Act and regulations, requisite elements include safety and effectiveness data, proposed labeling, product manufacturing information, and where necessary, complete information on food safety (including microbial food safety) and any methods used to determine residues of drug chemicals in edible tissue from food-producing animals. Applications must be prepared as appropriate to support the submission. Respondents to the information collection are persons developing, manufacturing, and/or researching new animal drugs.

We developed Form FDA 356v (Application for Approval of a New Animal Drug (or Submission To Support New Animal Drug Approval)) to provide a uniform format for submitting requisite information and to ensure efficient processing by the Agency. Form FDA 356v is available for download at *https://www.fda.gov/about-fda/reports-manuals-forms/forms.* We also develop Agency guidance documents that may assist respondents with understanding NADA/CNADA requirements and related information collection activity. This includes FDA Guidance #152—Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to Their Microbiological Effects on Bacteria of Human Health Concern (January 2023) (*https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-152-evaluating-safety-antimicrobial-new-animal-drugs-regard-their-microbiological-effects*), which outlines a risk assessment approach for evaluating the microbial food safety of antimicrobial new animal drugs and includes Agency recommendations in this regard.

Under section 512(b)(3) of the FD&C Act, any person intending to file an NADA or supplemental NADA or a request for an investigational exemption under section 512(j) of the FD&C Act may request a conference prior to making a submission. Section 514.5 of our regulations (21 CFR 514.5) sets forth procedures for presubmission conferences and describes documentation associated with making requests and preparing for and conducting meetings. We encourage sponsors to submit data for review at the most appropriate and productive times in the drug development process. Rather than submitting all data for review as part of a complete application, we have found that the submission of data supporting discrete technical sections during the investigational phase is most appropriate and productive. This ''phased review'' of data submissions has created efficiencies for both us and the animal pharmaceutical industry.

We also encourage, as appropriate, the submission of a Veterinary Master File (VMF). For more information on VMFs, we invite you to visit *https://www.fda.gov/animal-veterinary/development-approval-process/veterinary-master-files.* A VMF provides detailed information used in support of application submissions. Questions regarding VMF submissions may be directed to the Center for Veterinary Medicine at *cvmesubmitter@fda.hhs.gov.* We have found that utilizing VMFs has increased the efficiency of the animal drug development and animal drug review processes for both FDA and the animal pharmaceutical industry, providing for the confidential exchange of information with FDA, and a process for reporting information outside of an NADA/CNADA or an Investigational New Animal Drug file, as well as an opportunity for increased communication with FDA during early stages of product development. A holder of a VMF may also authorize other parties to reference information included in the VMF without disclosing information in the file to those parties. VMFs can be used as repositories for information that can be referenced in multiple submissions to the Agency.

Section 558.5(i) of our regulations (21 CFR 558.5(i)) describes the procedure for requesting a waiver of the labeling requirements in § 558.5(h) if there is evidence to indicate that it is unlikely a new animal drug would be used in the manufacture of a liquid medicated feed.

Finally, section 571 of the FD&C Act established requirements for the conditional approval of certain drugs [1] and the procedures for submitting CNADAs. Although FDA receives fewer than one application submission annually under section 571 of the FD&C Act when averaged over a 3-year period, we use a place holder of one response and 1 hour annually to account for the

[1] Animal drugs intended for use in minor species, minor use in major species, or for serious or life-threatening conditions or unmet animal or human health needs where a demonstration of effectiveness would require a complex or particularly difficult study or studies.

burden associated with these submissions.

The reporting associated with NADAs/CNADAs and related submissions is necessary to ensure that new animal drugs comply with sections 512(b)(1) and 571 of the FD&C Act. We use the information collected to review the data, labeling, and manufacturing controls and procedures to evaluate the safety and effectiveness of the proposed new animal drug.

In the **Federal Register** of December 20, 2024 (89 FR 106493), 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:

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
§ 514; applications and amendments, pre-submission conference requests, evidence to establish safety and effectiveness, manufacturing, labeling, and other changes, submission of data studies and other changes.	254	2.8	711	42.25	30,040
§ 558.5(i); requirements for liquid medicated feed	254	.01	2.5	5	13
Applications for conditional approval submitted under section 571 of the FD&C Act	3	1	3	1	3
Form FDA 356v	254	30.8	7,823	0.75 (45 minutes)	5,867
VMF submissions	16	1	16	20	320
Total			8,556		36,243

[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.

Although we have characterized the information collection activity as a reporting burden, we include in our estimate time required for searching data sources and preparing and maintaining necessary and applicable records. Based on the number of sponsors subject to animal drug user fees, we estimate that there are 254 respondents. We use this estimate to calculate the ''number of responses per respondent'' by dividing the total annual responses by the number of respondents except for CNADA submission and VMFs. For CNADAs, we calculate an average of three responses, and for VMF submissions, we calculate and average of 16 VMFs.

Our estimated burden for the information collection reflects an overall decrease of 2,606 hours and an increase of 928 responses. We attribute this adjustment to an increase in the number of submissions which generate a Form FDA 0356v; however, there is also a decrease to the submissions we received reported under part 514.

Dated: June 9, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–10884 Filed 6–13–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2023–E–3263 AND FDA–2023–E–3264]

Determination of Regulatory Review Period for Purposes of Patent Extension; BRIUMVI

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for BRIUMVI and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human biological product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect must submit either electronic or written comments and ask for a redetermination by August 15, 2025. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by December 15, 2025. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

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 August 15, 2025. 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: