

(Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug or biologic product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological product becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human biological product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human biologic product OMISIRGE (omidubicel-only). OMISIRGE is indicated for use in adults and pediatric patients 12 years and older with hematologic malignancies who are planned for umbilical cord blood transplantation following myeloablative conditioning to reduce the time to neutrophil recovery and the incidence of infection. Subsequent to this approval, the USPTO received a patent term restoration application for OMISIRGE (U.S. Patent No. 7,955,852) from Gamida Cell Ltd., and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated April 3, 2024, FDA advised the USPTO that this human biological product had undergone a regulatory review period and that the approval of OMISIRGE represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for OMISIRGE is 4,563 days. Of this time, 4,242 days occurred during the testing phase of the regulatory review period, while 321 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective:* October 21, 2010. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on October 21, 2010.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262):* June 1, 2022. FDA has verified the applicant's claim that the biologics license application (BLA) for OMISIRGE (BLA B125738) was initially submitted on June 1, 2022.

3. *The date the application was approved:* April 17, 2023. FDA has verified the applicant's claim that BLA B125738 was approved on April 17, 2023.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,826 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to <https://www.regulations.gov> at Docket

No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: December 19, 2024.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2024–31262 Filed 12–27–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–5603]

Agency Information Collection Activities; Proposed Collection; 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 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 collection of information associated with new animal drug applications and veterinary master files.

DATES: Either electronic or written comments on the collection of information must be submitted by February 28, 2025.

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 February 28, 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:

- *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-2024-N-5603 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Reporting Associated with New Animal Drug and Veterinary Master Files." 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:

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: 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.

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 in 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 (<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 pre-submission 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 cvmsubmitter@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.

Veterinary master files 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 drugs¹ 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 burden associated with these submissions.

The reporting associated with NADAs/CNADAs and related submissions is necessary to ensure that new animal drugs are in compliance 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.

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

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.

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: December 16, 2024.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2024–31308 Filed 12–27–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2024–E–0299, FDA–2024–E–0301, and FDA–2024–E–0302]

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

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 VEOZAH 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 drug product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by February 28, 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 June 30, 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 February 28, 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:

- **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 Nos. FDA–2024–E–0299, FDA–2024–E–0301, and FDA–2024–E–0302 for “Determination of Regulatory Review Period for Purposes of Patent Extension; VEOZAH.” 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 § 10.20 (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: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6200, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug or biological product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product’s regulatory review period forms the basis for determining the amount of extension an applicant may receive.