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: Patrick Clouser, Office of the Commissioner, Food and Drug Administration, 12420 Parklawn Drive, Rockville, MD 20852, 240–402–5276.

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.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug 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 drug 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 drug product VYALEV (foscarbidopa and foslevodopa). VYALEV is indicated for the treatment of motor fluctuations in adults with advanced Parkinson's disease (PD). Subsequent to this approval, the USPTO received patent term restoration applications for VYALEV (U.S. Patent Nos. 9,446,059; 10,174,061; and 10,730,895) from AbbVie Inc. and the USPTO requested FDA's assistance in determining these patents' eligibility for patent term restoration. In a letter dated September 23, 2025, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of VYALEV 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 VYALEV is 2,871 days. Of this time, 1,989 days occurred during the testing phase of the regulatory review period, while 882 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 (FD&C Act) (21 U.S.C. 355(i)) became effective*: December 8, 2016. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on December 8, 2016.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act*: May 19, 2022. FDA has verified the applicant's claim that the new drug application (NDA) for VYALEV (NDA 216962) was initially submitted on May 19, 2022.

3. *The date the application was approved*: October 16, 2024. FDA has verified the applicant's claim that NDA 216962 was approved on October 16, 2024.

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 1,091 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.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–13006 Filed 6–26–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–1305]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; New Animal Drugs for Minor Use and Minor Species

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) 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 29, 2026.

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 0910–0605. Also include the FDA docket number found in

brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Kelly Covington, Center for Veterinary Medicine, Food and Drug Administration, 5001 Campus Drive, College Park, MD 20740, 240–402–5661, *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 Drugs for Minor Use and Minor Species—21 CFR Part 516

OMB Control Number 0910–0605—Extension

This information collection supports implementation of sections 572 and 573 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.SC. 360ccc-1 and 21 U.S.C. 360ccc-2) which establish requirements for the Designation of a Minor Use or Minor Species New Animal Drug and Index of Legally Marketed Unapproved New Animal Drugs for Minor Species, respectively. Agency regulations are codified in 21 CFR part 516 and include recordkeeping and reporting requirements. The general provisions in 21 CFR 516 subpart A set forth its purpose, scope, and applicable definitions (21 CFR part 516 subpart A).

Regulations in 21 CFR part 516 subpart B provide for designation status for Minor Use and Minor Species (MUMS) drugs prior to their approval or conditional approval. MUMS-drug designation makes the sponsor eligible for incentives to support the approval or conditional approval of the designated use and is completely optional for drug sponsors. The regulations describe how to apply for designation, what needs to be submitted and other information pertaining to this option. Sponsors of designated new animal drugs are required to demonstrate ''due diligence'' toward approval or conditional approval through submission of annual reports documenting their progress for each designated use. The FDA uses this information to allow for determining eligibility for designation and the associated incentives and benefits described in section 573 of the act, including a 7-year period of exclusive marketing rights. It enables FDA to process requests for MUMS-drug designation, requests to amend MUMS-drug designation, changes in sponsorship, termination of MUMS-drug designation, requirements for annual reports from sponsors, and provisions for insufficient quantities of MUMS-designated drugs. Sponsors use FDA's ''eSubmitter'' system to fill out a series of system generated screens to submit their request and annual report electronically. To access the ''eSubmitter'' system, sponsors will use a previously established account.

Regulations in 21 CFR 516 subpart C are intended to make more medications legally available to veterinarians and animal owners for the treatment of minor animal species (21 U.S.C. 360ccc). The purpose of these regulations is to encourage the development of these new animal drugs, while still ensuring appropriate safeguards for animal and human health. In some cases, a minor species drug is intended for use in species that are too rare or too varied to be the subject of adequate and well-controlled studies in support of a drug approval. In such cases, FDA may add the drug to the Index of Legally Marketed Unapproved New Animal Drugs for Minor Species as provided for by Section 572 of the FD&C Act (21 U.S.C. 360ccc–2). Within limitations established by the statute, such indexing provides a basis for legally marketing an unapproved new animal drug intended for use in a minor species. FDA regulations in 21 CFR part 516 Subpart C specify, among other things, the criteria and procedures for requesting eligibility for indexing and for requesting addition to the Index, as well as the annual reporting requirements for index holders. The administrative procedures and criteria for indexing a new animal drug for use in a minor species, as well as modifications and removal of a drug from the index are also set forth. FDA uses the information for the activities described above. Requestors can either mail paper submissions to the FDA or use FDA's ''eSubmitter'' system to fill out a series of system generated screens to submit their request electronically. To access the ''eSubmitter'' system, sponsors will use a previously established account.

Description of Respondents: The respondents to this information collection are pharmaceutical companies that sponsor new animal drugs for designation or requesters wishing to add a new animal drug to the Index.

In the **Federal Register** of February 20, 2026 (91 FR 8253), FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment was received. While the commenter supported the collection of information requirements, they raised concerns about the administrative and financial burden on smaller companies, recommending that FDA develop templates or guidance materials to ease the process for these companies.

FDA appreciates the comment. FDA provides a Small Business Guide on the Agency's website at *http://www.fda.gov/ForIndustry/SmallBusinessAssistance/default.htm.* FDA has also published the following Guidance for Industry (GFI) documents to assist companies developing drugs for minor uses and minor species. Online or written comments on any guidance can be submitted at any time (see 21 CFR 10.115(g)(5)).

- CVM GFI #61—Special Considerations, Incentives, and Programs to Support the Approval of New Animal Drugs for Minor Uses and for Minor Species
- CVM GFI #170—Animal Drug User Fees and Fee Waivers and Reductions
- CVM GFI #200—SECG for Designation of New Animal Drugs for Minor Uses/Minor Species
- CVM GFI #201—SECG for Index of Legally Marketed Unapproved New Animal Drugs for Minor Species

In addition, we are currently revising CVM GFI#210—The Index of Legally Marketed Unapproved New Animal Drugs for Minor Species to help companies navigate the indexing process.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Designated New Animal Drugs for Minor Use and Minor Species, Subpart B					
516.20; content and format of MUMS-drug designation request	5	2	10	16	160

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

21 CFR section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
516.26; requirements for amending MUMS-drug designation	3	1	3	2	6
516.27; change in sponsorship of MUMS-drug designation	1	1	1	1	1
516.29; termination of MUMS-drug designation	2	1	2	1	2
516.30; requirements of annual reports from sponsor(s) of MUMS-designated drugs	26	2	52	2	104
516.36; consequences for insufficient quantities of MUMS-designated drugs	1	1	1	3	3
Subtotal	276				
Index of Legally Marketed Unapproved New Animal Drugs for Minor Species, Subpart C					
516.119; requires a foreign drug company to submit and update the name and address of a permanent U.S. resident agent	10	1	10	1	10
516.121; written request for a meeting with FDA to discuss the requirements for indexing a new animal drug	15	2	30	4	120
516.123; written request for an informal conference and a requestor's written response to an FDA initial decision denying a request	3	1	3	8	24
516.125; correspondence and information associated with investigational use of new animal drugs intended for indexing	2	3	6	20	120
516.129; content and format of a request for determination of eligibility for indexing	20	2	40	20	800
516.141; information to be submitted to FDA by a requestor seeking to establish a qualified expert panel	20	1	20	16	320
516.143; content and format of the written report of the qualified expert panel	20	1	20	120	2,400
516.145; content and format of a request for addition to the Index	10	1	10	20	200
516.161; content and format of a request for modification of an indexed drug	10	1	10	4	40
516.163; information to be contained in a request to FDA to transfer ownership of a drug's index file to another person	1	1	1	2	2
516.165; requires drug experience reports and distributor statements to be submitted to FDA	25	10	250	5	1250
Subtotal					5,286
Total					5,562

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section, activity	No. of recordkeepers	No. of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total
Index of Legally Marketed Unapproved New Animal Drugs for Minor Species, Subpart C					
516.141, requires the qualified expert panel leader to maintain a copy of the written report and all notes or minutes relating to panel deliberations that are submitted to the requestor for 2 years after the report is submitted.	30	2	60	0.5 (30 min.)	30
516.165, requires the holder of an indexed drug to maintain records of all information pertinent to the safety or effectiveness of the indexed drug, from foreign and domestic sources.	25	2	50	1	50
Total					80

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

Our estimated reporting and recordkeeping burden for the information collection reflects an overall increase of 60 hours and a corresponding increase of 120 responses and records. We attribute this adjustment to an increase in the number of submissions we received over the last few years.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–13005 Filed 6–26–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Rural Health Care Coordination Program Performance Improvement Measures, OMB No. 0906–0024—Revision

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than July 29, 2026.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *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.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Samantha Miller, the HRSA Information Collection Clearance Officer, at *paperwork@hrsa.gov* or call (301) 443–3983.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Rural Health Care Coordination Program Performance Improvement Measures, OMB No. 0906–0024—Revision.

Abstract: The Rural Health Care Coordination (Care Coordination) Program is authorized under 42 U.S.C. 254c(e) (section 330A(e) of the Public Health Service Act) to promote rural health care services outreach by improving and expanding the delivery of health care services through comprehensive care coordination strategies addressing a primary focus area: (1) heart disease, (2) cancer, (3) chronic lower respiratory disease, (4) stroke, or (5) maternal health. HRSA currently collects information about Care Coordination Program grants using an OMB-approved set of performance measures and seeks to revise that approved collection. The proposed changes are a result of keeping this instrument relevant, responsive to the Care Coordination Program needs and to improve clarity and ease of reporting for respondents.

A 60-day notice published in the **Federal Register** on March 24, 2026, vol. 91, No. 56; pp. 14029–30. There were two public comments recommending the following:

- Additional measures for tracking mental/behavioral and substance use disorder health providers and services,
- Collecting more granular demographic data,
- Establishing more concrete metrics related to workforce and leadership characteristics,
- Advocating for requiring that measures related to how well awardees meet community needs require standardized upstream drivers of health screening tools (*e.g.,* tracking closed-loop referrals), and
- A general recommendation to HRSA to allow grant funds to be used for electronic health record interoperability upgrades.

HRSA will take these suggestions into consideration on future iterations of measure development.

Need and Proposed Use of the Information: The purpose of the revised data collection is to assess Care Coordination Program awardees' progress in meeting the program goals and how well each awardee meets their community needs. Additionally, HRSA will be able to monitor and assess the impact of the Care Coordination Program and ensure that funds are effectively used to provide services that meet the needs of the awardees' target population(s) needs.

HRSA revised the performance measures that Care Coordination awardees will submit to HRSA on an annual basis. The proposed changes include adding one additional measure in the Leadership and Workforce Composition section, modifying the text of an existing measure to enhance clarity, and correcting the units of measurement on two existing measures.

There is a proposed increase in the total estimated burden hours compared to the currently approved information collection. The increase in burden is to account for changes to the instruments and the time it takes for awardees to refine their existing processes to coordinate and collect data from their partner organizations. These organizations vary in data collection and reporting capacity as well as in the number of member organizations each must coordinate with to report this data to HRSA. The amount of time it takes to build processes to coordinate and collect data from network partners will vary. Larger networks with multiple partners across different organizations are likely to report higher burdens due to the wait time in between coordinating data requests. Networks that already have established working relationships with member organizations may have existing processes in place to effectively collect data for this program.

Likely Respondents: Respondents will be the Care Coordination Program award recipients.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.