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

21 CFR section; activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
120.8(a), 120.8(b), and 120.12(a)(3), (b), and (c); written HACCP plan.	1,560	1.1	1,716	60	102,960
Total			21,980,369		461,426

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

Based on a review of the information collection since its last OMB approval, we have made no adjustments to our burden estimate.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–03332 Filed 2–19–26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–1305]

Agency Information Collection Activities; Proposed Collection; 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 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 information collection associated with designation of new animal drugs for minor use and minor species and indexing of new animal drugs for minor species.

DATES: Either electronic or written comments on the collection of information must be submitted by April 21, 2026.

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 April 21, 2026. 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–1305 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; New Animal Drugs for Minor Use and Minor Species.'' 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, Center for Veterinary Medicine, Food and Drug Administration, 5001 Campus Drive, College Park, MD 20740, 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.

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.

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
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

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
516.29; 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	1,250
Subtotal					5,286
Total					5,562

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section, activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
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. 2026–03353 Filed 2–19–26; 8:45 am]

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