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Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No FDA–2026–N–5829]

Agency Information Collection Activities; Proposed Collection; Comment Request; Extralabel Drug Use in Animals

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 requirements associated with extralabel drug use in animals.

DATES: Either electronic or written comments on the collection of information must be submitted by August 17, 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 August 17, 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–5829 for “Agency Information Collection Activities; Proposed Collection; Comment Request; Extralabel Drug Use In Animals.” 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, PRASStaff@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.

Extralabel Drug Use in Animals—21 CFR 530

OMB Control Number 0910-0325—
Extension

This information collection supports Food and Drug Administration (FDA, us

or we) 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 530, permit FDA, if we find that there is a reasonable probability that the extralabel use of an animal drug may present a risk to public health, to establish a safe level for a residue from the extralabel use of the drug, and to require the development of an analytical method for the detection of residues above that established safe level. This requirement is codified at 21 CFR 530.22(b). Although to date, we have not established a safe level for a residue from the extralabel use of any new animal drug and, therefore, have not required the development of analytical

methodology, we believe that there may be instances when analytical methodology will be required. We are, therefore, estimating the reporting burden based on two methods being required annually. The requirement to establish an analytical method may be fulfilled by any interested person. We believe that the sponsor of the drug will be willing to develop the method in most cases. Alternatively, FDA, the sponsor, and perhaps a third party may cooperatively arrange for method development. The respondents may be sponsors of new animal drugs, State, or Federal and/or State Agencies, academia, or individuals.

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
530.22(b); Submission(s) of analytical method	2	1	2	4,160	8,320

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 our last request for OMB approval, we have made no adjustments to our burden estimate.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation,
and International Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

**Agency Information Collection
Activities: Proposed Collection: Public
Comment Request; Information
Collection Request Title:
Questionnaire and Data Collection
Testing, Evaluation, and Research for
the Health Resources and Services
Administration, OMB No. 0915-0379—
Revision**

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

ACTION: Notice.

SUMMARY: In compliance with the
requirement for opportunity for public
comment on proposed data collection
projects of the Paperwork Reduction Act
of 1995, HRSA announces plans to
submit an Information Collection

Request (ICR), described below, to the
Office of Management and Budget
(OMB). Prior to submitting the ICR to
OMB, HRSA seeks comments from the
public regarding the burden estimate,
below, or any other aspect of the ICR.

DATES: Comments on this ICR should be
received no later than August 17, 2026.

ADDRESSES: Submit your comments to
paperwork@hrsa.gov or mail the HRSA
Information Collection Clearance
Officer, Room 13N82, 5600 Fishers
Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: To
request more information on the
proposed project or to obtain a copy of
the data collection plans and draft
instruments, email paperwork@hrsa.gov
or call Samantha Miller, the HRSA
Information Collection Clearance
Officer, at (301) 443-3983.

SUPPLEMENTARY INFORMATION: When
submitting comments or requesting
information, please include the ICR title
for reference.

Information Collection Request Title:
Questionnaire and Data Collection
Testing, Evaluation, and Research for
HRSA —OMB No. 0915-0379—
Revision.

Abstract: The purpose of this
umbrella ICR is to inform the
development of new questions,
questionnaires, and tools; pilot/pre-test
instruments under development; and
identify problems in instruments
currently in use by soliciting feedback

from members of the public. Using this
ICR, individual information collections
related to the development or revision
of HRSA data collection instruments go
through an abbreviated approval process
called a “generic” or “fast-track”
information collection. This allows
program offices to efficiently gather a
suitable pool of candidates within the
varied time periods available for
participant recruitment.

Information collected under this
generic clearance will not be used for
data collection, reports, or policy
documents to be released to the public.
It is anticipated that data collection
approved under this generic clearance
will rely heavily on qualitative
techniques and not the collection of
numerical data. In general, these
activities are not designed to yield
results that meet generally accepted
standards of statistical rigor but
designed to obtain information to
develop clearer and more effective and
efficient data collection tools that will
yield more accurate results and decrease
public non-response. The forms
submitted under this generic clearance
will be voluntary, low-burden, and
uncontroversial.

*Need and Proposed Use of the
Information:* HRSA conducts
interviews, focus groups, cognitive
testing, usability tests, field tests/pilot
interviews, and surveys for data
collection instrument development and
evaluation (including assessment of