

Program” (OMB Control number: 0938–0313). The CMS–643 is completed by surveyors during onsite survey activity and poses minimal to no burden on the hospice provider.

The data collected on the CMS–643 form is entered into the internet Quality Improvement and Evaluation System (iQIES) surveyor database during the course of an initial, recertification or complaint survey. Hospice surveyors that have access to the electronic iQIES system while onsite at a hospice, can enter the CMS–643 form data directly into the system. If this access is not available to the surveyor, they can record their finding directly onto the CMS–643 form and input the data into the system later. We removed the requirement for the surveyors to sign CMS–643 to certify their findings as this process has been automated once information is entered into the iQIES database. *Form Number:* CMS–643 (OMB control number: 0938–0379); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 7,029; *Total Annual Responses:* 2,343; *Total Annual Hours:* 1,172. (For policy questions regarding this collection contact Caecilia Andrews at 410–786–2190.)

**William N. Parham, III,**

*Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2026–N–3532]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Good Laboratory Practice Requirements for Nonclinical Laboratory Studies

**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 information collection applicable to the Good Laboratory Practice Requirements for Nonclinical Laboratory Studies established in Agency regulations.

**DATES:** Either electronic or written comments on the collection of information must be submitted by June 29, 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 June 29, 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–3532 for “Agency Information Collection Activities; Proposed Collection; Comment Request; Good Laboratory Practice Requirements for Nonclinical Laboratory Studies.” 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, [PRAStaff@fda.hhs.gov](mailto: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.

**Good Laboratory Practice Requirements for Nonclinical Laboratory Studies—21 CFR Part 58**

*OMB Control No. 0910–0119—Extension*

Sections 409, 505, 512, and 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348, 355, 360b, and 360e) and related statutes require manufacturers of food additives, human drugs and biological products, animal drugs, and medical devices to demonstrate the safety and utility of their product by submitting applications to FDA for research or marketing permits. Such applications contain, among other important items, full reports of all studies done to demonstrate product safety in man and/or other animals. In order to ensure adequate quality control for these studies and to provide an adequate degree of consumer protection, the Agency issued good laboratory practice (GLP) regulations for nonclinical laboratory studies in part 58 (21 CFR part 58). The regulations specify minimum standards for the proper conduct of safety testing and contain sections on facilities, personnel, equipment, standard operating procedures (SOPs), test and control articles, quality assurance, protocol and conduct of a safety study, records and reports, and laboratory disqualification,

and include information collection provisions.

Part 58 requires testing facilities engaged in conducting toxicological studies to retain, and make available to regulatory officials, records regarding compliance with GLPs. Records are maintained on file at each testing facility and examined there periodically by FDA inspectors. The GLP regulations require that, for each nonclinical laboratory study, a final report be prepared that documents the results of quality assurance unit inspections, test and control article characterization, testing of mixtures of test and control articles with carriers, and an overall interpretation of nonclinical laboratory studies. The GLP regulations also require written records pertaining to: (1) personnel job descriptions and summaries of training and experience; (2) master schedules, protocols and amendments thereto, inspection reports, and SOPs; (3) equipment inspection, maintenance, calibration, and testing records; (4) documentation of feed and water analyses and animal treatments; (5) test article accountability records; and (6) study documentation and raw data.

*Description of Respondents:*

Respondents to the collection of information are sponsors of nonclinical laboratory studies that support or are intended to support applications for research or marketing permits for products regulated by FDA.

We estimate the burden of the information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

21 CFR part	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
58.35(b)(7); Quality assurance unit .....	300	60.25	18,075	1	18,075
58.185; Reporting of nonclinical laboratory study results .....	300	60.25	18,075	27.65	499,774
<b>Total</b> .....					517,849

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN <sup>1</sup>

21 CFR part	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
58.29(b); Personnel .....	300	20	6,000	.21 (13 mins.) ....	1,260
58.35(b)(1)–(6), and (c); Quality assurance unit .....	300	270.76	81,228	3.36 .....	272,926
58.63(b) and (c); Maintenance and calibration of equipment .....	300	60	18,000	.09 (5 mins.) .....	1,620
58.81(a)–(c); SOPs .....	300	301.80	90,540	.14 (8 mins.) .....	12,676
58.90(c) and (g); Animal care .....	300	62.70	18,810	.13 (8 mins.) .....	2,445
58.105(a) and (b); Test and control article characterization ...	300	5	1,500	11.8 .....	17,700
58.107(d); Test and control article handling .....	300	1	300	4.25 .....	1,275
58.113(a); Mixtures of articles with carriers .....	300	15.33	4,599	6.8 .....	31,273
58.120; Protocol .....	300	15.38	4,614	32.7 .....	150,878
58.195; Retention of records .....	300	251.50	75,450	3.9 .....	294,255

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN <sup>1</sup>—Continued

21 CFR part	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Total .....	.....	.....	.....	.....	786,308

<sup>1</sup> 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**

**Food and Drug Administration**

[Docket No. FDA-2026-N-0008]

**Advisory Committee; Pharmacy Compounding Advisory Committee; Renewal**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; renewal of Federal advisory committee.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) is announcing the renewal of the Pharmacy Compounding Advisory Committee by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Pharmacy Compounding Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until the April 25, 2028, expiration date.

**DATES:** The current charter for the Pharmacy Compounding Advisory Committee will expire on April 25, 2026, unless the Commissioner formally determines that renewal is in the public interest.

**FOR FURTHER INFORMATION CONTACT:** Advisory Committee Oversight and Management Staff, Office of the Chief Scientist, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 3215, Silver Spring, MD 20993-0002, (301) 796-8220, [ACOMSSubmissions@fda.hhs.gov](mailto:ACOMSSubmissions@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** FDA is announcing the renewal of the Pharmacy Compounding Advisory Committee (the Committee). The

Committee is a non-discretionary Federal advisory committee established to provide advice to the Commissioner. The Committee advises the Commissioner or designee in discharging responsibilities as they relate to compounding drugs for human use and, as required, any other product for which FDA has regulatory responsibility.

The Committee shall provide advice on scientific, technical, and medical issues concerning drug compounding under sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353a and 353b), and, as required, any other product for which FDA has regulatory responsibility, and makes appropriate recommendations to the Commissioner.

The Committee shall consist of a core of at least 10 voting members including the Chair. Subject to legal and regulatory requirements, members and the Chair are selected by and serve at the discretion of the Commissioner or designee. Each member, including the Chair, will be selected from among authorities knowledgeable in the fields of pharmaceutical compounding, pharmaceutical manufacturing, pharmacy, medicine, and related specialties. These members will include representatives from the National Association of Boards of Pharmacy, the United States Pharmacopeia, pharmacists with current experience and expertise in compounding, physicians with background and knowledge in compounding, and patient and public health advocacy organizations.

Members may be invited to serve for terms of up to four years, or for less time in the discretion of the Commissioner or designee. Non-Federal members of this committee will serve as Special Government Employees or representatives. Federal members will serve as Regular Government Employees or Ex-Officios. In addition to the voting members, the Commissioner or designee may identify consumer and/or industry representatives to join the Committee (or serve as alternate representatives) as non-voting representative members(s), via a process consistent with legal and regulatory requirements.

The Commissioner or designee shall have the authority to select members of other scientific and technical FDA advisory committees to serve temporarily as voting members and to designate Special Government Employees to serve temporarily as voting members when: (1) expertise is required that is not available among current voting standing members of the Committee (when additional voting members are added to the Committee to provide needed expertise, a quorum will be based on the combined total of regular and added members), or (2) to comprise a quorum when, because of unforeseen circumstances, a quorum is or will be lacking. A quorum for the Committee is a majority of the current voting members present at the time, provided that FDA may specify a quorum that is less than a majority of the current voting members because of the size of the Committee and the variety in the types of issues that it will consider, or other reason determined appropriate in accordance with legal and regulatory requirements. 21 CFR § 14.22(d).

If functioning as a medical device panel, an additional non-voting representative member of consumer interests and an additional non-voting representative member of industry interests will be included in addition to the voting members.

Further information regarding the most recent charter and other information can be found at <https://www.fda.gov/advisory-committees/pharmacy-compounding-advisory-committee/pharmacy-compounding-advisory-committee-charter> or by contacting the Advisory Committee Oversight and Management Staff (see **FOR FURTHER INFORMATION CONTACT**). In light of the fact that no change has been made to the committee name or description of duties, no amendment will be made to 21 CFR 14.100.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app.). For general information related to FDA advisory committees,