Our estimated burden for the information collection reflects an overall increase of 22,073.50 hours and a corresponding increase of 15,117 responses. We attribute this adjustment to an increase in the number of submissions we received over the last few years. An increase of safety reports represents a pattern that aligns with expectations—as product availability and usage expand, adverse event reporting increases proportionally. The recent three-year increase appears to be a continuation of this established pattern rather than an indication of new safety concerns.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–10189 Filed 5–20–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–0746]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Current Good Manufacturing Practice (CGMP): Manufacturing, Processing, Packing, and Holding of Drugs; GMP for Finished Pharmaceuticals (Including Active Pharmaceutical Ingredients) and the Advanced Manufacturing Technologies Designation Program

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 June 22, 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 0910–0139. Also include the FDA docket number found in brackets in the heading of this document.

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.*

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.

Current Good Manufacturing Practice (CGMP): Manufacturing, Processing, Packing, and Holding of Drugs; GMP for Finished Pharmaceuticals (Including Active Pharmaceutical Ingredients), and the Advanced Manufacturing Technologies Designation Program

OMB Control Number 0910–0139—Revision

This information collection supports statutory and regulatory requirements that govern the manufacture, processing, packing, or holding of finished pharmaceuticals, including active pharmaceutical ingredients (APIs). Under section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 351(a)(2)(B)), a drug is adulterated if the methods used in, or the facilities or controls used for its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with CGMP regulations. FDA is responsible for enforcing the FD&C Act as well as related statutes, including the Public Health Service Act. Congress enacted these laws to ensure that covered products meet applicable requirements regarding the safety, identity and strength, and the quality and purity characteristics they purport or are represented to possess and are labeled with adequate warnings and instructions for use.

The pharmaceutical or drug quality-related regulations appear in several parts of Title 21 Code of Federal Regulations (CFR) (Food and Drugs), including sections in parts 1 through 99, 200 through 299, 300 through 499, 600 through 7 99, and 800 through 1299. The regulations enable a common understanding of the regulatory process by describing requirements to be followed by drug manufacturers, applicants, and FDA. The information collection also supports regulations codified under parts 610 and 680 (21 CFR parts 610 and 680), which reference certain CGMP regulations in part 211 (see §§ 610.12(g), 610.13(a)(2), 610.18(d), 680.2(f), and 680.3(f)). The information collection requirements help FDA ensure compliance with applicable requirements and meet its public health protection responsibilities.

The information collection also includes FDA's Center for Drug Evaluation and Research's (CDER) Program for the Recognition of Voluntary Consensus Standards Related to Pharmaceutical Quality. The National Technology Transfer and Advancement Act of 1995 (Pub. L. 104–113) and Circular A–119 by the Office of Management and Budget (OMB) have established Federal Government policies to improve the internal management of the executive branch by directing agencies to use voluntary consensus standards developed or adopted by a standards developing organization—rather than Government-unique standards—except where these standards are inconsistent with applicable law or otherwise impractical. The guidance document entitled, ''*CDER's Program for the Recognition of Voluntary Consensus Standards Related to Pharmaceutical Quality*'' (July 2023), outlines justifications for why a standard may be recognized wholly, partly, or not at all. (The guidance document is available for download from our website at: *CDER's Program for the Recognition of Voluntary Consensus Standards Related to Pharmaceutical Quality | FDA.*) The guidance document also communicates that interested parties may request recognition of a standard. We intend on finalizing the guidance document upon OMB approval of the attendant information collection.

The information collection also covers activities associated with FDA's Advanced Manufacturing Technologies (AMT) Designation Program, as provided for in section 506L of the FD&C Act (21 U.S.C. 356l) and added by section 3213 of the Food and Drug Omnibus Reform Act of 2022 (FDORA). The guidance document entitled, *Advanced Manufacturing Technologies Designation Program,* (December 2024), communicates the statutory goals, scope, and framework of the AMT program. The guidance document is available for download from our internet site at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/advanced-manufacturing-technologies-designation-program.*

We are revising the information collection to remove activities and burden attributable to medical gas requirements. Through rulemaking on

June 18, 2024, (89 FR 51738) (RIN 0910–AC53), current good manufacturing practice requirements applicable to medical gas are now established in 21 CFR parts 213 and 230 and accounted for under OMB control number 0910–0906.

In the **Federal Register** of February 20, 2026 (91 FR 8249), FDA published a 60-day notice requesting public comment on the proposed collection of information. Although three comments were received, the comments were not responsive to the four collection of information topics solicited.

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

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN—APIS AND FINISHED PHARMACEUTICALS [1] [2]

Information collection activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
CGMP API Manufacturers	1,260	256	322,560	0.82 (49.2 minutes)	264,499
CGMP Finished Pharmaceuticals Manufacturers (excludes medical gases).	3,270	299	977,730	0.64 (38 minutes)	625,747
Voluntary Consensus Standard Activities	9	1	9	1	9
AMT Program Activities, including designation requests	20	1	20	10	200
Total			1,300,319		890,455

[1] There are no capital or operating and maintenance costs associated with the information collection.
[2] Records and burden per activity have been averaged and rounded.

Our estimated burden for the information collection reflects a decrease of 396,293 hours and 639,491 responses annually, resulting from removal of burden attributable to information collection for medical gas requirements. We have otherwise retained currently approved estimates, noting that the AMT activity element has been inadvertently omitted from our burden summary table that appears at *www.reginfo.gov.*

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–10188 Filed 5–20–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–0497]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Patent Term Restoration; Due Diligence Petitions; Filing, Format, and Content of Petitions

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 June 22, 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 0910–0233. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Anne Taylor, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 240–402–5683, *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.

Patent Term Restoration; Due Diligence Petitions; Filing, Format, and Content of Petitions—21 CFR Part 60

OMB Control Number 0910–0233—Extension

This information collection supports Agency regulations. FDA's patent extension activities are conducted under the authority of section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) and the Generic Animal Drug and Patent Term Restoration Act of 1988 (Pub. L. 100–670) (21 U.S.C. 301, *et seq.*). The regulations are codified in part 60 (21 CFR part 60), Patent Term Restoration. New human drug, animal drug, human biological, medical device, food additive, or color additive products regulated by FDA must undergo FDA safety, or safety and effectiveness review before marketing is permitted. If the product is covered by a patent, part of the patent's term may be consumed during this review, which diminishes the value of the patent.

In enacting section 505(j) of the FD&C Act and the Generic Animal Drug and Patent Term Restoration Act of 1988, Congress sought to encourage development of new, safer, and more effective medical and food additive products. It did so by authorizing the U.S. Patent and Trademark Office (USPTO) to extend the patent term by a portion of the time during which FDA's safety and effectiveness review prevented marketing of the product. The length of the patent term extension is generally limited to a maximum of 5 years and is calculated by USPTO based on a statutory formula. When a patent holder submits an application for patent term extension to USPTO, USPTO requests information from FDA, including the length of the regulatory review period for the patented product. If USPTO concludes that the product is eligible for patent term extension, FDA publishes a notice that describes the length of the regulatory review period and the dates used to calculate that period. Interested parties may request, under § 60.24 (21 CFR 60.24), revision of the length of the regulatory review period, or may petition under § 60.30 (21 CFR 60.30) to reduce the regulatory review period by any time where marketing approval was not pursued with ''due diligence.''

In 21 CFR 60.36(a) *due diligence* is defined as ''that degree of attention, continuous directed effort, and timeliness as may reasonably be expected from, and are ordinarily