4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2026-N-0746]

Agency Information Collection Activities; Proposed Collection; 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 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 CGMP for drugs, finished pharmaceuticals, including active pharmaceutical ingredients (APIs), and the advanced manufacturing technologies (AMT) designation program.

DATES: Either electronic or written comments on the collection of information must be submitted by **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

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 **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. 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-0746 for "Agency Information Collection Activities; Proposed Collection; 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." 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.,

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.

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 799, 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.

We estimate the burden of this collection of information as follows:

Table 1.--Estimated Annual Recordkeeping Burden--APIs and Finished Pharmaceuticals[1,2]

Information Collection Activity	No. of Recordkeepers	No. 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.

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