

other interested person may also submit comments on this notice. The procedures and requirements governing this notice of opportunity for a hearing, notice of participation and request for a hearing, the information, and analyses to justify a hearing, other comments, and a grant or denial of a hearing are contained in § 314.200 and in 21 CFR part 12.

The failure of an ANDA holder to file a timely written notice of participation and request for a hearing, as required by § 314.200, constitutes an election by that ANDA holder not to avail itself of the opportunity for a hearing concerning CDER's proposal to withdraw approval of the ANDAs and constitutes a waiver of any contentions concerning the legal status of the drug products. FDA will then withdraw approval of the ANDAs, and the drug products may not thereafter be lawfully introduced or delivered for introduction into interstate commerce. Any new drug product introduced or delivered for introduction into interstate commerce without an approved ANDA is subject to regulatory action at any time.

A request for a hearing may not rest upon mere allegations or denials but must present specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. If a request for a hearing is not complete or is not supported, the Commissioner of Food and Drugs will enter summary judgment against the person who requests the hearing, making findings and conclusions, and denying a hearing.

All submissions under this notice of opportunity for a hearing must be filed in two copies. Except for data and information prohibited from public disclosure under 21 U.S.C. 331(j) or 18 U.S.C. 1905, the submissions may be seen at the Dockets Management Staff (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <https://www.regulations.gov>.

This notice is issued under section 505(e) of the FD&C Act and under authority delegated to the Director of CDER by the Commissioner of Food and Drugs.

Lowell M. Zeta,

Acting 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-2025-N-3656]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Current Good Manufacturing Practices for Positron Emission Tomography Drugs

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 January 28, 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 0910-0667. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, 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 Practices for Positron Emission Tomography Drugs—21 CFR Part 212

OMB Control Number 0910-0667—Extension

This information collection implements statutory and regulatory requirements that govern positron emission tomography (PET) drugs. FDA has promulgated regulations in 21 CFR part 212 establishing current good manufacturing practice (CGMP)

intended to ensure that PET drugs meet the requirements of the Federal Food, Drug, and Cosmetic Act (the act) regarding safety, identity, strength, quality, and purity. While regulations in 21 CFR part 212, subpart A set forth general provisions, additional requirements are established in 21 CFR part 212 as follows:

Subpart B—Personnel and Resources—212.10
 Subpart C—Quality Assurance—212.20
 Subpart D—Facilities and Equipment—212.30
 Subpart E—Control of Components, Containers, and Closures—212.40
 Subpart F—Production and Process Controls—212.50
 Subpart G—Laboratory Controls—212.60–212.61
 Subpart H—Finished Drug Product Controls and Acceptance—212.70–212.71
 Subpart I—Packaging and Labeling—212.80
 Subpart J—Distribution—212.90
 Subpart K—Complaint Handling—212.100
 Subpart L—Records—212.110

Records must be maintained at the PET drug production facility or another location that is reasonably accessible to responsible officials of the production facility and to employees of FDA designated to perform inspections. All records, including those not stored at the inspected establishment, must be legible, stored to prevent deterioration or loss, and readily available for review and copying by FDA employees. All records and documentation referenced in this part must be maintained for a period of at least 1 year from the date of final release, including conditional final release, of a PET drug product.

The regulations contain what we believe are the minimum standards for quality production of PET drugs at all types of PET drug production facilities. These CGMP requirements are designed according to the unique characteristics of PET drugs, including their short half-lives and because most PET drugs are produced at locations close to the patients to whom the drugs are administered. We have also taken into account that time spent on recording procedures, processes, and specifications may be somewhat higher in the year in which records are first established and correspondingly lower in subsequent years, when only updates and revisions will be required.

We have also issued Agency guidance entitled, "PET Drugs—Current Good Manufacturing Practice (CGMP)," (December 2009), available for download from our website at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/pet-drug-products-current-good-manufacturing-practice-cgmp>. The guidance document communicates

FDA’s thinking concerning compliance with the CGMP regulations. The guidance document addresses resources, procedures, and documentation for all PET drug production facilities, academic and commercial. In some cases, the guidance provides practical examples of methods or procedures that

PET drug production facilities can use to comply with the CGMP requirements.

Respondents to the information collection include are PET production facilities, including academic or hospital facilities as well as commercial facilities.

In the **Federal Register** of September 25, 2025 (90 FR 46218), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN ¹

Required recordkeeping activity; 21 CFR 212	Number of recordkeepers	Records per recordkeeper	Total annual records	Average burden per record	Total hours
Academia, Small Firms, & High-Risk Component Manufacture Records.	76	~824.26	62,644	~.81 (50 minutes) ..	50,862
Corporate Firm Records	91	~1,447.10	131,686	~.35 (21 minutes) ..	45,728
External Control Testing Laboratory Records	23	145	3,335	~.67 (40 minutes) ..	2,243
Total			197,665		98,833

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

TABLE 2—ESTIMATED ANNUAL DISCLOSURE BURDEN

Notifications required under 21 CFR 212.70	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Sterility Testing Failures	11	3	33	2.5	83

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

² Totals have been rounded to the nearest whole number.

³ Two reports are sent to FDA per incident, and one notification is sent to the receiving site.

Our estimated burden for the information collection reflects an overall increase of 14,348 hours and a corresponding increase of 12,851 records. We attribute this adjustment to an increase in our estimate of the number of small firms due to new facilities.

Brian Fahey,
Associate Commissioner for Legislation.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2024-E-1284; FDA-2024-E-1285; FDA-2024-E-1286; FDA-2024-E-1287; FDA-2024-E-1288]

Determination of Regulatory Review Period for Purposes of Patent Extension; ADZYNMA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for ADZYNMA and is publishing this notice of that determination as required

by law. FDA has made the determination because of the submission of applications to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human biological product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect must submit either electronic or written comments and ask for a redetermination by February 27, 2026. Furthermore, any interested person may petition FDA for a determination regarding whether the applicants for extension acted with due diligence during the regulatory review period by June 29, 2026. See “Petitions” in the **SUPPLEMENTARY INFORMATION** section for more information.

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 February 27, 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: