UNITED STATES FOOD AND DRUG ADMINISTRATION

Current Good Manufacturing Practices for Positron Emission Tomography (PET) Drugs

OMB Control No. 0910-0667 – Extension

SUPPORTING STATEMENT

Part A. Justification

1. Circumstances Making the Collection of Information Necessary

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 the procedural guidance document 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.

We therefore request extension of OMB approval for the information collection provisions found in part 212 of our regulations (21 CFR 212) and the associated procedural guidance, as discussed in this supporting statement.

2. Purpose and Use of the Information Collection

Respondents to the information collection include are PET production facilities, including academic or hospital facilities as well as commercial facilities. We use the information to ensure compliance with CGMP regulatory requirements applicable to PET drugs, including personnel and resources; quality assurance (QA); equipment and facilities; control of components; in-process materials and finished products; production and process controls; laboratory controls; and acceptance criteria.

3. Use of Improved Information Technology and Burden Reduction

While the regulations cover record availability, quality, and retention, they do not prescribe a specific means of recordkeeping other than that records be reasonably accessible to FDA upon inspection. Because electronic submissions are the standard means of submitting information to FDA, however, we estimate the vast majority of respondents will use electronic means to fulfill the recordkeeping requirements. FDA accepts any recordkeeping method that complies with the applicable requirements.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection. Information collection is required in accordance with statutory provisions that are exclusively the responsibility of FDA pertaining to the manufacture and distribution of PET drugs, and pursuant to 21 CFR 212.

5. Impact on Small Businesses or Other Small Entities

Although the information collection applies to small and large businesses alike, we provide resources, including small business and industry assistance, to respondents to our website at https://www.fda.gov/industry/small-business-assistance and through staff within our Center for Drug Evaluation and Research (CDER). No undue burden is posed on small entities as a result of the information collection.

6. Consequences of Collecting the Information Less Frequently

The information collection schedule is consistent with statutory and regulatory requirements associated with CGMP regulations applicable to PET drugs.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances for this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

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.

9. Explanation of Any Payment or Gift to Respondents

There are no incentives, payments or gifts associated with this information collection.

10. Assurance of Confidentiality Provided to Respondents

The Privacy Act of 1974

In preparing this supporting statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected. Although this ICR collects personally identifiable information (PII), it is collected in the context of the subject individuals' professional capacity and the FDA-related work performed for their employer (e.g., point of contact at a regulated entity). The PII submitted for the *Field Alert Report* (FAR) via **Form FDA 3331a** (New Drug Application/Abbreviated New Drug Application) is name, telephone number, and email address. We have determined that although PII is collected, it is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Privacy Act do not apply. Specifically, FDA does not use name or any other personal identifier to retrieve records from the information collected. Through appropriate form design, FDA limited submission fields and minimized the PII collected to protect the privacy of the individuals.

The Freedom of Information Act (FOIA)

Under FOIA (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9)). FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information.

11. Justification for Sensitive Questions

The collection of information does not involve sensitive questions.

12. Estimates of Annualized Burden Hours and Cost

12a. Annualized Hour Burden Estimate

Table 1 – Estimated Annual Recordkeeping Burden[1,2]

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			0		0

[1] Totals have been rounded to the nearest whole number.
[2] Two reports are sent to FDA per incident, and one notification is sent to the receiving site.

Table 2 – Estimated Annual Disclosure Burden[1, 2]

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] Totals have been rounded to the nearest whole number.
[2] Two reports are sent to FDA per incident, and one notification is sent to the receiving site.

12b. Annualized Cost Burden Estimate

Table 3 – Estimated Annual Cost Burden

	Number of Establishments	Labor (Months)	Wage (Annual Salary)	Cost
RECORDS DAILY IMPLEMENTATION, AUDITS, UPDATES				
Academia and Small Firms (Academia and Small PET Producers)	76	1.0	$266,762	$1,689,492.67
Corporate Firms (Commercial PET Producers)	91	2.25	$266,762	$4,551,626.63
TOTAL				$6,241,119.30
TRAINING				

Academia and Small Firms (Academia and Small PET Producers)	76	.11	$266,762	$185,844.19
Corporate Firms (Commercial PET Producers)	91	.11	$266,762	$222,523.97
TOTAL				$408,368.16

13. Estimates of Other Total Annual Costs to Respondents/Recordkeepers or Capital Costs

There are no capital, start-up, or operating or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

Costs for the information collection include periodic inspections of PET drug production facilities. Two full-time employees are needed to conduct these inspections annually and we calculate $594,864 in total costs to the Federal Government.

15. Explanation for Program Changes or Adjustments

Our estimated burden for the information collection reflects an overall increase of 14,348 hours and 12,851 records annually. We attribute this adjustment to a corresponding increase in new facility registrations..

16. Plans for Tabulation and Publication and Project Time Schedule

No tabulated results, or production or project schedules are associated with the information collection.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

The OMB expiration date will be displayed as required by 5 CFR 1320.5.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.