At the same time, on our own initiative and for efficiency of Agency operations, we are revising the information collection to include related activity currently approved and accounted for in OMB control no. 0910–0627. Specifically, our regulation at 21 CFR 589.2001 is designed to safeguard against the establishment and amplification of BSE in the United States through animal feed. The regulation prohibits the use of certain cattle origin materials in the food or feed of all animals. These materials are referred to as ''cattle materials prohibited in animal feed'' or CMPAF. Under § 589.2001, no animal feed or feed ingredient can contain CMPAF. As a result, we impose requirements to maintain adequate written procedures and recordkeeping on renderers that receive, manufacture, process, blend, or distribute raw material from cattle and to make these records available for inspection and copying by FDA to demonstrate they are taking measures to ensure that CMPAF is not introduced into animal feed.

Additionally, under § 589.2001(f), we may designate a country from which cattle materials are not considered CMPAF. A country seeking to be so designated must send a written request to the Director of the Center for Veterinary Medicine, including certain required information. We use the information provided to determine whether to grant a request for designation and to impose conditions if a request is granted. Designated countries will be subject to our future review to determine whether their designations remain appropriate. As part of this process, we may ask designated countries at any time to confirm that their BSE situation and the information submitted by them in support of their original application remains unchanged. We may revoke a country's designation if we determine that it is no longer appropriate. Therefore, designated countries may respond to our periodic requests by submitting information to confirm their designations remain appropriate.

We estimate the burden of the information collection as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR 589—Substances Prohibited From Use in Animal Food or Feed	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Written procedures (prohibited animal proteins); 589.2000(e)(1)(iv)	150	1	150	12	1,800
Exemption designation requests & response to FDA; 589.2001(f) ...	1	2	2	33	66
Written procedures (prohibited materials to prevent BSE) & maintenance of records	145	1	145	45	6,525
Total	.....	.....	297	.....	8,391

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

We characterize all collection activity as recordkeeping noting that a recordkeeping requirement, as defined by 5 CFR 1320.3(m), includes the requirement to retain, disclose, and report the information, including reporting the information to the Federal government.

We base our estimate of the number of recordkeepers on inspectional data. Upon evaluation, we have adjusted our burden estimate to reflect a decrease of 1,350 hours annually to the currently approved burden applicable to prohibited animal protein records required by 21 CFR 589.2000. Review of our inspection data suggests that the number of facilities that need to conduct these separation practices is gradually decreasing. These facilities are well aware of the requirements established in the BSE rule (*https://www.fda.gov/food/hfp-constituent-updates/fda-announces-final-rule-bovine-spongiform-encephalopathy*). Compliance with the rule's requirements also helps facilitate compliance with the requirements of the Food Safety Modernization Act Preventive Controls in Animal Food rule (*https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-preventive-controls-animal-food*) requiring every firm to have a written food safety plan. The written procedure required by the BSE rule could be used as part of a facility's food safety plan. Regardless, the number of facilities subject to this portion of the BSE rule is decreasing and therefore, we have decreased the number of facilities who must comply, as well as the total number of hours needed to comply with this burden.

We have retained the annual burden estimate that we attribute to activities under 21 CFR 589.2001 (147 responses, 6,591 hours) and currently approved in OMB control no. 0910–0627. We intend to discontinue the later control no. from our inventory upon OMB review and approval.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–18615 Filed 9–24–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–3656]

Agency Information Collection Activities; Proposed Collection; 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 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 collection of information under FDA's current good manufacturing practice (CGMP) regulations for positron emission tomography (PET) drug products. PET is

a medical imaging modality involving the use of a unique type of radiopharmaceutical drug product.

DATES: Either electronic or written comments on the collection of information must be submitted by November 24, 2025.

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 November 24, 2025. 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–2025–N–3656 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Current Good Manufacturing Practices for Positron Emission Tomography Drugs—21 CFR part 212.'' 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: Domini Bean, 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: 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 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.

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.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–18620 Filed 9–24–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–D–3403]

Innovative Designs for Clinical Trials of Cellular and Gene Therapy Products in Small Populations; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the availability of a draft document entitled ''Innovative Designs for Clinical Trials of Cellular and Gene Therapy Products in Small Populations.'' The draft guidance document provides recommendations to sponsors who are planning clinical trials of cell and gene therapy (CGT) products intended for use in a disease or condition that affects a small population, generally one that meets the definition of a rare disease or condition under section 526(a)(2) of the FD&C Act (21 U.S.C. 360bb(a)(2)). It describes FDA requirements and provides considerations for the use of various