of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved, and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

PEPCID (famotidine) for oral suspension, 40 mg/5 mL, is the subject of NDA 019527, held by Bausch Health US, LLC, and initially approved on February 2, 1987. PEPCID is indicated in adults for the treatment of active duodenal ulcer (DU); active gastric ulcer; symptomatic nonerosive gastroesophageal reflux disease (GERD); erosive esophagitis due to GERD, diagnosed by biopsy; treatment of pathological hypersecretory conditions (*e.g.,* Zollinger-Ellison syndrome, multiple endocrine neoplasias); and reduction of the risk of DU recurrence. PEPCID is indicated in pediatric patients 1 year of age and older for the treatment of peptic ulcer, and GERD with or without esophagitis and ulcerations. PEPCID is indicated in pediatric patients from birth to less than 1 year of age for the treatment of GERD.

In a letter received on January 11, 2019, the applicant notified FDA that PEPCID (famotidine) for oral suspension, 40 mg/5 mL, was being discontinued, and FDA moved the drug product to the ''Discontinued Drug Product List'' section of the Orange Book.

Ajanta Pharma USA Inc., submitted a citizen petition dated October 11, 2021 (Docket No. FDA–2021–P–1097), and Lachman Consultant Services, Inc., submitted a citizen petition dated October 13, 2021 (Docket No. FDA–2021–P–1111), both under 21 CFR 10.30, requesting that the Agency determine whether PEPCID (famotidine) for oral suspension, 40 mg/5 mL, was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petitions and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that PEPCID (famotidine) for oral suspension, 40 mg/5 mL, was not withdrawn for reasons of safety or effectiveness. The petitioners have identified no data or other information suggesting that PEPCID (famotidine) for oral suspension, 40 mg/5 mL, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of PEPCID (famotidine) for oral suspension, 40 mg/5 mL, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list PEPCID (famotidine) for oral suspension, 40 mg/5 mL, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to PEPCID (famotidine) for oral suspension, 40 mg/5 mL, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: March 31, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–07391 Filed 4–6–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0242]

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) drugs. PET is a medical imaging modality involving the use of a unique type of radiopharmaceutical drug product.

DATES: Submit either electronic or written comments on the collection of information by June 6, 2022.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before June 6, 2022. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 6, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is 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 Docket No. FDA–2013–N–0242 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Current Good Manufacturing Practices for Positron Emission Tomography Drugs.'' 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. Eastern Time, 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: 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: 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—Revision

FDA CGMP regulations in part 212 (21 CFR part 212) are intended to ensure that PET drug products meet the requirements of the Federal Food, Drug, and Cosmetic Act (FD&C Act) regarding safety, identity, strength, quality, and purity and are issued under the provisions of the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. 105–115). 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.

I. Investigational and Research PET Drugs

Section 212.5(b) (21 CFR 212.5(b)) provides that for investigational PET drugs produced under an investigational new drug application (IND) and research PET drugs produced with approval of a Radioactive Drug Research Committee (RDRC), PET producers must meet the requirement (FD&C Act) to follow CGMP by complying with the regulations under part 212 or complying with United States Pharmacopeia (USP) 32 Chapter 823. We believe that PET production facilities producing drugs under INDs and RDRCs are already substantially complying with the recordkeeping requirements of USP 32 Chapter 823 (see section 121(b) of FDAMA). Some IND and RDRC PET facilities also produce PET drugs approved under abbreviated new drug applications (ANDAs) or new drug applications (NDAs), and our estimates include these facilities. The facilities described above are included under academia or small firms. The corporate sites that also produce IND PET drugs are included in the estimated 91 individual corporate sites.

To estimate the amount of time that respondents have spent complying with

CGMP requirements, we relied on the following:

- Informal communications with PET producers.
- FDA staff visits to PET production facilities.
- Our experience with PET drug applications, including amendment and supplement submissions.
- Our general knowledge of pharmaceutical manufacturing practices.
- Various CGMP compliance reports FDA received from 2019 to 2021.

II. Recordkeeping Burden

A. One-Time Recordkeeping Burden for Corporate Firms

We estimate that corporate firms will have to employ one-time and annual recordkeeping. We estimate that, for some major PET manufacturing corporations, most of the quality, manufacturing, and testing procedures are developed at the corporate level and issued to the individual production and testing sites located in various States across the country. It is estimated that a total of 91 of these individual corporate sites are controlled among 4 major corporations. Thus, we have calculated the burden for 4 recordkeeping activities as a one-time effort for creating standard operating procedures (SOPs) and master batch records (MBRs) instead of 91 recordkeeping activities for individual corporate sites.

Each corporate firm is estimated to expend approximately 8 hours to create 1 MBR per PET drug. We estimate that 4 corporate firms will each create and maintain 10 MBRs associated with production and quality control (QC) testing procedures (a total of 40 records), which results in a total recordkeeping burden of approximately 320 hours.

Sections 212.20(c), 212.30(b), 212.50(d), and 212.60(f) (21 CFR 212.20(c), 212.30(b), 212.50(d), and 212.60(f) contain written SOP provisions for equipment operation, maintenance, and cleaning, including maintenance of physical facilities. We estimate that 4 corporate firms will expend approximately 5 hours each to establish and maintain 13 procedures for equipment and facility maintenance (a total of 52 procedures), which results in a total recordkeeping burden of approximately 260 hours.

Sections 212.20(b) and 212.40(a) and (b) contain requirements on SOPs regarding receiving, testing, and accepting components. We estimate that 4 corporate firms will expend approximately 8 hours each to create 1 procedure for acceptance of raw materials and components (a total of 4 procedures), which results in a total recordkeeping burden of approximately 32 hours.

We estimate that approximately 4 corporate firms will expend 2 hours each to create 25 specification data sheets for components (a total of 100 specification data sheets), which results in a total recordkeeping burden of approximately 200 hours.

Section 212.71(a) and (b) requires that PET drug firms establish procedures for rejecting PET drug batches that do not conform to established specifications and requires that PET drug firms establish procedures for investigating deviations and out-of-specifications (OOS) failures of products during manufacturing and testing. Section 212.50(a) also requires that firms establish written production and process control procedures to ensure and document that all key process parameters are controlled and that any deviations from the procedures are justified. We estimate that 4 corporate firms will expend approximately 8 hours each to establish 1 procedure (a total of 4 procedures), which results in a total recordkeeping burden of approximately 32 hours.

Section 212.90(a) requires the establishment and maintenance of written procedures for the distribution of PET drug products. We estimate that 4 corporate firms will each expend approximately 8 hours to establish and maintain 1 written procedure regarding the distribution of PET drugs (a total of 4 records), which results in a total recordkeeping burden of approximately 32 hours.

Sections 212.20(e) and 212.100(a), (b), and (c) require that PET drug firms establish and maintain written procedures for handling complaints and establish and maintain procedures for field alert reports (FARs). We estimate that 4 corporate firms will each establish 3 written procedures (a total of 12 procedures) and that each corporate firm will expend approximately 8 hours for each procedure. Establishing and maintaining written procedures results in a total recordkeeping burden of approximately 96 hours.

B. One-Time Recordkeeping Burden for Academia, Small Firms, and High-Risk Component Manufacturers

A total of 63 combined sites represent academia and small commercial firms, including some IND and RDRC sites manufacturing ANDA-approved and NDA-approved PET drugs, and high-risk component manufacturers. Of the 63 combined sites (herein and the other sections of this document referred to as ''entities''), 14 producers of starting materials, precursors, generators, and sterile component material manufacturing for kits are also required to comply with selected regulations in part 212, according to the *PET drug* definition in section 121(a) of FDAMA and codified in section 201(ii)(1)(A) of the FD&C Act (21 U.S.C. 321(ii)(1)(A)). We refer to such producers as high-risk component manufacturers in tables 2 and 5.

The 63 entities will expend approximately 8 hours each to create MBRs and manufacturing and quality procedures. We estimate that the entities will each maintain 8 records (a total of approximately 504 records), which results in a total recordkeeping burden of 4,032 hours.

Each of the entities will expend approximately 8 hours to create equipment-related and facility-related procedures (consistent with corporate firms discussed in section II.A above). A total of 63 entities will each maintain an estimated 12 records (a total of 756 records), which results in a total recordkeeping burden of approximately 6,048 hours.

The estimated burden for the 63 entities to each create and maintain 12 procedures for acceptance of raw materials and components (a total of 126 procedures) is approximately 8 hours per procedure. The creation and maintenance of these procedures results in a total recordkeeping burden of approximately 1,008 hours.

We estimate that the 63 entities will each expend approximately 30 minutes to create and maintain 21 specification data sheets (a total of 1,323). The creation and maintenance of specification data sheets results in a total recordkeeping burden of approximately 662 hours.

We estimate that approximately 63 entities will each create 1 procedure relating to deviations and OOS investigations and 1 procedure relating to the distribution of finished products (2 procedures for a total of 126). Each of these entities will expend 8 hours per procedure, which results in a total recordkeeping burden of 1,008 hours—504 hours for each procedure.

We estimate that each of the 63 entities will create approximately 3 procedures relating to customer complaints, returned products, and FAR (a total of 189 records). Each of these entities will expend 8 hours per record, which results in a total recordkeeping burden of 1,512 hours.

C. Annual Recordkeeping Burden for Corporate Firms

As discussed in section II.A, we estimate that there are a total of 91 individual corporate sites controlled under 4 major corporations. The information collection discussed in this section relates to individual PET drugs manufactured at each of the sites located across the country.

We estimate that the 91 corporate sites will each expend approximately 30 minutes to fill 240 batches (approximately 20 batches each month and a total of 21,840 batches for all 91 sites), which results in a total recordkeeping burden of 10,920 hours. We further estimate that, annually, corporate firms may have to create some new batch records or quality records for newly introduced or existing drugs.

We estimate that the 4 major corporations will each expend approximately 8 hours to create 9 new quality procedure and MBRs (a total of 36 records), which results in a total recordkeeping burden of 288 hours.

We estimate that approximately 91 individual corporate sites will each expend approximately 15 minutes to create 480 records for equipment maintenance, cleaning, calibration, and facilities maintenance (a total of 43,680 records), which results in a total recordkeeping burden of 10,920 hours.

Sections 212.20(b) and (c) and 212.40(a) and (b) set forth requirements for acceptance of raw materials and component shipments received at the centrally controlled, corporate quality assurance (QA) facilities annually. We estimate that the 4 corporate QA sites, internally located within corporate administrative sites, will create 48 records for incoming raw material acceptance (a total of 192 records) for approximately 4 bulk shipments per month (12×4) on behalf of the individual corporate sites. Corporate QA sites will expend approximately 2 hours to create records, which results in a total recordkeeping burden of 384 hours.

Sections 212.60(g), 212.61(b), and 212.70(d)(2) and (d)(3) set forth requirements for documenting laboratory testing results obtained from each PET drug manufactured and referred to in laboratory testing, including final release testing. Each of the 91 individual corporate firms must maintain records of different tests for each of their products. We estimate that approximately 91 individual corporate sites will each expend 30 minutes to document 240 records of cumulative QC test results (1 record that includes 5 to 6 tests and a total of 21,840 records), which results in a total recordkeeping burden of approximately 10,920 hours.

We estimate approximately 2 hours for each of the 91 individual corporate sites to record OOS events and perform investigations for each incident. We also estimate that the individual corporate sites will each conduct an average of 2 OOS investigations per site (a total of 182 records for OOS investigations), which results in a total recordkeeping burden of 364 hours. This estimate includes reprocessing or conditional release events, which are very rare.

Section 212.100(b) and (c) requires that PET drug firms document how they handle each complaint that they receive. We estimate that each of the 4 corporate QA sites will expend approximately 2 hours to document and investigate 1 complaint. Because complaints are usually investigated at the corporate firm level, we estimate that each corporate QA site will receive and handle 5 complaints annually (a total of 20 complaints for documentation), which results in a total recordkeeping burden of 40 hours.

Our estimate for PET drug firms-performing QA and release of manufactured PET drugs from the 91 individual corporate sites is approximately 5,460 hours from 21,840 released batches (15 minutes per batch for each of the 240 released batches).

Section 212.90(b) requires that corporate firms maintain distribution records. We estimate that each of the 91 corporate firms will expend approximately 5,460 hours to release 21,840 batches (15 minutes per batch for each of the 240 released batches).

D. Annual Recordkeeping Burden for Academia and Small Firms

We assume that each academia and small firm will expend the same amount of time to perform the same information collection activities as corporate firms (discussed in section II.A above).

Approximately 49 academia and small firms will each expend approximately 30 minutes to fill 96 batch and production records (a total of 4,704 records), which results in a total recordkeeping burden of 2,352 hours.

For the 49 academia and small firms to create new MBRs or quality records, we estimate they will expend 8 hours per record (147 total records (3 per site)), which results in a total recordkeeping burden of 1,176 hours.

We estimate that approximately 49 academia and small firms will maintain 23,520 calibration and cleaning records (480 records per site), such as logbooks for each piece of equipment and documentation of calibration records in each PET production firm. The calibration efforts for academia and small firms is twice per year per equipment (10 pieces of equipment per site). In addition, we estimate that academic and small firms will each expend 30 minutes to maintain records, which results in a total recordkeeping burden of 11,760 hours.

Under §§ 212.20(b) and (c) and 212.40(a) and (b), academia and firms will maintain a total of approximately 588 raw material and component acceptance records (12 shipments per year). We estimate that they will expend 30 minutes to create records, which results in a total recordkeeping burden of 294 hours.

We estimate that approximately 49 academia and small firms will each expend 30 minutes to document a total of 4,704 laboratory QC test records (96 records per site), which results in a total recordkeeping burden of approximately 2,352 hours.

We estimate that approximately 49 academic and small firms will each maintain records of OOS and customer-complaint events and perform investigations and that they will expend approximately 2 hours annually for these activities. We also estimate an average of 2 OOS events and 2 customer complaints and investigations per firm, with a total of 392 hours for each category (196 for each site). This estimate includes any reprocessing or special batch release events, which have been rarely observed.

We estimate that approximately 49 academia and small firms will each perform QA and release of manufactured PET drugs and that they will expend 15 minutes per batch (96 batches per site), which results in a total recordkeeping burden of 1,176 hours for 4,704 batches.

Section 212.90(b) requires that academia and small firms maintain distribution records. We estimate that it will take approximately 15 minutes per batch (96 batches per site) to create a distribution record for each batch of PET drug product, with a total recordkeeping burden of approximately 1,176 hours for 4,704 batches per site.

E. Annual Recordkeeping Burden for High-Risk Component Manufacturers (Producers of Starting Materials, Precursors, Generators, and Sterile Raw Materials)

According to section 121(a) of FDAMA, the *PET drug* definition includes any non-radioactive or radioactive reagents, kits, nuclidic generators, target materials, synthesizers, or other apparatus or computer program to be used in preparation of PET drug. FDA performs

risk assessments of each manufacturer and inspects such manufacturers. Producers of sterile kit components, precursors, and generators are included in this category, including producers of sterile raw materials. We have estimated that 14 such facilities be included in this category based on inspections and have included them in this section. These manufacturers must comply with selected sections of part 212 since they are not producing the final PET drug products to be administered to patients. As stated in section II.B, we refer to such producers as high-risk component manufacturers in tables 2 and 5.

We estimate that approximately 14 high-risk component manufacturers will expend 30 minutes to complete each manufacturing batch record (24 batches per site) and that there will be a total of 336 records, which results in a total recordkeeping burden of approximately 168 hours.

We also estimate that the 14 high-risk component manufacturers will each expend approximately 30 minutes to create and file equipment calibration and cleaning and facility maintenance-related records (130 records each and a total of 1,820), which results in a total recordkeeping burden of 910 hours.

We estimate that the 14 such manufacturers will each expend 30 minutes to document 24 records for components, containers, and closures for incoming acceptance tests (a total of 336 batches), which results in a total recordkeeping burden of approximately 168 hours from all sites.

We estimate that the 14 such manufacturers will expend 30 minutes to document 24 laboratory testing records for 336 batches, which results in a total burden of approximately 168 hours. These manufacturers will also document OOS investigations for any laboratory test failures (1 record for each site), which results in a total recordkeeping burden of 14 hours.

We also estimate that such manufacturers will perform QA and release manufactured PET drugs for a total of 336 batches (24 each) released annually. In addition, we estimate that such manufacturers will expend approximately 15 minutes per batch, which results in a total recordkeeping burden of 84 hours.

We estimate that such manufacturers will each expend approximately 15 minutes to create and maintain distribution records that will result in 336 records (24 each). The total recordkeeping burden hours will result in 84 hours.

F. One-Time and Annual Recordkeeping for External Control Testing Laboratories

We have included a new category of facilities—external control testing laboratories—in this information collection. These testing laboratories perform chemical, microbiological, or sterility testing functions to support manufacturing and release of final PET drug products. Assignment and inspection of control testing laboratories may be determined through risk-based assessments. We have estimated that 23 such facilities be included in this category, based on inspections and NDA and ANDA applications that FDA has received. These testing laboratories must comply with selected sections of part 212 (and compliance with 21 CFR part 211 is acceptable) since they are not producing the final PET drugs to be administered to patients. In this section, we refer to these testing laboratories as external testing facilities in general; however, in table 6, we refer to them as external control testing laboratories.

We estimate that approximately 23 external testing facilities will each expend 9 hours to complete testing SOP and validation of test methods and assays (6 records each and a total of 138), which results in a total recordkeeping burden of approximately 1,242 hours.

We estimate that 23 external testing facilities will expend approximately 30 minutes each to perform incoming acceptance test for testing materials and to create test result records, which results in a total recordkeeping burden of 368 hours. For incoming acceptance tests, sites will expend 276 hours (24 records for a total of 552), and for testing records, sites will expend 92 hours (8 records for a total of 184).

We estimate that 23 external testing facilities will each document 2,254 equipment cleaning and calibration records, 184 QA release records, and 23 OOS investigation records, which results in a total recordkeeping burden of approximately 564, 23, and 46 hours, respectively (see table 6).

III. Process Verification

Section 212.50(f)(2) requires the recordkeeping of any process verification activities and results. PET drug producers usually perform process verification as a one-time activity before a product is approved or if any major manufacturing process or equipment changes are made. We have estimated that PET drug producers will conduct process verification under one-time batch creation for existing products; annual new creation of MBRs; and manufacturing and quality procedures for ongoing activities, including media fills (see tables 1 and 2).

IV. Conditional Final Releases

Section 212.70(f) requires that PET drug producers document any conditional final releases of a product. We believe that conditional final releases will be uncommon, and we have included them in the burden estimates under annual OOS investigations and final QA release efforts for each manufactured batch in tables 3 and 4.

V. Reprocessing Procedures

Sections 212.20(c) and 212.71(d) require that PET drug producers establish and document procedures for reprocessing PET drugs. We have rarely received reprocessing options for application of such drugs and, if reprocessing occurs, we have included such rare events in the burden estimates under annual QA release efforts in tables 3 and 4.

VI. Third-Party Disclosure Burden for Sterility Test Failure Notices

Section 212.70(e) requires that PET drug producers notify all receiving facilities if a batch fails sterility tests. FDA receives FARs based on confirmed sterility failures of released PET drugs. Based on the last 3 years' sterility failure reports, we estimate that all 140 sites (91 individual corporate sites and 49 academia and small firms) will send notifications to the affected clinical or receiving facilities of approximately 7 failures. Therefore, we estimate that 7 PET drug producers will submit 2 reports to FDA and send 1 notification (a total of 3 reports) to FDA and the affected clinical or receiving site per year. PET drug producers would submit the notice to the receiving site by email or Fax and submit the FAR notice to FDA electronically and would expend 2.5 hours per incident, which results in a total burden of 53 hours.

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

TABLE 1—ESTIMATED ONE-TIME RECORDKEEPING BURDEN FOR CORPORATE FIRMS [1]

Information collection activity; 21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeper (in hours)	Total hours [2]
Subparts C and F; §§ 212.20 to 212.50					
Master Batch Production and Quality Control Procedures (§§ 212.20(c) and (e) and 212.50(a) and (b))	4	10	40	8	320
Subparts C, D, F, and G; §§ 212.20 to 212.60					
Equipment and Facilities Records (SOP) (§§ 212.20(c), 212.30(b), 212.50(d), and 212.60(f))	4	13	52	5	260
Subparts C and E; §§ 212.20 to 212.40					
Records of Components, Containers, and Closures (SOP) (§§ 212.20(b) and 212.40(a) and (b))	4	1	4	8	32
Records of Components, Containers, and Closures (specification data sheets) (§§ 212.20(b) and (c) and 212.40(a) and (b))	4	25	100	2	200
Subpart H; § 212.71					
. OOS Investigations (SOP) (§ 212.71(a) and (b))	4	1	4	8	32
Subpart J; § 212.90					
Distribution Records (SOP) (§ 212.90(a))	4	1	4	8	32
Subparts C and K; §§ 212.20 to 212.100					
Complaints and Returned Product (§§ 212.20(e) and 212.100(a), (b), and (c))	4	3	12	8	96
Total			216		972

[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.

TABLE 2—ESTIMATED ONE-TIME RECORDKEEPING BURDEN FOR ACADEMIA, SMALL FIRMS, AND HIGH-RISK COMPONENT MANUFACTURERS [1]

Information collection activity; 21 CFR section	Number of recordkeepers	Number of records per recordkeeper [2]	Total annual records	Average burden per recordkeeper (in hours)	Total hours [2]
Subparts C and F; §§ 212.20 to 212.50					
Batch Production and Control Records (§§ 212.20(c) and 212.50(a) and (b))	63	8	504	8	4,032
Subparts C, D, F, and G; §§ 212.20 to 212.60					
Equipment and Facilities Records (SOP) (§§ 212.20(c), 212.30(b), 212.50(d), and 212.60(f))	63	12	756	8	6,048
Subparts C and E; §§ 212.20 to 212.40					
Records of Components, Containers, and Closures (SOP) (§§ 212.20(b) and 212.40(a) and (b))	63	2	126	8	1,008
Records of Components, Containers, and Closures (specification data sheets) (§§ 212.20(b) and (c) and 212.40(a) and (b))	63	21	1,323	0.5	662
Subparts C and H; §§ 212.20 to 212.71					
OOS Investigations (SOP) (§§ 212.20(c) and 212.71(a) and (b))	63	1	63	8	504

TABLE 2—ESTIMATED ONE-TIME RECORDKEEPING BURDEN FOR ACADEMIA, SMALL FIRMS, AND HIGH-RISK COMPONENT MANUFACTURERS [1]—Continued

Information collection activity; 21 CFR section	Number of recordkeepers	Number of records per recordkeeper [2]	Total annual records	Average burden per recordkeeper (in hours)	Total hours [2]
Subpart J; § 212.90					
Distribution Records (SOP) (§ 212.90(a))	63	1	63	8	504
Subparts C and K; §§ 212.20 to 212.100					
Complaints and Returned Product (§§ 212.20(e) and 212.100(a), (b), and (c))	63	3	189	8	1,512
Total			3,024		14,270

[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.

TABLE 3—ESTIMATED ANNUAL RECORDKEEPING BURDEN FOR CORPORATE FIRMS [1]

Information collection activity; 21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeper (in hours)	Total hours [2]
Subparts C and F; §§ 212.20 to 212.50					
Batch Production Records (create batch-related records per year) (§§ 212.20(c) and (e) and 212.50(a) and (b))	91	240	21,840	0.5	10,920
Creating Any New Batch Records and Quality Records for New or Existing Drugs (§§ 212.20(c) and (e) and 212.50(a) and (b))	4	9	36	8	288
Subparts D, F, and G; §§ 212.30 to 212.60					
Equipment and Facilities Records (calibration and cleaning records systems) (§§ 212.30(b), 212.50(d), and 212.60(f))	91	480	43,680	0.25	10,920
Subparts C and E; §§ 212.20 to 212.40					
Records of Components, Containers, and Closures for incoming inspection (§§ 212.20(b) and (c) and 212.40(a) and (b))	4	48	192	2	384
Subparts G and H; §§ 212.60 to 212.70					
Laboratory Testing Records (record laboratory test results) §§ 212.60(g), 212.61(b), and 212.70(d)(2) and (d)(3)	91	240	21,840	0.5	10,920
Subpart H; § 212.71					
Out-of-Specification Investigations (record events and investigations) (§ 212.71(b))	91	2	182	2	364
Subparts H and K; §§ 212.70 to 212.100					
Complaints (§ 212.100(b) and (c))	4	5	20	2	40
QA and Release of Batches (§ 212.70)	91	240	21,840	0.25	5,460
Subpart J; § 212.90					
Distribution Records (§ 212.90(b))	91	240	21,840	0.25	5,460
Total			131,470		44,756

[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.

TABLE 4—ESTIMATED ANNUAL RECORDKEEPING BURDEN FOR ACADEMIA AND SMALL FIRMS [1]

Information collection activity; 21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeper (in hours)	Total hours [2]
Subparts C and F; §§ 212.20 to 212.50					
Batch Production Records (filling batch-related records per year) (§§ 212.20(c) and (e) and 212.50(a) and (b))	49	96	4,704	0.5	2,352
Creating Any New Batch Records and Procedures for New Drugs (§§ 212.20(c) and (e) and 212.50(a) and (b))	49	3	147	8	1,176
Subparts D, F, and G; §§ 212.30 to 212.60					
Equipment and Facilities Records (calibration and cleaning records) (§§ 212.30(b), 212.50(d), and 212.60(f))	49	480	23,520	0.5	11,760
Subparts C and E; §§ 212.20 to 212.40					
Records of Components, Containers, and Closures (incoming acceptance tests) (§§ 212.20(b) and (c) and 212.40(a) and (b))	49	12	588	0.5	294
Subparts G and H; §§ 212.60 to 212.70					
Laboratory Testing Records (QC test results) §§ 212.60(g), 212.61(b), and 212.70(d)(2) and (d)(3)	49	96	4,704	0.5	2,352
Subpart H; § 212.71					
Out-of-Specification Investigations (record events and investigations) (§ 212.71(b))	49	2	98	2	196
Subparts H and K; §§ 212.70 to 212.100					
Complaints (Record events and investigations) (§ 212.100(b) and (c))	49	2	98	2	196
QA and Release of Batches (§ 212.70)	49	96	4,704	0.25	1,176
Subpart J; § 212.90					
Distribution Records (§ 212.90(b))	49	96	4,704	0.25	1,176
Total			43,267		20,678

[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.

TABLE 5—ESTIMATED ANNUAL RECORDKEEPING BURDEN FOR HIGH-RISK COMPONENT MANUFACTURERS [1]

Information collection activity; 21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeper (in hours)	Total hours [2]
Subparts C and F; §§ 212.20 to 212.50					
Batch Production (creating manufacturing records and batch-related records per year) (§§ 212.20(c) and (e) and 212.50(a) and (b))	14	24	336	0.5	168
Subparts D, F, and G; §§ 212.30 to 212.60 and 212.90					
Equipment and Facilities Records (calibration and cleaning records systems) (§§ 212.30(b), 212.50(d), and 212.60(f))	14	130	1,820	0.5	910
Subparts C and E; §§ 212.20 to 212.40					
Records of Components, Containers, and Closures (incoming acceptance test) (§§ 212.20(c) and 212.40(a) and (b))	14	24	336	0.5	168

TABLE 5—ESTIMATED ANNUAL RECORDKEEPING BURDEN FOR HIGH-RISK COMPONENT MANUFACTURERS [1]—Continued

Information collection activity; 21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeper (in hours)	Total hours [2]
Subparts G and H; §§ 212.60 to 212.70					
Laboratory Testing Records (record QC test results) §§ 212.60(g), 212.61(b), and 212.70(d)(2) and (d)(3)	14	24	336	0.5	168
Subpart H; § 212.71					
OOS Investigations (record events and investigations) (§ 212.71(b))	14	1	14	1	14
QA and Release of Batches (§ 212.70)	14	24	336	0.25	84
Subpart J; §§ 212.90 to 212.50					
Distribution Records (§ 212.90(b))	14	24	336	0.25	84
Total			3,514		1,596

[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.

TABLE 6—ESTIMATED ONE-TIME AND ANNUAL RECORDKEEPING BURDEN FOR EXTERNAL CONTROL TESTING LABORATORIES [1]

Information collection activity; 21 CFR citation	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeper (in hours)	Total hours [2]
One-Time Recordkeeping Assay Validation (creating SOP and performing validation)	23	6	138	9	1,242
Subparts C, E, and F; §§ 212.20, 212.40, and 212.50					
Annual Recordkeeping Incoming Acceptance Tests Records (§§ 212.20(c), 212.40(a) and (b))	23	24	552	0.5	276
Annual Recordkeeping Batch Testing (creating testing records for sterility, periodic quality indicator test, or any test) (§§ 212.20(c) and (e) and 212.50(a) and (b))	23	8	184	0.5	92
Subparts D, F, and G; §§ 212.30, 212.50, and 212.60					
Annual Recordkeeping Equipment and Facilities Records (calibration, cleaning, and maintenance records) (§§ 212.30(b), 212.50(d), and 212.60(f))	23	98	2,254	0.25	564
Subpart H; § 212.71					
Annual OOS Investigations (recording events and investigations) (§ 212.71(b))	23	1	23	1	23
Annual QA and Release of Test Results	23	8	184	0.25	46
Total			3,335		2,243

[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.

TABLE 7—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN FOR PET DRUG PRODUCERS [1]

Information collection activity; 21 CFR section	Number of sterility failure incidents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure (in hours)	Total hours [2]
Subpart H; § 212.70					
Sterility Test Failure Notices [3] (§ 212.70(e))	7	3	21	2.5	53

[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 1 notification is sent to the receiving site.

Our estimated burden for the information collection reflects an overall increase of 25,425 hours and a corresponding increase of 84,703 records. We attribute this increase to the inclusion of external control testing laboratories that perform only specialized chemical, microbiological, or sterility testing functions to support manufacturing and release of final PET drug products.

Dated: March 30, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–07392 Filed 4–6–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–4951]

Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Devices; Humanitarian Use Devices

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 information collection requirements for humanitarian use devices (HUDs).

DATES: Submit either electronic or written comments on the collection of information by June 6, 2022.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before June 6, 2022. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 6, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is 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–2017–N–4951 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Devices; Humanitarian Use Devices.'' 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: 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: 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