VI. Fee Payment Options and Procedures

A. Application Fees

The appropriate application fee established in the new fee schedule must be paid for any application subject to fees under PDUFA VII that is submitted on or after October 1, 2022. Payment must be made in U.S. currency by electronic check, check, bank draft, wire transfer, or U.S. postal money order payable to the order of the Food and Drug Administration. The preferred payment method is online using electronic check (Automated Clearing House (ACH) also known as eCheck) or credit card (Discover, VISA, MasterCard, American Express).

FDA has partnered with the U.S. Department of the Treasury to use Pay.gov, a web-based payment application, for online electronic payment. The Pay.gov feature is available on the FDA website after completing the Prescription Drug User Fee Cover Sheet and generating the user fee ID number. Secure electronic payments can be submitted using the User Fees Payment Portal at *https://userfees.fda.gov/pay* (Note: only full payments are accepted. No partial payments can be made online). Once an invoice is located, ''Pay Now'' should be selected to be redirected to Pay.gov. Electronic payment options are based on the balance due. Payment by credit card is available for balances that are less than $25,000. If the balance exceeds this amount, only the ACH option is available. Payments must be made using U.S. bank accounts as well as U.S. credit cards.

If a check, bank draft, or postal money order is submitted, make it payable to the order of the Food and Drug Administration and include the user fee ID number to ensure that the payment is applied to the correct fee(s). Payments can be mailed to: Food and Drug Administration, P.O. Box 979107, St. Louis, MO 63197–9000. If a check, bank draft, or money order is to be sent by a courier that requests a street address, the courier should deliver your payment to: U.S. Bank, Attention: Government Lockbox 979107, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This U.S. Bank address is for courier delivery only. If you have any questions concerning courier delivery, contact the U.S. Bank at 314–418–4013. This telephone number is only for questions about courier delivery). Please make sure that the FDA post office box number (P.O. Box 979107) is written on the check, bank draft, or postal money order.

For payments made by wire transfer, include the unique user fee ID number to ensure that the payment is applied to the correct fee(s). Without the unique user fee ID number, the payment may not be applied, which could result in FDA not filing an application and other penalties.

Note: The originating financial institution may charge a wire transfer fee, especially for international wire transfers. Applicable wire transfer fees must be included with payment to ensure fees are paid in full. Questions about wire transfer fees should be addressed to the financial institution. The account information for wire transfers is as follows: U.S. Department of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Acct. No.: 75060099, Routing No.: 021030004, SWIFT: FRNYUS33. If needed, FDA's tax identification number is 53–0196965.

B. Prescription Drug Program Fees

FDA will issue invoices and payment instructions for FY 2023 program fees under the new fee schedule in October 2022. Under section 736(a)(2)(A)(i) of the FD&C Act, prescription drug program fees are generally due on October 3, 2022. However, given the late date of the PDUFA reauthorization, invoices should be paid within 30 days of invoice.

FDA will issue invoices in December 2023 for products that qualify for FY 2023 program fee assessments after the October 2022 billing.

C. Fee Waivers and Refunds

To qualify for consideration for a waiver or reduction under section 736(d) of the FD&C Act, an exemption under section 736(k) of the FD&C Act, or the return of an application or program fee paid under section 736 of the FD&C Act, including if the fee is claimed to have been paid in error, a person must submit to FDA a written request justifying such waiver, reduction, exemption or return not later than 180 days after such fee is due (section 736(i) of the FD&C Act). A request submitted under this paragraph must include any legal authorities under which the request is made.

Dated: October 4, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–21968 Filed 10–5–22; 11:15 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0242]

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 November 7, 2022.

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—Revision

FDA current good manufacturing practice (CGMP) regulations in part 212 (21 CFR part 212) are intended to ensure that positron emission tomography (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 U.S. 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 one 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) (21 CFR 212.40(a) and (b)) contain requirements on SOPs regarding receiving, testing, and accepting components. We estimate that four corporate firms will expend approximately 8 hours each to create one procedure for acceptance of raw materials and components (a total of four 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) (21 CFR 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 four corporate firms will expend approximately 8 hours each to establish one procedure (a total of four procedures), which results in a total recordkeeping burden of approximately 32 hours.

Section 212.90(a) (21 CFR 212.90(a)) requires the establishment and maintenance of written procedures for the distribution of PET drug products. We estimate that four corporate firms will each expend approximately 8 hours to establish and maintain one written procedure regarding the distribution of PET drugs (a total of four records), which results in a total recordkeeping burden of approximately 32 hours.

Sections 212.20(e) and 212.100(a), (b), and (c) (21 CFR 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) (21 CFR 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 four corporate QA sites will expend approximately 2 hours to document and investigate one 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 a 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 (one 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 tests 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 seven PET drug producers will submit two reports to FDA and send one notification (a total of three 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.

In the **Federal Register** of April 7, 2022 (87 FR 20420), FDA published a 60-day notice requesting public comment on the proposed collection of information. Five comments were received and are summarized here.

The comments did not question the necessity of this proposed collection with two of the comments specifically stating that they support the collection of information as it is necessary for the performance of FDA's functions. However, the comments questioned the FDA's burden collection estimates.

FDA believes that this proposed collection is necessary in keeping with the Agency's mission of ensuring the safety and efficacy of human drugs. Regarding the estimates included, FDA has taken a generalized approach for these estimates, assuming that corporate firms will take on certain burdens for all facilities under their purview, rather than calculating all burdens per facility, and understanding that due to variation among facilities the number of batches and products being produced will vary. We have also only included estimates for tasks that are included within part 212 and note that three comments referenced tasks, such as annual product review, that are outside the scope. We also note that there are no new information collections or revisions to these existing information collections since 2019. We will continue to update the burden estimate as circumstances warrant.

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 recordkeeping	Total hours [2]
Subparts C and F; §§ 212.20 and 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 through 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 and 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 and 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 recordkeeping	Total hours [2]
Subparts C and F; §§ 212.20 and 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 through 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 and 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 (30 minutes)	662
Subparts C and H; §§ 212.20 and 212.71					
OOS Investigations (SOP) §§ 212.20(c) and 212.71(a) and (b)	63	1	63	8	504
Subpart J; § 212.90					
Distribution Records (SOP) § 212.90(a)	63	1	63	8	504
Subparts C and K; §§ 212.20 and 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 recordkeeping	Total hours [2]
Subparts C and F; §§ 212.20 and 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 (30 minutes)	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, 212.50, and 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 (15 minutes)	10,920
Subparts C and E; §§ 212.20 and 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 through 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

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

Information collection activity; 21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours [2]
Subpart H; § 212.71					
OOS Investigations (record events and investigations) § 212.71(b)	91	2	182	2	364
Subparts H and K; §§ 212.70 and 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 (15 minutes)	5,460
Subpart J; § 212.90					
Distribution Records § 212.90(b)	91	240	21,840	0.25 (15 minutes)	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 recordkeeping	Total hours [2]
Subparts C and F; §§ 212.20 and 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 (30 minutes)	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, 212.50, and 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 (30 minutes)	11,760
Subparts C and E; §§ 212.20 and 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 (30 minutes)	294
Subparts G and H; §§ 212.60 through 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 (30 minutes)	2,352
Subpart H; § 212.71					
OOS Investigations (record events and investigations) (§ 212.71(b))	49	2	98	2	196
Subparts H and K; §§ 212.70 and 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 (15 minutes)	1,176
Subpart J; § 212.90					
Distribution Records § 212.90(b)	49	96	4,704	0.25 (15 minutes)	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 recordkeeping	Total hours [2]
Subparts C and F; §§ 212.20 and 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 (30 minutes)	168
Subparts D, F, and G; §§ 212.30, 212.50, and 212.60					
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 (30 minutes)	910
Subparts C and E; §§ 212.20 and 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 (30 minutes)	168
Subparts G and H; §§ 212.60 through 212.70					
Laboratory Testing Records (record QC test results) §§ 212.60(g), 212.61(b), and 212.70(d)(2) and (3)	14	24	336	0.5 (30 minutes)	168
Subpart H; §§ 212.70 and 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 (15 minutes)	84
Subpart J; § 212.90					
Distribution Records § 212.90(b)	14	24	336	0.25 (15 minutes)	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 section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	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 (30 minutes)	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 (30 minutes)	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 (15 minutes)	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 (30 minutes)	46

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

Information collection activity; 21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours [2]
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	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 one notification is sent to the receiving site.

Our estimated burden for the information collection reflects an overall increase of 25,463 hours and a corresponding increase of 84,709 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: September 30, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–21842 Filed 10–6–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–2375]

Authorization of Emergency Use of an In Vitro Diagnostic Device for Detection of Monkeypox Virus; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of an Emergency Use Authorization (EUA) (the Authorization) under the Federal Food, Drug, and Cosmetic Act (FD&C Act) in response to an outbreak of monkeypox. FDA has issued an Authorization for an in vitro diagnostic device as requested by Quest Diagnostics Nichols Institute (Quest Diagnostics). The Authorization contains, among other things, conditions on the emergency use of the authorized product. The Authorization follows the August 9, 2022, determination by the Secretary of Health and Human Services (HHS) that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of United States (U.S.) citizens living abroad, and that involves monkeypox virus. On the basis of such determination, the Secretary of HHS declared, on September 7, 2022, that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of infection with the monkeypox virus, including in vitro diagnostics that detect and/or diagnose infection with non-variola *Orthopoxvirus,* pursuant to the FD&C Act, subject to terms of any authorization issued under that section. The Authorization, which includes an explanation of the reasons for issuance, is reprinted in this document.

DATES: The Authorization is effective as of September 7, 2022.

ADDRESSES: Submit written requests for a single copy of the EUA to the Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4338, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the Authorization may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the Authorization.

FOR FURTHER INFORMATION CONTACT: Jennifer Ross, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4332, Silver Spring, MD 20993–0002, 301–796–8510 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb–3) allows FDA to strengthen public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. With this EUA authority, FDA can help ensure that medical countermeasures may be used in emergencies to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by biological, chemical, nuclear, or radiological agents when there are no adequate, approved, and available alternatives (among other criteria).

Section 564(b)(1) of the FD&C Act provides that, before an EUA may be issued, the Secretary of HHS must declare that circumstances exist justifying the authorization based on one of the following grounds: (1) a determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a biological, chemical, radiological, or nuclear agent or agents; (2) a determination by the Secretary of Defense that there is a military