development of type 2 diabetes. This proposed project's primary purposes are to (1) increase knowledge of recruitment strategies, specifically introductory sessions, used by CDC-recognized organizations to increase enrollment in the National DPP LCP (Phase 1), and (2) evaluate introductory sessions, specifically a CDC-developed behaviorally-informed introductory session known as the Be Your Best (BYB) Discovery Session, on enrollment compared with other types of introductory sessions that organizations currently use (Phase 2).

CDC is requesting OMB approval to collect information needed for this evaluation. For Phase 1 of this project, the Introductory Session Landscape Assessment, CDC is seeking approval to disseminate a brief Landscape Assessment (survey) to all National DPP CDC-recognized organizations (approximately 1,700) and their affiliate class locations (up to 540). The survey will initially be disseminated electronically (web-based survey), and then a hard copy will be mailed to non-respondents. The overall evaluation objectives of the Introductory Session Landscape Assessment are to increase knowledge of recruitment strategies (specifically introductory sessions) used by CDC-recognized organizations to increase enrollment in LCPs; understand how CDC-recognized organizations are using introductory sessions (including session content and delivery); and inform the subsequent Phase 2 Introductory Session Evaluation that will evaluate the BYB Discovery Session compared with other types of introductory sessions.

For the Phase 2 Introductory Session Evaluation, CDC is seeking approval to disseminate the following data collection tools: (1) Pre-Session Survey (to be completed by up to 2,640 introductory session attendees), (2) Post-Session Survey (to be completed by up to 2,640 introductory session attendees), (3) Registration and Attendance Tracking Form (to be completed by up to 132 LCP staff), and (4) Discovery Session Implementation Fidelity Checklist (to be completed by up to 66 LCP staff). The Pre-Session and Post-Session Surveys will be distributed as hard copies to introductory session attendees. The BYB Discovery Session Implementation Fidelity Checklist and the Registration and Attendance Tracking Form will be designed in Microsoft Excel and distributed to participating LCP staff using secure FTP upload for LCP personnel to complete electronically.

Information collected will be analyzed to evaluate the effectiveness of the BYB Discovery Session intervention in increasing enrollment in the National DPP LCP compared with already occurring introductory sessions (*i.e.,* standard care), with a secondary aim of better understanding how it is implemented and the context of its implementation. This data collection is important because if the BYB Discovery Session is determined to be an effective recruitment strategy compared with other existing introductory sessions, it should be promoted to maximize the National DPP's potential to reduce type 2 diabetes incidence. CDC requests approval for 1,572 Burden Hours annually. There are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
LCP Staff	Landscape Assessment	2,240	1	15/60	560
Introductory Session Attendees (Individuals).	Pre-Session Survey	2,640	1	10/60	440
Introductory Session Attendees (Individuals).	Post-Session Survey	2,640	1	10/60	440
LCP Staff	Registration Attendance and Tracking Form.	132	1	15/60	33
LCP Staff	BYB Discovery Session Implementation Fidelity Checklist.	66	1	90/60	99
Total					1,572

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2019–19017 Filed 9–3–19; 8:45 am]

BILLING CODE 4163–18–P

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: Fax written comments on the collection of information by October 4, 2019.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0667. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *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 Practice (CGMP) for Positron Emission Tomography (PET) Drugs

OMB Control Number 0910–0667—Extension

PET is a medical imaging modality involving the use of a unique type of radiopharmaceutical drug product. Our CGMP regulations at 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. The CGMP requirements for PET drugs 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 the fact that most PET drugs are produced at locations close to the patients to whom the drugs are administered.

The CGMP regulations require the establishment of written procedures as well as recordkeeping related to ongoing manufacturing of individual PET drugs, testing, and product release activities, including any third-party disclosure requirements for producing PET drugs. To estimate time spent to comply with the requirements, we relied on informal communications with PET producers, FDA staff visits to PET facilities, our familiarity with PET and general pharmaceutical manufacturing practices with application and supplement submissions, and various reports FDA received from 2016 through 2018.

I. Investigational and Research PET Drugs

Section 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), the requirement (FD&C Act) to follow CGMP is met 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 approved NDA (new drug application) and abbreviated new drug application (ANDA) PET drugs. While we do not have sufficient information to estimate burdens for all IND and RDRC PET facilities, our estimates have included those facilities that also produce NDA and ANDA PET drugs. Those facilities are included under academic and small firms.

II. Recordkeeping Burden

A. One-Time Burden for Corporate Firms

We estimate corporate firms will have to employ one-time and ongoing annual recordkeeping. There are three major PET manufacturing corporations and most of the quality, manufacturing, and testing procedures are developed at the corporate level and then issued to the individual sites located in various States across the country. There are an estimated 115 such sites under three major corporations. Thus, the burden has been calculated for 3 recordkeepers instead of 115 individual sites.

It would take approximately 8 hours for each corporate firm to create one master batch record per drug, and an average of three PET drugs have been taken into consideration. We also estimate that approximately 3 firms will create and maintain approximately 27 records associated with production and quality testing for an average of 3 drugs, with a total recordkeeping burden of approximately 216 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 standard operating procedures (SOPs) dealing with equipment operation, maintenance, and cleaning, including maintenance of physical facilities.

It would take approximately 5 hours for each corporate firm to establish and maintain procedures for equipment and facility maintenance. We estimate that the 3 corporate firms will establish and maintain 39 procedures, with a total recordkeeping burden of approximately 195 hours.

Sections 212.20(c) and 212.40(a) and (b) contain requirements on SOPs regarding receiving, testing, and accepting components. We estimate that the burden for corporate firms to create procedures for acceptance of raw materials and components would be approximately 8 hours and that there will be approximately three corporate firms performing these activities, with a total recordkeeping burden of approximately 48 hours. The burden for corporate firms to create component specification data sheets would be approximately 2 hours with approximately 3 corporate firms performing these activities, with a total recordkeeping burden of approximately 150 hours for approximately 25 component specification sheets for each firm.

Sections 212.20(c) and 212.71(a) and (b) require that PET drug firms establish procedures for investigating ''deviations'' and ''out of specifications failures'' of products during manufacturing and testing that do not conform to specifications and to conduct these investigations and record them as needed. We estimate that it will take approximately 8 hours for three corporate firms to establish one procedure, with a total recordkeeping burden of approximately 24 hours.

Sections 212.20(c) and 212.90(a) require that written procedures regarding distribution of PET drug products be established and maintained. We estimate that it will take approximately 8 hours for each corporate firm to establish written procedures regarding distribution of PET drugs with a total of approximately three records, with a total recordkeeping burden of approximately 24 hours.

Sections 212.20(c) and 212.100(a), (b), and (c) require that PET drug firms establish and maintain written procedures for handling complaints and procedures for field alert reports (FARs). We estimate that each corporate firm will create three written procedures to establish complaints and FARs process and it will take approximately 24 hours for each corporate firm. A total of 72 hours will be required to create 27 procedures by 3 corporate firms.

B. One-Time Burden for Academia, Small Firms, and Precursors

There is a total of 52 sites combined for academic and small commercial firms, including some IND and RDRC sites. There are nine starting material/precursors/sterile raw material manufacturing entities who are required to follow selected regulations from part 212, according to the PET drug definition under 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 will refer to them as high-risk component manufacturing firms in the tables and other sections of this document.

It would take approximately 8 hours for each firm to perform the same activities as corporate firms regarding creating master batch records and manufacturing and quality procedures. We estimate that there will be a total of approximately 488 records, with a total recordkeeping burden of approximately 3,904 hours.

It would take approximately 8 hours for each firm to create equipment and facility related procedures as corporate firms. We also estimate that there will be a total of approximately 793 records, with a total recordkeeping burden of approximately 6,344 hours.

We also estimate that the burden for each firm to create and maintain specification sheets would be approximately 2 hours and that there will be a total of approximately 61 firms performing these activities, with a total recordkeeping burden of approximately 3,050 hours. Furthermore, the burden for these firms to create and maintain procedures for acceptance of raw materials and components would be approximately 8 hours and that there will be a total of approximately 61 firms performing these activities, with a total recordkeeping burden of approximately 976 hours.

It would take approximately 8 hours for each firm to perform the same activities as corporate firms. We estimate that there will be a total of approximately 61 records, with a total recordkeeping burden of approximately 488 hours.

We estimate that 61 academia, small firms, and high-risk component manufacturers will create about one procedure related to deviations and out of specifications and that each firm will expend approximately 8 hours, for a total of 488 hours. Similarly, 488 hours will be spent for procedures on distribution of PET drugs. There will be 3 procedures created by each firm related to customer complaints, recalls, and FARs, with a total of 156 records from 52 sites and a total of 1,248 hours.

C. Annual Burden for Corporate Firms

In this section, we considered 115 individual corporate sites under the 3 major corporations in our estimates. These activities will be related to individual PET drugs manufactured at each of the sites located across the country. We estimate that it would take 30 minutes each to fill 144 batches (approximately 4 batches/month), for a total of 8,280 hours. In the second row of table 3, we have also estimated that on an annual basis, some new batch records or quality records may have to be created for newly introduced or existing drugs. It would take each firm approximately 24 hours for three new quality procedure/master batch records, with a total recordkeeping burden of approximately 216 hours for nine records from three corporate organizations.

We estimate that 115 individual corporate sites belonging to 3 major corporate entities will create 164 records for equipment maintenance, cleaning, calibration, and facilities maintenance records, with a total recordkeeping burden of 9,430 hours.

Sections 212.20(c) and 212.40(a) and (b) also set out requirements for raw material and component shipments received at the manufacturing facility on an ongoing basis. We estimate that the burden for each firm to create incoming raw material acceptance records for 2 shipments per month and 30 minutes per shipment will be 1,380 hours for 2,760 records from 115 sites.

Sections 212.60(g), 212.61(b), and 212.70(d)(2) and (3) set out requirements for documenting laboratory testing results from each PET drug manufactured referred to in laboratory testing, including final release testing. Each firm must keep records of different tests for each of their products. We estimate that approximately 115 corporate sites will document 144 records of cumulative quality control (QC) test results (one record with 5 to 6 tests included), with a total recordkeeping burden of approximately 8,280 hours.

We estimate that each firm will take approximately 1 hour to record out-of-specification (OOS) events and perform investigations for each incident. We also estimate an average of 2 ''Out of Specification'' investigations per firm, with a total of 230 records for ''OOS'' investigations from 115 sites, which results in a burden of 460 hours. This estimate includes any reprocessing or special release events, which are very rare.

Section 212.100(b) and (c) requires that PET drug firms document how each complaint is handled. We estimate that this will take approximately 2 hours for each site to document and investigate one complaint. We estimated 2 complaints per year per site, with a total expended hour of 460 hours for 115 individual sites. We believe the estimate is appropriate since not all sites receive complaints.

We also estimate annual recordkeeping for PET drug firms to perform quality assurance (QA) and release of manufactured PET drugs from the 115 corporate sites to be 4,140 hours, for a total of 144 released batches estimating 15 minutes per batch.

Section 212.90(b) requires that corporate firms maintain distribution records. We estimate that it will take each firm approximately 15 minutes to create a distribution record for each batch of PET drug products, with a total burden of approximately 4,140 hours for 144 released batches from 115 sites.

D. Annual Burden for Academia and Small Firms

It is estimated that each firm will expend the same amount of time to perform the same activities as corporate firms. Approximately 52 academia and small firms will fill 1,248 batch and production records, totaling 624 hours. For any new master batch record or quality procedures we have estimated 156 total records (3 per site), with a total of 1,248 hours.

For calibration and cleaning records like filling information in log books for each piece of equipment and documenting calibration records in each PET production firm, we estimate approximately 30 minutes on average for each piece of equipment for all firms. The calibration efforts are once per year per equipment, with estimated 10 pieces of equipment per site. We estimate that 52 academic and small firms will record a total of 884 hours for 34 records per site and a total of 1,768 records.

For §§ 212.20(c) and 212.40(a) and (b), approximately 1,768 raw material and component acceptance records will be filled on an ongoing annual basis. We estimate that the burden for each firm to create incoming raw material acceptance records for 12 shipments per year and 30 minutes per shipment will be 312 hours for 624 records from 52 sites.

We also estimate that approximately 52 academia and small firms will document 1,248 laboratory QC tests for 24 batches of drugs, with a total recordkeeping burden of approximately 624 hours.

We estimate that each firm will take approximately 1 hour each to record OOS and customer complaint events and perform investigations. We also estimate that an average of two ''Out of Specification'' and customer complaints and investigations per firm, with a total of 208 hours for each category. This estimate has included any reprocessing or special batch release events, which have been rarely observed.

We also estimate annual recordkeeping for PET drug firms to perform QA and release of manufactured PET drugs from 52 sites to be 312 hours, for a total of 24 batches per site released if estimating 15 minutes per batch.

Section 212.90(b) requires that corporate firms maintain distribution records. We estimate that it will take approximately 15 minutes to create a distribution record for each batch of PET drug products, with a total burden of approximately 312 hours for 24 batches per site.

E. Annual Burden for High-Risk Component Manufacturers

According to section 121(a) of FDAMA, the PET drug definition includes any non-radioactive or radioactive reagents, kits, nuclidic generators, target materials, synthesizers, and so forth. FDA performs risk assessments of each manufacturer and inspects such manufacturers. Sterile manufacturers and complex labels fall under this category, including sterile raw material or reagent manufactures. We have estimated nine such facilities based on inspections so far and have included them in this section. These manufacturers must comply with selected sections of part 212 since they are not final PET drug manufacturers. We will refer to them as high-risk component manufacturers in general in this document.

We estimate that it would take 9 high-risk component manufacturers about 30 minutes to fill each manufacturing batch records (12 per year) and that there will be a total of approximately 108 records, with a total recordkeeping burden of approximately 54 hours.

We also estimate that it will take nine component manufacturers 30 minutes to fill and create equipment and facilities related records, with a total recordkeeping burden of 72 hours.

We estimate that 9 high-risk component manufacturers will document 54 components, containers, and closures for incoming acceptance tests, with a total recordkeeping burden of approximately 27 hours.

We estimate that 9 high-risk component manufacturers will document 12 QC records related to 12 batches, with a total recordkeeping burden of approximately 54 hours.

We also estimate annual recordkeeping for PET drug firms to perform QA and release manufactured PET drugs from 9 sites to be 27 hours, for a total of 108 batches released, estimating 15 minutes per batch.

We further estimate that it would take each precursor 15 minutes to create and maintain distribution records and that there will be approximately 108 records, with a total recordkeeping burden of approximately 27 hours.

III. Process Verification

Section 212.50(f)(2) requires that any process verification activities and results be recorded. Process verification is usually performed as a one-time activity before a product is approved or if any major manufacturing process or equipment changes are made. This effort to conduct process verification has been estimated under annual new creation of master batch records and manufacturing and quality procedures in section II of this document.

IV. Conditional Final Releases

Section 212.70(f) requires PET drug producers to document any conditional final releases of a product. We believe that conditional final releases will be uncommon, and we have them estimated under annual ''OOS'' investigations and final QA release efforts for each manufactured batch.

V. Reprocessing Procedures

Sections 212.20(c) and 212.71(d) require PET drug producers to establish and document procedures for reprocessing PET drugs. We rarely see any reprocessing option being submitted for application of such drugs and, if reprocessing occurs, we have estimated such rare events under annual QA release efforts.

VI. Third-Party Disclosure Burden

Section 212.70(e) requires that PET drug producers notify all receiving facilities if a batch fails sterility tests. FDA receives FARs reports based on confirmed sterility failures of released PET drugs. Based on our experience of such reporting, we estimated a total of 12 failures from all 167 sites (corporate, small firms, and academia). Therefore, we have estimated that 12 PET drug producers will file 2 reports to FDA and send a notification to the affected clinical/receiving site per year. PET drug producers would transmit the notice by email or Fax and submit the FARs notice to FDA electronically, with 2.5 hours per incident in total.

In the **Federal Register** of November 30, 2018 (83 FR 61653), FDA published a 60-day notice requesting public comment on the proposed collection of information. Three comments were received and are summarized here.

One comment questioned the necessity of this proposed collection. One comment suggested that FDA allow both paper recordkeeping and simplified electronic report submission. Two comments questioned some of FDA's burden collection estimates. Two comments questioned whether Annual Product Review (APR) is being required by the regulations. Two comments pertained to an inadvertent oversight in section VI. Third-Party Disclosure.

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 some of the comments referenced tasks, such as APR, that are outside that scope. Electronic recordkeeping is also outside the scope of this regulation. Regarding the typographical error in section VI. Third Party Disclosure, on page 9350, we estimate that it will take PET drug producers 2 hours to submit to FDA notices of sterility test failures. We intended to estimate 2.5 hours as accurately shown in Table 6, page 9352. In section VI of this document, we have included this change. We appreciate these comments and will continue to consider the burden estimate. If commenters believe certain estimates are insufficient, we request comments on specific estimates for these requirements and why alternative estimates would be more accurate.

The estimated burden of the information collection, therefore, is as follows:

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

Activity/type of respondent/21 CFR section	Number of recordkeepers	Number of records per recordkeeper	One-time records	Average burden per recordkeeper	Total hours [2]
Batch Production and Control Records (§§ 212.20(c) and (e) and 212.50(a) and (b))	3	9	27	8	216

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

Activity/type of respondent/21 CFR section	Number of recordkeepers	Number of records per recordkeeper	One-time records	Average burden per recordkeeper	Total hours [2]
Equipment and Facilities Records (SOP) (§§ 212.20(c), 212.30(b) 212.50(d), and 212.60(f))	3	13	39	5	195
Records of Components, Containers, and Closures (SOP) (§§ 212.20(c) and 212.40(a) and (b))	3	2	6	8	48
Records of Components, Containers, and Closures (specifications data sheets) (§§ 212.20(c) and 212.40(a) and (b))	3	25	75	2	150
Out-of-Specification Investigations (SOP) (§§ 212.20(c) and 212.71(a))	3	1	3	8	24
Distribution Records (SOP) (§§ 212.20(c) and 212.90(a))	3	1	3	8	24
Complaints, Recalls (§§ 212.20(c) and 212.100(a))	3	3	9	8	72
Total					729

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Number rounded to the nearest whole number.

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

Activity/type of respondent/21 CFR section	Number of recordkeepers	Number of records per recordkeeper	One-time records	Average burden per recordkeeper	Total hours [2]
Batch Production and Control Records (§§ 212.20(c) and (e) and 212.50(a) and (b))	61	8	488	8	3,904
Equipment and Facilities Records (SOP) (§§ 212.20(c), 212.30(b) 212.50(d), and 212.60(f))	61	13	793	8	6,344
Records of Components, Containers, and Closures (specification only) (§§ 212.20(c) and 212.40(a) and (b))	61	25	1,525	2	3,050
Records of Components, Containers, and Closures (SOP) (§§ 212.20(c) and 212.40(a) and (b))	61	2	122	8	976
Out-of-Specification Investigations (SOP) (§§ 212.20(c) and 212.71(a))	61	1	61	8	488
Distribution Records (SOP) (§§ 212.20(c) and 212.90(a))	61	1	61	8	488
Complaints, Recalls (§§ 212.20(c) and 212.100(a))	52	3	156	8	1,248
Total					16,498

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Number rounded to the nearest whole number.

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

Activity/21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeper	Total hours [2]
Batch Production (Creating Manufacturing Records (creating batch-related records per year) (§§ 212.20(c) and (e) and 212.50(a) and (b))	115	144	16,560	*0.50	8,280
Creating Any New Batch Records/Quality Records for New or Existing Drugs (§§ 212.20(c) and (e) and 212.50(a) and (b))	3	9	27	8	216
Equipment and Facilities Records (calibration and cleaning records systems) (§§ 212.30(b), 212.50(d), and 212.60(f))	115	164	18,860	*0.50	9,430
Records of Components, Containers, and Closures (§§ 212.20(c) and 212.40(a) and (b))	115	24	2,760	*0.50	1,380
Laboratory Testing Records (record laboratory test results) (§§ 212.60(g), 212.61(b), and 212.70(d)(2) and (3))	115	144	16,560	*0.50	8,280
Out-of-Specification Investigations (record events and investigations) (§ 212.71(b))	115	2	230	2	460
Complaints (§§ 212.100(b) and (c))	115	2	230	2	460
QA and Release of Batches	115	144	16,560	+0.25	4,140
Distribution Records (§ 212.90(b))	115	144	16,560	+0.25	4,140
Total					36,786

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Number rounded to the nearest whole number.

* (30 minutes).
+ (15 minutes).

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

Activity/21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeper	Total hours [2]
Batch Production (creating manufacturing records) (filling batch related records per year) (§§ 212.20(c) and (e) and 212.50(a) and (b))	52	24	1,248	* 0.50	624
Creating Any New Batch Records/Procedures for New Drugs (§§ 212.20(c) and (e) and 212.50(a) and (b))	52	3	156	8	1,248
Equipment and Facilities Records (calibration and cleaning records) (§§ 212.30(b), 212.50(d), and 212.60(f))	52	34	1,768	* 0.50	884
Records of Components, Containers, and Closures (incoming acceptance tests) (§§ 212.20(c) and 212.40(a) and (b))	52	12	624	* 0.50	312
Laboratory Testing Records (QC test results) (§§ 212.60(g), 212.61(b) and 212.70(d)(2) and (3))	52	24	1,248	* 0.50	624
Out-of-Specification Investigations (record events and investigations) (§ 212.71(b))	52	2	104	2	208
Complaints (Record events and investigations) (§§ 212.100(b) and (c))	52	2	104	2	208
QA and Release of Batches	52	24	1,248	+ 0.25	312
Distribution Records (§ 212.90(b))	52	24	1,248	+ 0.25	312
Total					4,732

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Number rounded to the nearest whole number.
* (30 minutes).
+ (15 minutes).

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

Activity/21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeper	Total hours [2]
Batch Production (creating manufacturing records and batch related records per year) (§§ 212.20(c) and (e) and 212.50(a) and (b))	9	12	108	* 0.50	54
Equipment and Facilities Records (calibration and cleaning records systems) (§§ 212.30(b), 212.50(d), and 212.60(f))	9	16	144	* 0.50	72
Records of Components, Containers, and Closures (incoming acceptance test) (§§ 212.20(c) and 212.40(a) and (b))	9	6	54	* 0.50	27
Laboratory Testing Records (record QC test results) (§§ 212.60(g), 212.61(b) and 212.70(d)(2) and (3))	9	12	108	* 0.50	54
Out-of-Specification Investigations (Record events and investigations) (§ 212.71(b))	9	1	9	1	9
QA and Release of Batches	9	12	108	+ 0.25	27
Distribution Records (§ 212.90(b))	9	12	108	+ 0.25	27
Total					270

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Number rounded to the nearest whole number.
* (30 minutes).
+ (15 minutes).

TABLE 6—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Activity/21 CFR section	Number of sterility failure incidents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Sterility Test Failure Notices (§ 212.70(e))	12	[2] 3	36	2.5	90

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] There are two reports sent to FDA per incident and notification to receiving site.

These burden estimates reflect adjustments since last OMB approval. Previously we had based the estimated number of respondents on the number of individual production sites, however we believe using the number of registered organizations better reflects the burden attributable to information collection. This results in an overall decrease to the collection.

Dated: August 26, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–19030 Filed 9–3–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Docket No. FDA–2019–N–1517]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Abbreviated New Animal Drug Applications

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: Fax written comments on the collection of information by October 4, 2019.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0669. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *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.

Abbreviated New Animal Drug Applications—Section 512(b)(2) and (n)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(b)(2) and (n)(1))

OMB Control Number 0910–0669—Extension

Under section 512(b)(2) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), any person may file an abbreviated new animal drug application (ANADA) seeking approval of a generic copy of an approved new animal drug. The information required to be submitted as part of an ANADA is described in section 512(n)(1) of the FD&C Act. Among other things, an ANADA is required to contain information to show that the proposed generic drug is bioequivalent to, and has the same labeling as, the approved new animal drug. We allow applicants to submit a complete ANADA or to submit information in support of an ANADA for phased review. Applicants may submit Form FDA 356v with a complete ANADA or a phased-review submission to ensure efficient and accurate processing of information. We use the information submitted, among other things, to assess bioequivalence to the originally approved drug and thus, the safety and effectiveness of the generic new animal drug.

We believe the demonstration of bioequivalence required by the statute does not need to be established on the basis of in vivo studies (blood level bioequivalence or clinical endpoint bioequivalence) for soluble powder oral dosage form products and certain Type A medicated articles. We are adding to this information collection applicant requests to waive the requirement to establish bioequivalence through in vivo studies (biowaiver requests) for soluble powder oral dosage form products or certain Type A medicated articles based upon either of two methods. We will consider granting a biowaiver request if it can be shown that the generic soluble powder oral dosage form product or Type A medicated article contains the same active and inactive ingredient(s) and is produced using the same manufacturing processes as the approved comparator product or article. Alternatively, we will consider granting a biowaiver request without direct comparison to the pioneer product's formulation and manufacturing process if it can be shown that the active pharmaceutical ingredient(s) (API) is the same as the pioneer product, is soluble, and that there are no ingredients in the formulation likely to cause adverse pharmacologic effects. We use the information submitted by applicants in the biowaiver request as the basis for our decision whether to grant the request.

Additionally, we have found that various uses of veterinary master files have increased the efficiency of the drug development and drug review processes for both us and the animal pharmaceutical industry. A veterinary master file is a repository for submission to FDA's Center for Veterinary Medicine of confidential detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of one or more veterinary drugs. Veterinary master files are used by the animal pharmaceutical industry in support of information being submitted for new animal drug applications (NADAs), ANADAs, investigational new animal drug (INAD) files, and generic investigational new animal drug (JINAD) files. In previous information collection requests, we included the time necessary to compile and submit such information to veterinary master files within the burden estimates provided for applications and amended applications (for NADAs and INAD files) and abbreviated applications and amended abbreviated applications (for ANADAs and JINAD files), respectively. We recently combined the time necessary to compile and submit such information to veterinary master files within the burden estimates provided in the collection of information supporting new animal drug applications (OMB control number 0910–0032).

The reporting associated with ANADAs and related submissions is necessary to ensure that new animal drugs are in compliance with section 512(b)(2) of the FD&C Act. As noted, we use the information submitted, among other things, to assess bioequivalence to the originally approved drug and thus, the safety and effectiveness of the generic new animal drug.

Description of Respondents: The respondents for this collection of information are veterinary pharmaceutical manufacturers.

In the **Federal Register** of April 18, 2019 (84 FR 16270), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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