producing an essential medical device. In this initial call, the intent and goals of the data collection effort will be described, and the specific data request made. Data will be collected, using least burdensome methods, in a structured manner to answer specific questions. After the initial outreach, we will request updates to the information on a quarterly basis to keep the data current and accurate. Additional followup correspondence may occasionally be needed to verify/validate data, confirm receipt of followup correspondence(s), and/or request additional details to further inform FDA's public health response.

In the **Federal Register** of December 28, 2018 (83 FR 67298), 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:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN[1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Shortages Data Collection	260	4	1,040	0.5 (30 minutes)	520

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

FDA based the burden estimates in table 1 on past experience with direct contact with the medical device manufacturers and anticipated changes in the medical device manufacturing patterns for the specific devices being monitored. FDA estimates that approximately 260 manufacturers would be contacted by telephone and/or electronic mail 4 times per year either to obtain primary data or to verify/validate data. Because the requested data represent data elements that are monitored or tracked by manufacturers as part of routine inventory management activities, it is anticipated that for most manufacturers, the estimated time required of manufacturers to complete the data request will not exceed 30 minutes per request cycle.

This information collection is a reinstatement without change. There is an increase (an adjustment) of 332 hours in the total estimated burden compared with that identified in the information collection request previously approved by OMB. This increase reflects changes in market demands, in which manufacturers are increasingly adopting just-in-time production methods.

Dated: November 18, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–25368 Filed 11–21–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3728]

Agency Information Collection Activities; Proposed Collection; Comment Request; Collection of Information for Participation in the Food and Drug Administration Non-Employee Fellowship and Traineeship Programs

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 for Participation in FDA Non-Employee Fellowship and Traineeship Programs.''

DATES: Submit either electronic or written comments on the collection of information by January 21, 2020.

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 January 21, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 21, 2020. 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–2018–N–3728 for ''Collection of Information for Participation in FDA Non-Employee Fellowship and Traineeship Programs.'' 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.

• 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.gpo.gov/fdsys/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.

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 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.

Collection of Information for Participation in FDA Non-Employee Fellowship and Traineeship Programs

OMB Control Number 0910–NEW

In compliance with 44 U.S.C. 3507, FDA will submit to OMB a request to review and approve a new collection of information: Collection of Information for Participation in FDA Non-Employee Fellowship and Traineeship Programs. Section 746(b) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 379*l*(b)) allows FDA to conduct and support intramural training programs through fellowship and traineeship programs. These mandatory collection forms provide FDA with information from the non-employee to: (1) Begin the program, (2) administer the program, (3) coordinate training, and (4) end the program.

(1) To begin the program, the non-employee must submit the following information: (A) New Non-Employee Data Form; (B) Proof of Health Insurance; (C) Emergency Contact Information; (D) Unified Financial Management System (UFMS) Supplier and Site Information for Stipend Payments, Financial Information; and (E) CONCUR GOV New Traveler Profile Form.

(A) New non-employee data form to begin on-boarding process—The New Non-Employee Data form collects information that includes: (1) Name; (2) Gender; (3) Birthplace; (4) Date of Birth; (5) Email; (6) Home Address; (7) FDA Center/Organization/Supervisor; (8) Citizenship; (9) Social Security number (SSN); (10) Start Date; (11) End Date; (12) Contract Information; (13) Location; and (14) Question regarding current or previous Federal work experience.

(B) Proof of health insurance—Participants in FDA fellowship and traineeship programs will be asked for certain information to demonstrate proof of health insurance: (1) Name of Health Insurance Plan Provider; (2) Name/Contact Information of Primary Member; (3) Member Identification Number/Group Number; (4) Begin Date/Policy Expiration Date; and (5) Signature. The purpose of the health insurance information is for FDA to substantiate that participants of the program are covered by health insurance.

(C) Emergency contact information—Participants in FDA fellowship and traineeship programs will be asked for certain information about emergency contact demographics: (1) Name of Fellow/Trainee; (2) Center; (3) Name of Emergency Contact; (4) Telephone Number of Emergency Contact; and (5) Relationship to Contact. The purpose of emergency contact information of Fellows/Trainees is to ensure there is a primary contact should emergencies arise.

(D) UFMS supplier and site information for stipend payments, financial information—Participants in FDA fellowship and traineeship programs will be asked for their financial institution routing number and account information for direct deposit of stipend payments: (1) Name; (2) Taxpayer ID or SSN; (3) Classification/Vendor type; (4) Payment Options (Electronic Payment Only); (5) Mailing Address; (6) Bank/Financial Institution Information (Name, Routing Number, Account Number, Account type); and (7) Signature. The purpose of the financial information is for FDA to process a direct deposit transaction for a monthly stipend payment.

(E) CONCUR GOV new traveler profile form—Participants in FDA's Non-Employee Scientist programs may be asked to travel and will need to complete an online profile for the Concur Government Edition (CGE) System, which requires the following information: (1) Personal Information (Name, Agency, Office/Operating Division, Residence City, Residence State, Signatures); (2) Agency Information (ID #, Title, CAN); (3) Business Contact Information; (4) Email Addresses; Emergency Contact; (5) Travel Preferences (Preferred Airline, Hotel, Airline Seats, Frequent Flyer Number); (6) Credit Card Number; (7) Banking Account for Reimbursement; and (8) Approving Signatures. The CGE Profile provides assistance to travel preparers who are booking travel for FDA program participants.

(2) To administer the program, non-employee scientists must submit information for: (A) Absence Recording Form, (B) Personal Custody Property Record, (C) FDA Health Summary, and (D) Discovery and Invention.

(A) Absence recording form—Participants in FDA fellowship and traineeship programs will be asked for certain information about tracking attendance and absences: (1) Name of Fellow/Trainee; (2) Office/Division of Placement; (3) Mentor/Sponsor Name; (4) Type of Absence; (5) Dates of Absence; (6) Reason for Absence; and (7) Mentor/Sponsor Approval. The purpose of tracking attendance and absences for Fellows/Trainees is to determine the monthly stipend payment and potential modifications to purchase orders for extended absences.

(B) Personal custody property record—Participants in FDA fellowship and traineeship programs will be required to sign the property request, acknowledging personal responsibility for government property. The plan collects the following information: (1) Fellow Name; (2) Operative Division/Division; (3) Location; (4) Telephone; (5) Description of Items; (6) Items to be Returned; (7) Return Date; (8) Fellow Signature; (9) Custodial Officer Signature; and (10) Issuing Office. The purpose of this record is to acknowledge that an individual has received government property and accepts personal responsibility for items issued to perform their roles.

(C) FDA health summary—Participants in FDA fellowship and traineeship programs will be asked for information about health for laboratory activities. The FDA Occupational Health Services Health Summary form collects information that includes: (1) Name; (2) Program; (3) Email; (4) Work Phone; (5) FDA Mentor; (6) Center/Office Division; (7) Location; (8) Date; (9) Primary Care Physician and Contact Information; (10) Immunizations; (11) Social History; (12) Relationship History; (13) Allergies; and (14) Medical History.

(D) Discovery and invention—Participants in FDA fellowship and traineeship programs will be asked for information about discoveries and inventions at FDA. The Discovery and Invention Report collects information that includes: (1) Title of Discovery; (2) Description of Discovery; (3) Identification of collaborators, Cooperative Research and Development Agreement (CRADA), and human materials or subjects; (4) Publications; (5) Technology Stage; (6) Commercial Potential; and (7) Competition, Potential Users, and Manufacturers.

(3) For the coordination of training, non-employee scientists must complete information for the: (A) Training Development Plan; (B) Final Project Report; (C) Training Request; (D) Travel Request; (E) Learning Management System (LMS) Request; (F) Standard Operating Procedures (SOP) Verification; and (G) Program Evaluation.

(A) Training development plan—Participants in FDA fellowship and traineeship programs will be required to develop the individual plan in partnership with their Mentor. The plan collects the following information: (1) Fellow Name; (2) Mentor(s)/Preceptor(s) Name; (3) Sign-On Date; (4) Year 1 Goals, Courses/Training, Regulatory Activities, and Completion Date; (5) Year 2 Goals, Courses/Trainings, Regulatory Activities, and Completion Date; (6) Fellow Signature; and (7) Mentor(s)/Preceptor(s) Signature. The purpose of this individual development/training plan is to have a record of mandatory training and specific goals and tasks for the contributions and/or completion of a project.

(B) Final project report—Participants in FDA fellowship and traineeship programs will be required to complete the final report in partnership with their Mentor. The plan collects the following information: (1) Fellow Name; (2) Mentor/Preceptor Name; (3) Goals; (4) Objectives; (5) Alignment with Center or FDA Goals; (6) Project Summary/Abstract; (7) Accomplishments; and (8) Impact on Public Health. The purpose of this report is to acknowledge the contributions to the overall project and identify performance successes or challenges. The collection of information is mandatory to participate in FDA's fellowship and traineeship programs.

(C) Training request—Participants in FDA fellowship and traineeship programs will be asked to identify the following for external training requests: (1) Name of Fellow/Trainee; (2) Operating Office/Staff Division; (3) Title and Topic of Training; (4) Name of Hosting Agency/Organization; (5) Purpose/Justification for External Training; (6) Dates; (7) Location; and (8) Approving Signatures. The purpose of the External Training Request is to provide justification substantiating the benefits to the Operating Office/Staff Division and/or benefits to the Fellows/Trainee professional development and training. The collection of information is mandatory to participate in FDA's fellowship and traineeship programs.

(D) Travel request—Participants in FDA fellowship and traineeship programs will be asked for certain information about travel requests and authorizations/approvals: (1) Office/Division; (2) Research Project Title; (3) Mentor/Sponsor Name; (4) Mentor/Sponsor Email and Telephone; (5) Fellow's Name; (6) Appointment Period; (7) Funding Source and Fiscal Year; (8) Brief Description of Travel; (9) Anticipated Travel Dates; and (10) Travel Justification and Relation to Project. The purpose of authorization for travel of Fellows/Trainees is to determine if the travel has been approved by the Sponsor/Mentor and if the travel is a mission-related activity to the Fellow/Trainee training plan or appointment/assignment. The collection of information is mandatory to participate in FDA's fellowship and traineeship programs.

(E) Learning Management System (LMS) access—Participants in FDA fellowship and traineeship programs will be asked for information to obtain access to the LMS: (1) Name, (2) Location, (3) Organizational Unit, and (4) Email Address. The purpose of LMS Access Request is to obtain information of Non-Employee Scientists to ensure they have access to receive training and educational opportunities offered in the Health and Human Services LMS System.

(F) SOP verification—Participants in FDA fellowship and traineeship programs will be asked for certain information to verify that they have read and received instructional training on the SOPs for said program. The form collects the following: (1) Name; (2) Signature; (3) Date; and (4) Center.

(G) Program Evaluation—Participants in FDA fellowship and traineeship programs will be asked to complete an evaluation providing program data that will be synthesized into program reports on the overall effectiveness of the

program. The evaluation collects the following information: (1) Demographic Data; (2) Expectations of Fellowship or Training Program; (3) Administration Processes and Support to Fellow or Trainee; (4) FDA Retention and Plans of Fellow or Trainee; (5) Training and Education Completed; and (6) Professional/Research Goals. The purpose of this evaluation is to assess the effectiveness of the program and feedback from participants to improve the quality of the experience.

(4) To end the program, a non-employee must submit the Exit Check List—Participants in FDA fellowship and traineeship programs may be asked to complete the exit check list to manage the exit process and return of FDA property. The Exit Checklist guides the exit process for the following operations components: (1) Access Key/Pass; (2) Accountable Property; (3) System Applications inactive; (4) Library Materials; (5) Government Issued Documents (*i.e.,* passports); (6) Personal Identity Verification Card/Badge; (7) Borrowed Records; (8) Employee Records; and (9) Information Technology Accounts.

All exit information will be entered to terminate access to any FDA information.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
New Non-Employee Data Form	1,220	1	1	0.25 (15 minutes)	305
Proof of Health Insurance	600	1	1	0.25 (15 minutes)	150
Emergency Contact Information	1,220	1	1	0.25 (15 minutes)	305
UFMS Supplier and Site Information for Stipend Payments, Financial Information.	600	1	1	0.25 (15 minutes)	150
CONCUR GOV New Traveler Profile	620	1	1	0.25 (15 minutes)	155
Absence Recording Form	1,220	1	1	0.25 (15 minutes)	305
Personal Custody Property Record	1,220	1	1	0.25 (15 minutes)	305
FDA Health Summary	1,220	1	1	1	1,220
Discovery and Invention Form	1,220	1	1	1	1,220
Training Development Plan	1,220	1	1	1	1,220
Final Project Report	1,220	1	1	1	1,220
Training Request	610	1	1	0.5 (30 minutes)	305
Travel Request	610	1	1	0.5 (30 minutes)	305
LMS Access	1,220	1	1	0.25 (15 minutes)	305
SOP Verification	1,220	1	1	0.25 (15 minutes)	305
Program Evaluation	1,220	1	1	0.5 (30 minutes)	610
Exit Checklist	1,220	1	1	1	1,220
Total					9,605

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

Dated: November 15, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–25332 Filed 11–21–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–2066]

Agency Information Collection Activities; Proposed Collection; Comment Request; Certification of Identity for Freedom of Information Act and Privacy Act Requests

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection associated with certain Freedom of Information Act and Privacy Act requests.

DATES: Submit either electronic or written comments on the collection of information by January 21, 2020.

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 January 21, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 21, 2020. 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: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://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 *http://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