U.S. Food and Drug Administration
Application for Participation in Food and Drug Administration
Fellowship and Traineeship Programs

OMB Control Number 0910-0780

SUPPORTING STATEMENT **Part A: Justification**

A. Justification

1. Circumstances Making the Collection of Information Necessary

   This information collection supports Food and Drug Administration (FDA, us or we) programs. The FDA has established fellowship and traineeship programs to train scientist in intramural research and/or review. Section 5 CFR Chapter 1, Sections 250 and 293 of Title 5 of the United States Code, provides authorization for Federal agencies to collect applications for Federal positions. The collection of applications for FDA traineeship and fellowship programs will allow FDA to easily and efficiently solicit and review information from students and health care professionals who are interested in becoming involved in FDA-wide activities. The process will reduce the time and cost of submitting written documentation to the agency and lessen the likelihood of applications being misrouted within the agency mail system. It will assist the agency in promoting and protecting the public health by encouraging outside persons to share their expertise with the FDA. Section 746(b) of the Federal Food, Drug and Cosmetic Act authorizes FDA to provide non-employees with intramural research training and support all aspects of the program to include collection of application materials.

   We therefore request extension of OMB approval for the information collection associated with fellowship and traineeship programs, as discussed in this supporting statement, including the associated forms.

2. Purpose and Use of the Information Collection

   The information collection is used to develop a pool of qualified applicants and to increase the range and depth of collaborations between the Agency and the outside scientific community. This collection supports FDA programs to train scientists in the regulatory research process, share expertise with FDA staff, and when applicable train in regulatory review. The information collected enables FDA to determine the applicant's level of education, experience, expertise, citizenship, and whether there are any conflict(s) of interest for the applicant.

3. Use of Improved Information Technology and Burden Reduction

   Respondents applying to FDA programs are encouraged to complete an online application.

Medical Device Fellowship Program - http://www.fda.gov/AboutFDA/WorkingatFDA/FellowshipInternshipGraduateFacultyPrograms/MedicalDeviceFellowshipProgramCDRH/default.htm. Alternatively, applicants may submit their applications by mail or by facsimile. FDA estimates that 95% of the respondents will use electronic means to submit the information.

FDA Traineeship Program – https://www.access.fda.gov/TPEXT/#/
100% of the respondents will use electronic means to submit the information.

4. Efforts to Identify Duplication and Use of Similar Information

   The information is not duplicative of information collected elsewhere.

5. Impact on Small Businesses or Other Small Entities

   No respondents are small businesses. Respondents are individuals and applications are voluntary.

6. Consequences of Collecting the Information Less Frequently

   Each respondent will submit the information once.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

   There are no special circumstances that occur when collecting this information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

   In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the FEDERAL REGISTER of October 22, 2018(83 FR 53257). Although one comment was received, it wasn't responsive to the four collection of information topics solicited and therefore will not be discussed in this document.

   FDA published a 30-day notice for this information collection on February 3, 2020 (85 FR 5966. We reopened the 30-day comment period to satisfy PRA requirements.

9. Explanation of Any Payment or Gift to Respondents

   This is a recruitment process for temporary positions within the FDA. Individuals selected through these programs will be paid in accordance with Federal regulations and policies. No gifts will be given to these individuals.

10. Assurance of Confidentiality Provided to Respondents

FDA assures confidentiality as prescribed under the Federal Privacy Act of 1974. Information collected is shared with FDA management and appropriate personnel for the purpose of recruiting external expertise.

11. Justification for Sensitive Questions

For employee Fellowship programs, the Office of Personnel Management is authorized to rate applicants for Federal jobs under sections 1302, 3301, and 3304 of title 5 of the U.S. Code. Section 1104 of title 5 allows the Office of Personnel Management to authorize other Federal agencies to rate applicants for Federal jobs.

For both FDA employee and non-employee Fellowship and Traineeship Programs, FDA requires the information included on this form and associated documentation to see how well each applicant's education and experience qualifies him/her for a position at the FDA. FDA also requires information regarding citizenship to determine whether he/she is affected by laws that we must follow in deciding who may be employed by the Federal government.

Information collected may be given to Federal, State, and local agencies to verify the absence of legal violations, or for other lawful purposes. We may send an applicant's name and address to state and local government agencies, Congressional and other public offices and public international organizations, if they request names of people to consider for employment. Providing personal information is voluntary, however, applications cannot be processed if the requested information is not provided.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

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

Table 1.--Estimated Annual Recordkeeping Burden[1]

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Medical Device Fellowship Program	250	1	250	1	250
FDA Traineeship Program	1000	1	1000	1	1000
Total					1,250

[1] There are no capital costs or operating and maintenance costs associated with this [1]

FDA based these estimates on the number of inquiries that have been received concerning the program and the number of requests for application forms over the past 3 years.

For Medical Device Fellowship Program – 250 respondents annually x 1 hour per response = 250 hours.

For the FDA Traineeship – 1000 respondents annually x 1 hour per response = 1,000 hours

12b. Annualized Cost Burden Estimate

There are no costs to the respondents associated with this information collection.

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

For the respondents, there are no operating and maintenance costs or capital costs associated with this collection of information.

14. Annualized Cost to the Federal Government

There is no cost to the federal government other than staff time. We approximate that 2,500 hours of staff time is spent reviewing documents and managing the process.

At the GS 13 ($63.96/hour) level, the expenses to the Federal Government are ($159,900).

15. Explanation for Program Changes or Adjustments

This information collection is being submitted with changes. We have revised the information collection to include an application for a new program – FDA Traineeship Program. We have also terminated two programs – Commissioner's Fellowship Program and Regulatory Science Internship. Our estimated burden of 1,250 hours, formerly 1,298 hours, for the information collection reflects an adjustment increase of 1,000.

FDA published a 60-day and 30-day notice which included a new program, Reagan-Udall Fellowship. Since the publication of the 30 day notice the program has been removed from this collection. FDA isn't seeking approval for Reagan-Udall Fellowship at this time.

16. Plans for Tabulation and Publication and Project Time Schedule

FDA does not have plans to tabulate or publish this information.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

FDA is not seeking exemption from displaying the OMB expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.