Application for Participation in Food and Drug Administration Fellowship Program

0910-0780

SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

   The Center for Device and Radiological Health (CDRH) and the Office of the Commissioner (OC) established fellowship programs to bring in outside expertise from the community. http://www.access.gpo.gov/uscode/title5/title5.html.

   Section 5 CFR Chapter 1, Sections 250 and 293 of Title 5 of the United States Code, http://www.access.gpo.gov/nara/cfr/waisidx_07/5cfr293_07.html, authorize Federal agencies to collect applications for Federal jobs. Collecting applications for t FDA fellowship programs will allow for 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.

2. Purpose and Use of the Information Collection

   The purpose of this collection is to develop a pool of qualified external experts and to increase the range and depth of collaborations between the Agency and the outside community. This collection supports FDA and CDRH programs to utilize external experts in the regulatory process, share expertise with FDA staff, and serve as additional reviewers to meet statutory deadlines. The information collected enables FDA to determine the applicant's level of education, experience, expertise, citizenship, and whether or not there are any conflict(s) of interest for the applicant. Respondents are individuals.

3. Use of Improved Information Technology and Burden Reduction

   Applicants are encouraged to complete an online application.

   Commissioner's Fellowship Program -website at www.fda.gov/commissionersfellowshipprogram. 100% of the respondents will use electronic means to submit the information. The app is available annually here: http://www.fda.gov/AboutFDA/WorkingatFDA/FellowshipInternshipGraduateFacultyPrograms/CommissionersFellowshipProgram/ucm115802.htm

   Medical Device Fellowship Program - website at http://www.fda.gov/AboutFDA/WorkingatFDA/FellowshipInternshipGraduateFacultyPro

grams/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.

Regulatory Science Internship Program – website at https://www.fda.gov/ScienceResearch/ScienceCareerOpportunities/ucm391199.htm. 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 June 20, 2017 (82 FR 28075). 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.

9. Explanation of Any Payment or Gift to Respondents

This is a recruitment process for temporary positions within the FDA. Individuals hired through this program 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

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. We require 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 through the fellowship program. We also

require 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. We may also notify the applicant's school placement office if he/she is selected for a Federal job. 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
Commissioner's Fellowship Program	600	1	600	1.33	798
Regulatory Science Internship Program	250	1	250	1	250
Medical Device Fellowship Program	250	1	250	1	250
Total					1,298

[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 Commissioner's Fellowship Program – 600 respondents annually x 1.33 hours per response = 798 hours.

For Regulatory Science Internship Program – 250 respondents annually x 1 hour per response = 250 hours.

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

12b. Annualized Cost Burden Estimate

Companies do not pay their employees to respond to this information request. Respondents use personal time. 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

    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 410 hours of staff time is spent reviewing documents and managing the process (an estimate of staff time at the GS 13 ($59.04) level to manage the process annually. These expenses include application reviews and data management and result in a total of $24,206.40 per year to the Federal Government.

15. Explanation for Program Changes or Adjustments

    The program change resulting in burden increase is due to the consolidation of 0910-0551 and development of a form for Regulatory Science Internship. The estimated annual hourly burden, formerly estimated as 798 hours, has increased by 500 hours to a total estimated annual hourly burden of 1,298 hours.

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.