Application for Participation in the Medical Device Fellowship Program

0910-0551

SUPPORTING STATEMENT

Terms of Clearance: None.

A. Justification

1. Circumstances Making the Collection of Information Necessary

   The Center for Devices and Radiological Health (CDRH) established the Medical Device Fellowship Program (MDFP) to bring in outside expertise from the scientific community. http://www.access.gpo.gov/uscode/title5/title5.html

   Section 5 CFR Chapter 1, Section 293 of Title 5 of the United States Code, http://www.access.gpo.gov/nara/cfr/waisidx_07/5cfr293_07.html, authorizes Federal agencies to rate applicants for Federal jobs. Collecting applications for the MDFP will allow CDRH to easily and efficiently solicit and review information from students and health care professionals who are interested in becoming involved in CDRH 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 CDRH.

2. Purpose and Use of the Information Collection

   The purpose of this collection is to develop a pool of qualified external scientific experts and to increase the range and depth of collaborations between CDRH and the outside scientific community. This collection supports an FDA and CDRH program 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 CDRH 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 on the Medical Device Fellowship Program website at 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.

4. Efforts to Identify Duplication and Use of Similar Information

This is a program within CDRH to develop a central source for CDRH staff to request and utilize experts on an as-needed basis. The information is not duplicative of information collected elsewhere.

5. Impact on Small Businesses or Other Small Entities

   No small businesses will be involved in this information collection. 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 for this collection of 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 9/6/2016 (81 FR 61221). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

   This is a recruitment process for temporary positions within CDRH. 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 privacy as prescribed under the Federal Privacy Act of 1974. Information collected is shared with CDRH 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 CDRH through the Medical Device 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

We estimate this information collection will take approximately 60 minutes, which includes time to review the instructions, gather information, and complete the form. FDA based these estimates on the number of inquiries it has received about the program and past requests for application forms.

Table 1.--Estimated Annual Reporting Burden

FDA Form	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Application Form (FDA 3608)	250	1	250	1	250

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

There are no capital, start-up, operating or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

We estimate 250 hours of staff time at the GS 13 level ($57.40 per hour, https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/16Tables/html/DCB_h.aspx) to manage the process annually. These expenses include application reviews and data management and result in a total of $14,350 per year to the Federal Government.

15. Explanation for Program Changes or Adjustments

FDA is requesting approval for the extension, without change, of this information collection. There are no program changes or adjustments.

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.