Supporting Statement for
Application for Participation in the
Medical Device Fellowship Program
0910-0551

A. JUSTIFICATION

1. Circumstances Necessitating Information Collection

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, authorize 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 of Collecting this Information

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.

3. Use of Information Technology and Burden Reduction

Applicants are encouraged to complete an online application on the MDFP website at www.fda.gov/cdrh/mdfp. 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 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. Consultation Outside the Agency

In the Federal Register of Wednesday, October 27, 2010 (75 FR 66103), FDA requested public comments on the information collection. 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 confidentiality 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. Estimate of Hour Burden Including Annualized Hourly Costs

12a. 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.

TABLE 1. ESTIMATED ANNUAL REPORTING BURDEN[1]

5 U.S.C. Section; FDA Form No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
§§ 1104, 1392, 3301, 3320, 3361, 3394; FDA Form 3608	250	1	250	1	250

FDA based these estimates on the number of inquiries it has received about the program and requests for application forms over the past 3 years.

12b. Annualized Cost Burden Estimate

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

13. Estimate of Other Total Annual Cost to Respondents or Recordkeepers

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

14. Annualized Cost to the Federal Government

We approximate 250 hours of staff time at the GS 13 level ($43.00) to manage the process annually. These expenses include application reviews and data management and result in a total of $10,750.00 per year to the Federal Government.

15. Explanation for Program Changes of Adjustments

The are no changes to this collection of information.

16. Plans for Tabulation and Publication and Project Time Schedule

CDRH will not be publishing the results of this information collection.

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

N/A

18. Exceptions to Certification for Paperwork Reduction Act Submissions

FDA is not requesting any exemption from the certification statement identified in Item 19 of OMB Form 83-I.