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 FDA's Center for Devices and Radiological Health (CDRH) to easily and efficiently elicit 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 is a result of 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 may complete an online application on the MDFP website at www.fda.gov/cdrh/mdfp. Otherwise, applicants may utilize the U.S. Postal Service or a facsimile machine to inquire and apply to the MDFP program.

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. There does not exist any duplication of this information.

5. **Impact on Small Businesses or Other Small Entities**

   This is not applicable, since this collection will impact individuals and will applications will be voluntary.

6. **Consequences of Collecting the Information Less Frequently**

   Collection for each individual is typically a one-time event.

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 Friday, November 9, 2007 (62 FR 63614), 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 in 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. 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 the Center for Devices and Radiological Health 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 that we collect about you may be given to Federal, State and local agencies for checking on 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 us with personal information is voluntary; however, we cannot process your application if applicants do not provide the information that we request.

12. <u>Estimate of Hour Burden Including Annualized Hourly Costs</u>

We estimate the burden of this information collection will take approximately 60 minutes, including time for reviewing instructions, gathering information, completing the form and reviewing the information.

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 / Form No. 3608	250	1	250	1	250

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

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

Cost to Respondents: There are no costs to the respondents except for one hour of personal time.

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 to manage the process. These expenses include the application reviews and data management. Cost to the Federal government is $ 66,951.00 x 250 hours = $ 167,377.50

15. Explanation for Program Changes of Adjustments

There is a burden increase of 150 hours, due to the increase in the number of respondents.

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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.