Supporting Statement For
Collecting Applications for Participation in the
Medical Device Fellowship Program

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.

Although these appointments are temporary in nature, the information collected is that typically collected from individuals applying for permanent positions in the Food and Drug Administration (FDA.) 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.

This collection is a result of an FDA and CDRH initiative to utilize external experts in the regulatory process, share expertise with FDA staff and serve as additional reviewers to meet statutory deadlines.

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. The information will be collected electronically and via U.S. mail and will be used to recruit qualified experts.

3. Use of Information Technology and Burden Reduction

Applicants may utilize the U.S. Postal Service to inquire and apply to the MDFP program. Otherwise, applicants would require access to an electronic mail service or to a facsimile machine. MDFP will utilize our electronic systems to collect the electronic applications or scan faxed information and will utilize electronic mail to disseminate the information to CDRH managers.

4. Efforts to Identify Duplication and Use of Similar Information

This is a new initiative 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 September 20, 2004 (69 FR 56228), FDA requested public comments on the information collection. No comments were received. CDRH is establishing relationships with universities in an effort to expedite and reduce the burden on students applying to the program. Similar relationships will be established with professional societies and hospitals to make applying to the program less burdensome to professional level applicants.

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 give 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. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services

Food and Drug Administration

9200 Corporate Blvd.

Rockville, MD 20850

An agency may not conduct or sponsor and, a person is not required to respond to, a collection of information unless it displays a current valid OMB control number.

This burden chart identifies how many applications we think we will receive annually for the next 3 years.

TABLE 1. ESTIMATED ANNUAL REPORTING BURDEN[1]

FDA Form No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
FDA Form 3608	100	1	100	1	100
Total					100

[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 year. We anticipate receiving 100 applications every year. FDA believes it will take individuals one hour to complete the application. This is based on similar applications submitted to FDA.

13. <u>Estimate of Other Total Annual Cost to Respondents or Recordkeepers</u>

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

14. <u>Annualized Cost to the Federal Government</u>

We approximate 100 hours of staff time to manage the process. These expenses include both the application reviews and the training of accepted applicants.

15. Explanation for Program Changes of Adjustments

There are no burden changes.

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.