**Application for Participation in the FDA Commissioner's Fellowship Program**

0910-NEW

SUPPORTING STATEMENT

## A. Justification

1. Circumstances Making the Collection of Information Necessary

   The Office of the Commissioner (OC) established the FDA Commissioner's Fellowship Program (CFP) to bring in outside expertise from the scientific community.

   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 the CFP will allow the FDA 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 CFP.
2. Purpose and Use of the Information Collection

   The purpose of this collection is to develop a pool of qualified external scientific experts who could potentially be offered a CFP 2-year fellowship position. The information collected enables the OC to determine the applicant's level of education, experience, expertise, citizenship, and whether or not they will be considered to be a top applicant for the CFP for the current application cycle.
3. Use of Improved Information Technology and Burden Reduction

   Applicants are required to complete an online application on the FDA CFP 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

4. Efforts to Identify Duplication and Use of Similar Information

This program is coordinated within the OC to develop a central source for FDA staff to request and utilize experts during the CFP application process. 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

   Applicants apply yearly as there are different available fellowship positions to apply to each year. The application period is yearly so the CFP can bring in new fellows yearly. If not collected yearly, the FDA would be unable to accomplish this. Each respondent will submit the information once. There are no legal obstacles to reduce the burden.

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 August 4, 2014 (79 FR 45196). Although one comment was received, it was not responsive to the four collection of information topics solicited and therefore will not be discussed in this document. There was not any outside consultation with the industry on the information collection request.

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. See the privacy act statement here: http://www.fda.gov/AboutFDA/WorkingatFDA/FellowshipInternshipGraduateFacultyPrograms/CommissionersFellowshipProgram/ucm115802.htm The information is handled and stored in the FDA Agency Information Management System (AIMS). The CFP office has an internal office shared drive where some of the information is transferred to (top applicant files) to be handled and stored.

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 FDA Commissioner's 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. See our Eligibility Criteria:

> *Applicants must have a Doctoral level degree (M.D., D.O., D.V.M., D.D.S., D.P.M., Pharm.D., or Ph.D.) to be eligible. Applicants with a Bachelor's degree in an engineering discipline will also be considered. Applicants must be U.S. citizens, non-citizen nationals of the U.S., or have been admitted to the U.S. for permanent residence at the time their applications are submitted. Applicants cannot be current FDA employees or FDA contractors (such as ORISE fellows). Applicants must have received their doctoral degree within 7 years of the start date. Applicants who have a Bachelor's or Master's degree in an engineering discipline may also apply, and applicants must have received their degree within 7 years of the start date. NOTE: All degree requirements (including thesis defense) must be complete before applying.*

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. The CFP does not ask respondents questions that related to sexual behavior and attitudes, or religious beliefs. The CFP does not ask for social security numbers (SSN) – the CFP instructs applicants to not submit their SSNs.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

We estimate this information collection will take approximately 120 minutes, which includes time to review the instructions, gather information, and complete the form.

Information on the required applications materials:
http://www.fda.gov/AboutFDA/WorkingatFDA/FellowshipInternshipGraduateFacultyPrograms/CommissionersFellowshipProgram/ucm115802.htm

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Recordkeeping Burden[1]

| Activity/ 5 U.S.C. Section | No. of Respondents | No. of Responses per Respondent | Total Annual Responses | Average Burden per Response | Total Hours |
|---|---|---|---|---|---|
| CFP Online Application/1104,1302, 3301, 3304, 3320, 3361, 3393, 3394 | 600 | 1 | 600 | 1.33 | 798 |
| Total | | | | | 798 |

[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 that have been received concerning the program and the number of requests for application forms over the past 5 years.

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 80 hours of staff time is spent reviewing documents and managing the process (an estimate of staff time at the GS 12 ($36.23) level to manage the process annually. These expenses include application reviews and data management and result in a total of $2,898.40 per year to the Federal Government.

15. Explanation for Program Changes or Adjustments

This is a new collection.

16. Plans for Tabulation and Publication and Project Time Schedule

The OC 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.