U.S. Food and Drug Administration
Collection of Conflict of Interest Information for Participation in Food and Drug Administration Non-Employee Fellowship and Traineeship Programs

OMB Control Number 0910-NEW

SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

   This information collection supports Food and Drug Administration's (FDA, us or we) non-employee fellowship and traineeship programs. FDA has established fellowship programs to bring in outside expertise.https://www.fda.gov/about-fda/jobs-and-training-fda/scientific-internships-fellowships-trainees-and-non-us-citizens

   Under Section 746(b) of the Food, Drug and Cosmetic (FDC) Act authorizes FDA to have intramural research training programs. The scientists and physicians in the training programs are subject to all legal and ethical requirements applicable to employees of the HHS (section 746(b) of the FDC Act). Collecting financial and relationship interests from the fellows and trainees will allow FDA to determine if there is a conflict of interest between the fellow's or trainee's financial and relationship interests and their activities at FDA.

   Because FDA has been advised by HHS and FDA ethics staff that the OGC 450 may only be used with federal employees; we therefore request Office of Management and Budget (OMB) approval for the information found in Report of Financial and Other Relationships for Non-Employee Scientists at FDA form; and discussed in this supporting statement.

2. Purpose and Use of the Information Collection

   FDA is seeking to collect this information from fellow's or trainee's which will be used by the FDA Mentor and Ethics staff to conduct a conflict of interest analysis. FDA obtains background information and conflict of interest information using a standardized format, referred to as the Conflict of Interest (COI) form to determine if the potential non-employee fellow or trainee will not be compromised by a significant conflict of interest

3. Use of Improved Information Technology and Burden Reduction

   FDA estimates that 95% of the respondents will use electronic form to submit the information.

4. Efforts to Identify Duplication and Use of Similar Information

   The non-employee fellowship and traineeship programs are centrally coordinated by the Office of the Chief Scientist, Office of the Commissioner. The Office of the Chief Scientist coordinates the collection of information from each fellow or trainee. The collected information is not duplicative of information collected elsewhere.

5. Impact on Small Businesses or Other Small Entities

   No respondent is a small business. Respondents are individuals who have been selected to an FDA non-employee fellowship or traineeship program.

6. Consequences of Collecting the Information Less Frequently

   Each respondent will submit the information annually and within 30 days of acquiring an interest. If FDA does not have the information annually and within 30 days of acquiring a new interest, then a conflict of interest may not be identified.

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 October 22, 2018 (83 FR 53257). One comment, that was not related to the collection, was received.

9. Explanation of Any Payment or Gift to Respondents

   This information collection does not provide for any payment or gift to respondents.

10. Assurance of Confidentiality Provided to Respondents

    This ICR collects personally identifiable information (PII) or other information of a personal nature. PII is collected via the FDA Form Report of Financial Interests and other Relationships for Non-Employee Scientist. PII collected is name, address, telephone number, fax number, cell phone number, email address, financial information, and relationship/s with a significantly regulated organization (SRO). PII is collected in the context of the individual's professional capacity. FDA is seeking to collect this information from fellow's or trainee's which will be used by the FDA Mentor and Ethics staff to conduct a conflict of interest analysis.

    Information collected via the FDA Form Report of Financial Interest and other Relationships for Non-Employee Scientist is maintained in a Privacy Act system of records as described in OPM/GOVT-5, Recruiting, Examining and Placement Records. Individuals completing the application will complete it via a webpage where a notice will be displayed.

The information collected will be protected in a database that has had a privacy impact assessment under HHS PIA P-4685007-054817 and the database will only be accessed by individuals who have been given permissions. In preparing this Supporting Statement, FDA staff consulted with the FDA Privacy Office to ensure appropriate handling of information collected. FDA minimized the PII to be collected to protect the privacy of the individuals.

11. Justification for Sensitive Questions

There are no questions of a sensitive nature on the COI form.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

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

Table 1.--Estimated Annual ReportingBurden[1]

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
ORISE Fellowship	500	500	500	1	500
Traineeship Program	500	500	500	1	500
Reagan Udall Fellowship at FDA	50	50	50	1	50
Total					1050

12b. Annualized Cost Burden Estimate

Respondents use personal time to provide the information. There are not costs to the respondents associated with this information collection. There will be no companies paying their employees to provide this information.

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 approximate that 1050 hours of staff time will be spent reviewing the form and managing the process. The estimated annual cost to the federal government for staff time at the GS 13 ($61.77/hour) level is $64,858.50.

15. Explanation for Program Changes or Adjustments

This is a new data collection.

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.