4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-3728]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Collection of Conflict-of-Interest Information for Participation in Food and Drug Administration Non-Employee Fellowship and Traineeship Programs

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to https://www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under Review - Open for Public Comments" or by using the search function. The OMB control number for this information collection is 0910-0882. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

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

OMB Control Number 0910-0882--Extension

Section 742(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379l(b)) allows FDA to conduct and support intramural training programs through fellowship and traineeship programs. Prospective participants in these programs must complete financial disclosure forms to determine if there is a conflict of interest that would preclude participation. These new forms provide FDA with information about financial investments and relationships from non-employee scientists who participate in FDA fellowship and traineeship programs. Participants in FDA fellowship and traineeship programs will be asked for certain information about financial interests and current relationships: (1) description of the financial interest; (2) the type of financial interest (e.g., stocks, bonds, stock options); (3) if the financial interest is an employee benefit from prior employment; (4) value of financial interest; (5) who owns the financial interest (e.g., self, spouse, minor children); (6) employment relationship with an FDA significantly regulated organization (SRO); and (7) service as a consultant to an FDA SRO, and/or proprietary interest(s) in one of more product(s) regulated by FDA, including a patent, trademark, copyright, or licensing agreement. The purpose of the financial information is for 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. The collection of information is mandatory to participate in FDA's fellowship and traineeship programs.

In the *Federal Register* of July 7, 2022 (87 FR 40537), FDA published a 60-day notice requesting public comment on the proposed collection of information. Although one comment was received, it was not responsive to the four collection of information topics solicited.

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

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

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Oak Ridge Institute for Science and Education Fellowship	500	1	500	1	500
Traineeship Program	500	1	500	1	500
Reagan Udall Fellowship at FDA	50	1	50	1	50
Total					1,050

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

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: December 12, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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