



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) 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: Fax written comments 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 faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-NEW and title "Collection of Conflict of Interest Information for Participation in Food and Drug Administration Non-Employee Fellowship and Traineeship Programs." 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-NEW

In compliance with 44 U.S.C. 3507, FDA will submit to the Office of Management and Budget a request to review and approve a new collection of information: "Collection of Conflict of Interest Information for Participation in FDA Non-Employee Fellowship and Traineeship Programs." Section 742 (b) of the Food, Drug and Cosmetic Act (21 U.S.C. 379i) allows FDA to conduct and support intramural training programs through fellowship and traineeship programs. These new forms provide the 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); (7) and service as a consultant to an FDA SRO, and /or proprietary interest(s) in one of more product(s) regulated by FDA, including 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 October 22, 2018 (83 FR 53257), FDA published a 60-day notice requesting public comment on the proposed collection of information. Although two comments were received, they were 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 Burden¹

| Activity | No. of Respondents | No. of Responses per Respondent | Total Annual Responses | Average Burden per Response | Total Hours |
|---|--------------------|---------------------------------|------------------------|-----------------------------|-------------|
| Collection Form--Report of Financial Interests and Other Relationships for Non-Employee Scientists at FDA | | | | | |
| 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 | | | | | 1050 |

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

Dated: October 2, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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