



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-3885]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Center for Tobacco Products, Food and Drug Administration Funded Trainee/Scholar Survey

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 "Center for Tobacco Products, Food and Drug Administration Funded Trainee/Scholar Survey." Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-7726, 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.

Center for Tobacco Products, Food and Drug Administration Funded Trainee/Scholar Survey

OMB Control Number 0910-NEW

The Tobacco Control Act (Pub. L. 111-31) amends the Federal Food, Drug, and Cosmetic Act (FD&C Act) to grant FDA authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health and to reduce tobacco use by minors.

FDA's Center for Tobacco Products (CTP) and the National Institutes of Health maintain an interagency partnership to foster the development of the emerging field of tobacco regulatory science (TRS). This study will use the CTP, FDA Funded Trainee/Scholar Survey to gather data on the characteristics, activities, and impact of training programs funded by the CTP and other partners. This evaluation will also determine how CTP-funded research and associated training programs and activities increase knowledge and skills related to TRS and interest to pursue careers in a TRS-related field. This survey provides support to determine the extent to which programs and activities generate positive impacts to increase the number of researchers who focus on TRS and TRS-related topics, specifically within CTP's priority domains. The survey builds upon previous evaluations of trainees and training activities and provides necessary evidence to inform FDA decision making. The web survey will gather responses from Tobacco Centers of Regulatory Science (TCORS) trainees and other CTP-funded trainees and scholars. Results will provide insights and directions to support future training and funding investments.

FDA CTP will use findings from this study to determine whether its TRS training support investments lead to meaningful change that supports CTP aims, and to inform decisions about potential future investments. CTP's training support intends to build additional capacity for TRS that establishes an evidence base related to CTP's research priorities so that FDA regulations, communications, and application review are founded on rigorous, relevant scientific study.

Respondents include current and former TCORS or other CTP-funded trainees and trainee principal investigators (PIs) or training directors. PIs and training directors will be asked to provide trainee names and email addresses and encourage trainees to participate in the survey. Current and former trainees will be asked to read an informed consent and take a brief web-based survey.

In the *Federal Register* of September 12, 2019 (84 FR 48148), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

Table 1.--Estimated Annual Reporting Burden¹

Type of Respondent/Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Current or Former Trainee/Scholar					
Lead Letter	350	1	350	0.025 (2 minutes)	9
Email invitation	350	1	350	0.016 (1 minute)	6
Informed consent	298	1	298	0.033 (2 minutes)	10
Survey	298	1	298	0.16 (10 minutes)	48
Followup email	176	3	528	0.016 (1 minute)	8
PI or Training Director					
Trainee list email	350	1	350	0.16 (10 minutes)	56
Notification email	350	1	350	0.016 (1 minute)	6
Total					143

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

Table 1 summarizes the total annual burden hours estimated for this information collection. There is no cost to participants other than their time. The total estimated annualized burden hours are 143. A total of approximately 350 trainees will be invited to participate in the web survey. Burden hours were estimated based on experience with prior similar survey activities and information obtained from informal testing by contractor staff.

Dated: December 31, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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