



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-2683]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Data to Support Social and Behavioral Research as Used by the Food and Drug Administration

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 0910-0847. 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, PRASStaff@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. Data to Support Social and Behavioral Research as Used by the Food and Drug Administration

OMB Control Number 0910-0847--Extension

Understanding patients, consumers, and healthcare professionals' perceptions and behaviors plays an important role in improving FDA's regulatory decisionmaking processes and communications impacting various stakeholders. The methods used to achieve these goals include individual in-depth interviews, general public focus group interviews, intercept interviews, self-administered surveys, gatekeeper surveys, and focus group interviews. The methods used serve the narrowly defined need for direct and informal opinion on a specific topic and as a qualitative and quantitative research tool, and have two major purposes:

1. To obtain information that is useful for developing variables and measures for formulating the basic objectives of social and behavioral research and
2. To assess the potential effectiveness of FDA communications, behavioral interventions and other materials in reaching and successfully communicating and addressing behavioral change with their intended audiences.

FDA will use these methods to test and refine its ideas and to help develop communication and behavioral strategies research, but will generally conduct further research before making important decisions such as adopting new policies and allocating or redirecting significant resources to support these policies.

FDA's Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research, Office of the Commissioner, and any other Centers or Offices will use this mechanism to test communications and social and behavioral methods about regulated drug products on a

variety of subjects related to consumer, patient, or healthcare professional perceptions, beliefs, attitudes, behaviors, and use of drug and biological products and related materials including, but not limited to, social and behavioral research, decision-making processes, and communication and behavioral change strategies.

Annually, FDA projects about 45 social and behavioral studies using the variety of test methods listed in this document. FDA is requesting this burden so as not to restrict the Agency's ability to gather information on public sentiment for its proposals in its regulatory and communications programs.

In the *Federal Register* of June 19, 2019 (84 FR 28557), 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

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Interviews/Surveys	5,040	14.6	73,584	0.25 (15 minutes)	18,396

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

Our estimated burden for the information collection reflects an overall increase of 9,198 hours and a corresponding increase of 36,792 responses due to an increase in grant funding for universities and others to perform research for FDA.

Dated: October 16, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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