



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0345]

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

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 0910-0695. 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 Drug Product Communications as Used by the Food and Drug Administration

OMB Control Number 0910-0695--Extension

This information collection supports Agency outreach efforts. Testing of communication messages in advance of a communication campaign provides an important role in improving FDA communications as they allow for an indepth understanding of individuals' attitudes, beliefs, motivations, and feelings. The methods to be employed include individual indepth interviews, general public focus group interviews, intercept interviews, self-administered surveys, gatekeeper surveys, and professional clinician focus group interviews, all on a voluntary basis.

The methods to be used serve the narrowly defined need for direct and informal opinion on a specific topic and, as a qualitative research tool, have two major purposes: (1) to obtain information that is useful for developing variables and measures for formulating the basic objectives of risk communication campaigns and (2) to assess the potential effectiveness of messages and materials in reaching and successfully communicating with their intended audiences. We will use these methods to test and refine our ideas and to help develop messages and other communications 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. We will use this mechanism to test messages about regulated drug products on a variety of subjects related to consumer, patient, or healthcare professional perceptions and about use of drug products and related materials, including but not limited to, direct-to-consumer prescription drug promotion, physician labeling of prescription drugs, medication guides, over-the-counter drug labeling, emerging risk communications, patient labeling, online sale of medical products, and consumer and professional education.

Annually, we project about 45 communication studies using the variety of test methods listed in this document. We are requesting an extension of these burden hours so as not to restrict our ability to gather information on public sentiment for FDA's proposals in its regulatory

and communications programs.

In the *Federal Register* of June 17, 2020 (85 FR 36591), we 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 | 43,875 | 1 | 43,875 | 0.21925 (12 minutes) | 9,620 |

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: January 11, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.