4164-01-P

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) 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 oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0695. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-7729, 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.

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 in-depth understanding of individuals' attitudes, beliefs, motivations, and feelings. The methods to be employed include individual in-depth 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: to obtain information that is useful for developing variables and measures for formulating the basic objectives of risk communication campaigns, and to assess the potential effectiveness of messages and materials in reaching and successfully communicating with their intended audiences.

FDA will use these methods to test and refine its 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. FDA will use this mechanism to test messages about regulated drug products on a variety of subjects related to consumer, patient, or health care 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, FDA projects about 45 communication studies using the variety of test methods listed in this document. FDA is requesting an extension of these burden hours 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, 2017 (82 FR 27840), we published a 60-day notice requesting public comment on the proposed extension of the collection of information. One comment was received requesting that FDA publish an annual list of its planned drug product communication studies and strive to reflect an overall work plan. The comment also noted the rather broad topic areas included in the information collection and suggested that perhaps additional notice regarding individual studies would allow for more meaningful feedback on whether that particular study would be necessary. FDA appreciates this comment. In determining which drug product communications it will undertake, we first consider those we believe will best address current or immediate public health issues. We also note that, in accordance with the PRA, any proposed study under this information collection request must first be submitted to and approved by OMB to determine whether it falls within the scope of the collection. At the same time, as resources are available, we will make every effort to communicate to our stakeholders anticipated studies so that ongoing or related research can be coordinated.

We therefore estimate 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 (in hours)	Total Hours
Interviews/Surveys	19,822	1	19,822	0.24 (14 minutes)	4,757

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

Dated: December 5, 2017.

Leslie Kux,
Associate Commissioner for Policy.
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