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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: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, 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

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. 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.

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 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 April 7, 2014 (79 FR 19096), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received one comment; however, this comment did not address the information collection.

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	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: September 24, 2014

Leslie Kux,

Assistant Commissioner for Policy.

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