4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-3586]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Focus Groups About Drug Products as Used by the Food and Drug Administration

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) 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 (PRA).

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 0910-0677. 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.

Focus Groups About Drug Products as Used by the Food and Drug Administration

OMB Control Number 0910-0677--Extension

Focus groups provide an important role in gathering information because they allow for a more indepth understanding of individuals' attitudes, beliefs, motivations, and feelings than do quantitative studies. Focus groups serve the narrowly defined need for direct and informal opinion on a specific topic and, as a qualitative research tool, have three major purposes:

- to obtain information that is useful for developing variables and measures for quantitative studies;
- to better understand people's attitudes and emotions in response to topics and concepts; and
- to further explore findings obtained from quantitative studies.

We use information gathered from focus group findings to test and refine 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.

Our Center for Drug Evaluation and Research, as well as other Agency components, engage focus groups about regulated drug products on a variety of topics related to consumer, patient, or healthcare professional perceptions and use of drug products and related materials. These materials may include, but are 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 sales of medical products, and consumer and professional education.

In the *Federal Register* of July 17, 2019 (84 FR 34186), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

Annually, we project that 20 studies will be initiated using 160 focus groups with an average of 9 persons per group. We assume each focus group will last an average of 1.75 hours.

We estimate the burden for the information collection 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	Total Hours
Focus Group Study	1,440	1	1,440	1.75	2,520

[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: December 18, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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