DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–2781]

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: Submit written comments (including recommendations) on the collection of information by April 5, 2024.

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: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *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 and other proactive communication efforts. Evaluating communication messages and supporting materials in advance of a communication campaign provides an important role in improving FDA communications as they allow for an indepth understanding of individuals knowledge, attitudes, beliefs, motivations, feelings, and behaviors. Such evaluations are critical in helping FDA develop public health communications that meet the needs and desires of its many diverse target audiences.

We intend to use the following methods with general public health consumers and healthcare professionals in our efforts: individual indepth interviews, focus group discussions, intercept interviews, self-administered surveys, and gatekeeper surveys, 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 and/or quantitative research tools, 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 qualitative and/or quantitative research 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: (1) direct-to-consumer prescription drug promotion; (2) labeling and information about prescription and over-the-counter drugs; (3) patient medication guides; (4) safety and risk communications; (5) online sale of medical products; and (6) consumer and professional education. Annually, we project about 75 communication studies using the variety of research methods listed in this document. FDA is requesting an extension of these burden hours so as not to restrict its ability to gather information on public opinion for its regulatory and communications programs.

In the **Federal Register** of September 29, 2023 (88 FR 67311), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Interviews/Surveys	45,000	1	45,000	0.75 (45 minutes)	33,750

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

We have increased our estimated burden to allow for additional individual collections under the approved generic clearance. For more detailed information regarding individual collections conducted under the currently approved generic clearance, please see our supporting statement at *https://www.reginfog.gov.* We believe that increasing the frequency of individual collections will improve our ability to timely deliver important drug product communications to specific populations, including vulnerable populations that include patients with certain medical conditions.

Dated: February 29, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

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