This document is scheduled to be published in the Federal Register on 03/29/2023 and available online at **federalregister.gov/d/2023-06434**, and on **govinfo.gov**

4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0796]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Testing Communications by the Food and Drug Administration's Center for Devices and Radiological Health

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 [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 0910-0678. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-3794, 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.

Testing Communications by FDA's Center for Devices and Radiological Health

OMB Control Number 0910-0678--Extension

FDA is authorized by section 1003(d)(2)(D) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(d)(2)(D)) to conduct educational and public information programs. FDA must conduct needed research to ensure that such programs have the highest likelihood of being effective. Improving communications by FDA's Center for Devices and Radiological Health (CDRH) involves many research methods, including individual indepth interviews, mall-intercept interviews, focus groups, self-administered surveys, gatekeeper reviews, and omnibus telephone surveys.

The information collected will serve three major purposes. First, as formative research it will provide critical knowledge needed about target audiences to develop messages and campaigns about product use. Knowledge of consumer, caregiver, and healthcare professional decision-making processes will provide a better understanding of target audiences that FDA needs to design effective communication strategies, messages, and labels.

Second, as initial testing, the collected information will allow FDA to assess the potential effectiveness of messages and materials in reaching and successfully communicating with intended audiences. Testing messages with a sample of the target audience will allow FDA to refine messages while still in the developmental stage. Respondents will be asked to give their reaction to the messages in either individual or group settings.

Third, as evaluative research, the collected information will allow FDA to ascertain the effectiveness of the messages and the distribution method in achieving the objectives of the message campaign. Evaluation of message campaigns is a vital link in continuous improvement of communications at FDA.

FDA expects to conduct studies under this generic information collection using a variety of research methods. We estimate that the burden to respondents will average 16 minutes each (varying from 5 minutes to 90 minutes). FDA estimates the burden of this collection of

information based on prior experience with the various types of data collection methods described earlier.

In the *Federal Register* of November 2, 2022 (87 FR 66192), FDA 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 Burden[1,2]

Type of Respondent/Survey	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
General Public					
Individual indepth interviews	420	1	420	0.75 (45 minutes)	315
General public focus group interviews	288	1	288	1.50 (1 hour, 30 minutes)	432
Intercept interviews: central location	200	1	200	0.25 (15 minutes)	50
Intercept interviews: telephone	4,000	1	4,000	0.08 (5 minutes)	320
Self-administered surveys	2,400	1	2,400	0.25 (15 minutes)	600
Gatekeeper reviews	400	1	400	0.50 (30 minutes)	200
Omnibus surveys	1,200	1	1,200	0.17 (10 minutes)	204
Total (general public)					2,121
Healthcare Professional					
Healthcare professional individual indepth interviews	72	1	72	0.75 (45 minutes)	54
Healthcare professional focus group interviews	144	1	144	1.50 (1 hour, 30 minutes)	216
Total (healthcare professional)					270
Total (overall)					2,391

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Numbers have been rounded.

Over the next 3-year approval period, we anticipate increasing our capability to conduct more communication surveys, which aligns with CDRH's strategic priorities. We have adjusted our burden estimates accordingly. Additionally, we have added an estimated hour burden for "healthcare professional individual indepth interviews." These changes reflect an overall increase of 315 burden hours and a corresponding increase of 276 responses annually.

Dated: March 23, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023-06434 Filed: 3/28/2023 8:45 am; Publication Date: 3/29/2023]