

UNITED STATES FOOD & DRUG ADMINISTRATION
Request for Data to Support Social and Behavioral Research

OMB Control Number 0910-0847

Request for Individual Collection under an Approved Generic Clearance:

Title: Social Media Usability; Consumer Interviews

1. Statement of Need

The mission of the U.S. Food and Drug Administration's (FDA's) Office of Prescription Drug Promotion (OPDP) is to protect the public health by helping to ensure that prescription drug promotional materials is truthful, balanced, and accurately communicated. Social media platforms have a number of characteristics that make them different from print and broadcast media; for instance, there may be character space limitations; consumer interactions through comments, shares, or likes; or interactive properties such as clicking and hovering. Although the use of social media for promotions is increasing, there is little research on this topic. It is critical for FDA to understand how consumers interact with prescription drug promotions on social media.

2. Intended Use of the Information

In line with the purpose of the generic clearance, FDA will use the qualitative data gathered here to support the development of a quantitative study that requires a full Information Collection Request on consumers' interactions with prescription drug promotional materials on social media. The long-term objective is to ensure effective communication of prescription drug information.

3. Description of Respondents

L&E Research, the subcontractor, is a marketing research firm with access to a diverse national population. Participants will be recruited through L&E Research's panel. Participants can join L&E's panel by filling out an interest form on their website. L&E also recruits panelists through social media.

Participants will be 54 adults in the Raleigh-Durham, NC, metropolitan area who are social media users with type 2 diabetes. Because the interviews will be conducted in person, participants will need to be able to drive to or otherwise be transported to the study location. To reduce the risk of bias, we will exclude participants who work in marketing, in the pharmaceutical industry, or for the U.S. Department of Health and Human Services. Individuals who have participated in a focus group or interview-based research study in the previous 3 months will also be ineligible to participate. Participants must consent to the interview being recorded and live-streamed.

L&E Research will recruit participants using an email with a link to an online screener programmed into a web-based screening platform using approved recruitment materials; potential participants who are interested in participating and appear to qualify will be contacted by phone to complete the screening process.

The following materials are appended: the recruitment materials (attachment A) and the study screener (attachment B).

4. How the Information is Collected

We plan to conduct 54 in-person, one-on-one, 60-minute interviews facilitated by the contractor, RTI International. Before the interview, participants will be screened and receive a copy of the informed consent form as an attachment to their confirmation email. During the interviews, participants will use a mobile device or laptop to view prescription drug promotional materials on Facebook or Instagram. The interviewer will prompt participants to view social media feeds and posts and will ask questions about their interpretations and reactions. The researchers will also record the participants' behavior on the social media site (e.g., clicking, scrolling). Interviews will be audio- and video-recorded and live-streamed to FDA observers.

The following materials are appended: the consent form (attachment C) and the moderator guide (attachment D).

5. Confidentiality of Respondents

The consent form will include the following information: "All information you share in this study will be kept secure to the extent permitted by law. The study team will not disclose your name or any of your responses, and your personal information (name, address, phone number) will not be linked to any of your responses. Some staff from FDA may choose to silently observe and listen in to the interviews in real time and may also ask questions of participants at the conclusion of the interview. The information you share with us will be combined into a summary report so that details of individual interviews cannot be linked to a specific participant. With your permission, the interviews will be audio and video recorded, but we will not connect your name to the recordings. These recordings will be stored on RTI's network, which is protected by a password and two-factor authentication. The information collected in this study may be used or shared for future research studies."

6. Amount and Justification for Proposed Incentive

Participants will receive a \$75 e-gift card as a token of appreciation after completing their interview. The proposed incentive is based on our experience with specific populations, the amount of time the participant spends in the study, what is required of participants, recent consultation with our recruiting vendor, and OMB-approved incentives on recent FDA projects. Following OMB's guidance, we offer the following justification for our use of this incentive.

Data quality and reduced survey costs: In this research study, we are asking participants to travel to the study location and to provide feedback on concepts that require a high level of engagement; specifically, engaging with a social media platform on a smartphone or laptop. Incentives that are too low may result in higher rates of participants who do not show up to participate in the study. Low participation can cause a difficult and lengthy recruitment process that, in turn, can cause delays in launching the research, which leads to increased costs. Thus, the proposed incentive is intended to reduce costs and data quality issues such as nonresponse bias and sampling bias.

Burden on the respondent: The use of incentives treats participants justly and with respect by recognizing and acknowledging the total effort that they expend to participate in the interview (105 minutes), which includes time for screening (5 minutes), time for reviewing the consent form and confirmation emails in advance of the interview (10 minutes), time for participating in the interview (60 minutes), and time for traveling to the study location.

Incentives must be high enough to equalize the burden placed on respondents with respect to their time and cost of participation. The Bureau of Labor Statistics (BLS) calculated in March 2023 that the average hourly compensation for civilian workers, including benefits, was \$43.07 (located at <https://www.bls.gov/news.release/pdf/ecec.pdf>). If we were to strictly follow industry standards, a minimum incentive that does not also consider the burden of transportation costs or childcare costs would be approximately \$75.37. Although the incentive is a token of appreciation and not a wage, this estimate represents the amount of money participants would earn if they spent the same amount of time working at a job.

7. Questions of a Sensitive Nature

There will be no questions of a sensitive nature asked of participants during the interviews.

8. Description of Statistical Methods

A sample size of 54 interview participants, split into 6 groups of 9 interviews each (mobile Facebook users 18 years and older, desktop Facebook users 18 years and older, mobile Instagram users 18 years and older, mobile Instagram users 18 to 24 years old, mobile Facebook users 62 years and older, desktop Facebook users 62 years and older), was selected based on saturation (i.e., the point at which no more information is expected to emerge from more data collection) and patterns of social media use. Data analysis will be qualitative.

9. Burden

Respondent Type/Category	Number of Respondents	Participation Time (hours)	Total Burden (hours)
Screener respondents	270	0.08	22
Interview respondents ¹	54	1.17	63
Totals	270	1.25	85

¹ Includes 60 minutes for the interview and 10 minutes for reviewing the consent and confirmation email.

10. Date(s) to be Conducted

We anticipate beginning the interviews by October 2023 or within 1 month following OMB approval.

11. Requested Approval Date

September 2023

12. FDA Contacts

Program Office Contact	FDA PRA Contact
Helen Sullivan Helen.sullivan@fda.hhs.gov Office of Prescription Drug Promotion Center for Drug Evaluation and Research	Domini Bean Paperwork Reduction Act Staff Office of Enterprise Management Services Office of Operations