FDA DOCUMENTATION FOR THE GENERIC CLEARANCE, "TESTING COMMUNICATIONS ON DRUGS PRODUCTS" (0910-0695)

.

TITLE OF INFORMATION COLLECTION: Individual Interview Study of Healthcare Provider Perceptions of Boxed Warnings

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. **Statement of need:**

   The prescribing information (sometimes referred to as the "PI", "package insert", or "prescription drug labeling") provides a summary of the essential information needed for the safe and effective use of a drug or biological product. A drug's prescribing information may include a boxed warning in addition to other sections of the labeling to highlight important safety information to healthcare providers (HCPs). Boxed warnings are an important and frequently used communication tool intended to promote informed treatment decisions and promote safer use behaviors that can mitigate a specific risk in patients who are using a drug. There is limited research exploring changes in drug utilization, safer use behaviors, and health outcomes that may be associated with inclusion of a boxed warning on a drug product or class of drug products, with variable results across studies. However, this research does not yield direct insight into how HCP receive, process, and use boxed warning information to support their treatment and follow-up decisions. Research that taps directly into providers' perceptions and decision-making processes is critical to understanding how FDA can achieve its public health goals through effective boxed warning information.

   The purpose of this project is to conduct individual interviews with healthcare providers to gain formative understanding of 1) HCPs' knowledge, beliefs, and attitudes toward boxed warning information, 2) how HCPs' use this information to support their treatment and follow up decisions, and 3) how HCPs communicate boxed warning information to their patients.

   For this project, FDA is seeking OMB approval to conduct 52 remote individual in-depth interviews with healthcare providers who have prescribing authority across the United States. Each interview will last 60 minutes and conducted via telephone and utilizing web-based teleconferencing software.

2. **Intended use of information:**

   FDA will use the results of this research to strengthen understanding of how healthcare providers perceive boxed warnings and identify HCP's potential information needs with respect to BWs. The research will also provide the opportunity to explore potential differences in perceptions and decision making considerations on (1) the condition being treated and (2) general practitioners and specialist. The data collected will not be statistically representative of population segments characterized by the groups. In addition, the data will not be used for making policy or regulatory decisions.

3. **Description of respondents:**

FDA's contractor for this work, Fors Marsh Group (FMG), LLC will conduct 52 one-hour remote individual in-depth interviews with healthcare providers who have prescribing authority across the United States. Audience segments for individual in-depth interview are described further below:

- General practitioner /Nurse Practitioners/ Physician Assistants (26)
- OBGYNs (13)
- Hepatologists/ Infectious Disease Specialist (13)

Potential research participants will be identified, screened and scheduled by a subcontractor, Lightspeed Health, who maintains a physician research panel.

4. **Date(s) to be Conducted:**

FDA's contractor for this work, Fors Marsh Group, LLC plans to conduct interviews between March and May 2018.

5. **How the Information is being collected:**

Fors Marsh Group, LLC will conduct remote in-depth interviews. For each 60-minute remote interview, a trained interviewer of Fors Marsh Group, LLC will lead the discussion using a semi-structured interview guide that ensures consistency in major topics but allows flexibility in probing each participant on particular questions. Data collection will be remote, conducted at a location of each participant's choice and convenience

With the consent of participants, Fors Marsh Group will audio record all interview sessions. FMG will also use screen-sharing software in concert with telephones to conduct these remote interviews. For one portion of the interview, participants will be asked to click through a website on their computer screen and respond to a series of questions. During this portion of the interview, FMG will video-capture participants' computer screen, but these recordings will only be used as needed for reporting purposes and then destroyed once reporting is finalized. There will be no use of webcams nor video recordings of the participants' faces.

FMG will produce a written transcript of each interview. FMG will provide FDA with transcripts of all interviews. In addition, FMG will provide FDA with at least six (6) audio recording of interviews, for quality control purposes.

6. **Confidential of Respondents:**

The following procedures will be used by Fors Marsh Group, LLC to ensure participants identity and information will remain private to the extent permitted by law before, during, and after fielding.

1. Full names of the participants will be used only for scheduling purposes and will not be used on any interview materials provided to FDA (e.g., typed lists of participants); instead, each participant will be assigned a unique ID by which they will be referred. Moderators will only address the participants by their first name (e.g., Mary).

2. Transferring of screening- and scheduling-related information between Lightspeed Health and Fors Marsh Group will be conducted via a password-protected, secure FTP site. All screening-related information will not be tied to any PII, but identified and matched by the assigned unique ID. For scheduling information, this will be limited to first name, last name, email, and phone number(s).

3. With consent of participants, FMG will provide remote login of the sessions for FDA personnel who are directly involved in the research to listen in on the interview and observe the screen sharing. Observers will be in listen-only mode; only the moderator will interact with the participant. As indicated in #1, the moderator will refer to the interview participant by first name only.

4. Transcripts, audio recordings, and reports will not contain any PII.

5. Respondents will not be tied to their individual responses, and all analyses will be conducted on the aggregate (e.g., any quotes used reporting will not be attributed to specific participants).

The informed consent will contain language that notifies participants of the audio recording, screen capturing, and livestreaming. Before each interview begins, the moderator will confirm consent by receiving verbal affirmation from the participants to record and livestream the session.

All data will also be maintained in consistency with the FDA Privacy Act System of Records #09-10-0009 (Special Studies and Surveys on FDA Regulated Products).

7. **Amount and justification for any proposed incentive**

For this study, PCPs will receive an honorarium of $150 and specialists will receive an honorarium of $175 for the participating in the 60-minute interview. Incentives must be high enough to equalize the burden placed on respondents in respect to their time and cost of participation. Particularly in the case of healthcare professionals, incentives need to be high enough to entice these HCPs to make time in their busy schedules and participate in the study. Low participation can cause a difficult and lengthy recruitment process that in turn, can cause delays in launching the research, both of which lead to increased costs. Low participation may result in inadequate data collection.

Market incentive rates for physicians are approximately $250 or more for similar research activities, with higher rates for specialists. The flexibility and convenience that the remote interview affords to participants—e.g., no travel time to/from facility, conducted on the HCPs' schedules-- should minimize risks of low participation in light of the lower honorarium proposed. To ensure a successful recruitment and fielding, FDA and the contractor will closely monitor status. Additionally, Fors Marsh Group will ensure that other considerations are in place to increase likelihood of participation, such as:

1. Ensuring adequate recruiting period prior to fielding start (as well as ongoing recruiting as needed during fielding period
2. Availability of sessions at time slots that in our experience have been popular among HCPs—e.g., early morning, evenings, lunch
3. Having the flexibility and appropriate staff availability to run concurrent sessions to leverage popular session times

8. **Questions of a Sensitive Nature**

Fors Marsh Group does not anticipate asking any sensitive questions in the interviews. Instead, the questions will focus on individuals' knowledge, understanding and perceptions of boxed warnings and the impact of boxed warnings upon their prescribing decisions and communications to patients. Participants will also be asked generally about their experiences with prescribing/dispensing particular products which contain a boxed warning.

Nevertheless, respondents will be told that they may skip questions that they do not want to answer or may stop participating at any time.

9. **Description of Statistical Methods**

Fors Marsh Group, LLC does not plan to use formal statistical methods in this study but rather qualitative analysis methods.

A full qualitative analysis will be conducted on all data collected from semi-structured interviews. Specifically, Fors Marsh Group will obtain verbatim transcripts of the interviews based on the audio recordings. Fors Marsh Group will review each transcript and code participant responses using a qualitative analysis software tool and a codebook with detailed definitions and examples to help coders differentiate among themes and reduce ambiguity. The resulting content at the various "nodes" (or codes) will be used to facilitate a systematic, thematic review of the qualitative data. This analytic approach will allow us to determine what knowledge, attitudes, perceptions, and decision processes are consistent across healthcare providers and to identify whether any of these elements differ by medical specialty or other factors.

BURDEN HOUR COMPUTATION *(Number of responses (X) estimated response or participation time in minutes (/60) = annual burden hours):*

Type/Category of Respondent	No. of Respondents	Participation Time (minutes)	Burden (hours)
Screening (Healthcare Providers)	100	5	8.33
Individual Interviews (healthcare providers)	52	60	52
TOTAL			**60.33**

REQUESTED APPROVAL DATE: March, 2018.

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