FDA DOCUMENTATION FOR THE GENERIC CLEARANCE, "Testing Communications on Drugs" (0910-0695)

TITLE OF INFORMATION COLLECTION: Rapid Message Testing with Consumer Panel —Asthma Fact Sheet

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. **Statement of need:**

   The purpose of this project is to conduct timely message testing of an FDA fact sheet about asthma. The fact sheet will be tested in both English and Spanish.

   Asthma is a chronic lung disease that causes the airways to become inflamed and narrow. According to the Centers for Disease Control and Prevention, about 8.3 percent of Americans — nearly 20 million adults and 6 million children— have asthma. In November 2018, the FDA approved a new version of Primatene Mist, an over-the-counter (OTC) rescue medication to treat symptoms of mild, intermittent asthma. This OTC product is not right for everyone with asthma, and it should not be used without first consulting a health care provider (HCP) to get a proper diagnosis and treatment plan. The goal of the fact sheet is to encourage asthmatics and parents of asthmatic children to talk with their HCP about creating an asthma action plan and possibly participating in a clinical trial.

   Communications science tells us that we must test messages with our intended audiences before communicating them. Thus, FDA plans to test this communication using online cognitive interviews with a small sample of 16 U.S. adults drawn from a diverse consumer panel.

   This data collection is the ninth in a series of FDA rapid message testing projects submitted to OMB under generic clearance. These projects are part of FDA's effort to make consumer testing part of its routine communication development processes. This project is in keeping with the spirit of the 2015 Executive Order[1] to improve how information is presented to consumers by applying behavioral science insights, and it meets repeated calls from FDA's Risk Communication and Advisory Committee to conduct message testing with targeted samples of the general public.

2. **Intended use of information:**

   FDA's contractor Westat will test the fact sheet with a small sample of target audience members to ensure the message meets its objectives without causing unintended negative effects. FDA's Risk Communication and Advisory Committee includes renowned experts and researchers in social sciences, marketing, health literacy, and related fields. From its very first meeting in 2008, the Committee has consistently advised and reaffirmed that testing communications with the target audience is necessary for FDA,

[1] https://obamawhitehouse.archives.gov/the-press-office/2015/09/15/executive-order-using-behavioral-science-insights-better-serve-american

and that using small samples is an effective approach for testing and communicating in a timely manner. In fact, research has shown that "saturation," or the point at which no new information or themes are observed, can occur with as few as 12 interviews, as described in Guest et al (2006).

FDA will use the collected interview data to refine its messaging by improving the comprehensibility, enhancing the cultural appropriateness and sensitivity, and improving the personal relevance for a higher public health impact. Specifically, FDA is asking Westat to gain insight to the following questions:

- Is the fact sheet clear and understandable?
- What is the main message that participants get from the fact sheet?
- Does the fact sheet provide useful information about treating asthma?
- What topics covered in the fact sheet are of most interest?
- Do participants indicate that any information in the fact sheet is new to them?
- Do participants recognize the call to action of talking with their healthcare provider to create an asthma action plan and discuss clinical trials?
- Do participants recognize the asthma medication devices shown in the picture?
- Is the summary at the top of the page helpful?
- Is the general layout appealing?

The data collected will not be statistically representative of the target audience population. Therefore, the data will not be used for making policy or regulatory decisions.

3. **Description of respondents:**

We will conduct 16 30-minute interviews with U.S. adults. Westat has partnered with Research Now Group, Inc., a global leader in digital data collection, to recruit respondents from its general population research panel and avoid "professional" panelists through proprietary recruitment and enrollment techniques. Research Now tracks and stores all panel member activity and assigns a unique ID number which stays with the panelist throughout their entire panel membership. These tracking records consist of profile information provided during enrollment, profile updates, survey screeners, past survey participation, and client feedback. Research Now monitors the quality of their data through various quality checks to save time and provide confidence in data accuracy. These quality checks include participation limits, screening questions, digital fingerprinting, random and illogical responding, capturing and removing flatliners and speeders, and more.

We will use a participant screener to recruit a mix of men and women between the ages of 18 to 64 who are either asthmatic themselves or the parent of an asthmatic child. The fact sheet will be tested with eight participants in English and eight participants who speak Spanish as their first language. The participant screener and moderator's guide are currently being translated for the Spanish interviews. The participant pool will be diverse in terms of race/ethnicity, education, and geography.

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

We plan to conduct interviews in February 2019.

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

We will conduct all interviews remotely using telephone and screen sharing technology with participants on web-enabled devices such as desktop computers, laptops, tablets or mobile phones. We will ensure that any materials provided to the participants for the test are compatible with all devices.

For each 30-minute interview, a trained interviewer 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.

Note takers will chart their findings into a standardized reporting template so that all notes are organized in a consistent manner. Interviewers will review the notes to ensure accuracy. With the consent of participants, we will audio record each interview.

FDA staff will have the ability to listen to the interview sessions, and this will be made known to participants as part of the informed consent.

6. **Confidentiality of Respondents:**

We will provide all respondents with informed consent language that ensures they understand the project purpose, that their participation is voluntary, and that their responses will be kept secure to the extent permitted by law. As part of the consent procedure, respondents will be asked whether they allow audio recording of the interview. Recording will not begin before participants have had the opportunity to ask for any clarification and provide consent. Participants will be asked to again confirm their consent when recording begins. Participants who do not allow audio recording may still participate in the interview. In these cases, Westat will take notes that are more detailed than when relying on the audio recording.

No participant's identifiable information such as name will be included in the interview notes. All interview materials will be stored on a secure network drive, which will only be accessible to individuals granted access to work on the project. Interview notes will be zipped electronically and password-protected for email or secure file transfer delivery. Prior to forwarding any data to FDA, Westat will destroy all names and contact information of participants to protect their personal identity. Additionally, the interview notes and interpretive report delivered to FDA after message testing will omit all information that could be used to identify respondents.

All electronic data storage media that contain confidential, private, or proprietary information will be maintained within secure areas. Data collected in hard copy will be kept in locked cabinets when not in use.

FDA's IRB, the Research Involving Human Subjects Committee (RIHSC) reviewed this study and determined it is exempt from the requirements of 45 CFR §46.101b(2).

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

For this project, Research Now will provide $35 incentives to participants at the end of each 30-minute interview in the form of virtual currency. The virtual currency is redeemable for a wide range of award items, vouchers, and publications.

Research Now uses a "by-invitation-only" recruitment methodology, and incentivizes panelists for any participation to maintain a quality filled panel. Panel members do not volunteer their time. Research Now's incentive scale is based on set time increments and panelist profiles and is applied equally across all study topics, sponsors, and data collection modes. The table below details the previous incentives approved by OMB for this series of rapid message tests.

Project #	Communication Tested	Interview Length/Incentive	OMB approval date
1	Clinical Trials Brochure	45 min/$50	August 4, 2017
2	Caregiver Tipsheet	30 min/$35	September 26, 2017
3	Public Service Announcement Video about Generic Drugs	30 min/$35	October 25, 2017
4	Opioid Analgesics Patient Counseling Guide	45 min/$50	November 27, 2017
5	Vaccines and Seniors Brochure	30 min/$35	May 10, 2018
6	Public Service Announcements about Safe Disposal of Opioids	30 min/$35	July 26, 2018
7	Nicotine Dialogue Campaign Branding	30 min/$35	August 23, 2018
8	Testosterone Medication Guide	45 min/$50	October 12, 2018

8. **Questions of a Sensitive Nature**

We do not anticipate asking any sensitive questions in the interviews. Instead, the questions will focus on individuals' experience with asthma and their reactions to the messages and material.

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

9. **Description of Statistical Methods**

We do not plan to use formal statistical methods in this study but rather qualitative analysis methods. Our analysis approach is based on the Framework method, as described in Spencer et al (2003). Framework is a matrix-based approach to data management, which facilitates both case and theme based analysis. The Framework method allows for data reduction through summarization and synthesis yet retains links to original data, in this case the interview notes. We will use the qualitative analysis software NVivo, which has included a Framework functionality since 2011. The

software will allow us import interview notes, create links between the notes and the Framework matrices, and develop new queries or matrices as needed.

The Framework method will allow us to recognize patterns within the data. Findings will be supported with verbatim participant quotes and grounded in accepted principles of health communications.

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)
Screener	250	3	13
Interviews	16	30	8
		Total	**21**

REQUESTED APPROVAL DATE: February 12, 2019

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