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

TITLE OF INFORMATION COLLECTION: Rapid Message Testing with Consumer Panel — FDA's Purple Book Website

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. **Statement of need:**

The purpose of this project is to conduct timely consumer testing of FDA's Purple Book website. Under the Biologics Price Competition and Innovation (BPCI) Act of 2009, Congress established an abbreviated licensure pathway for biological products that are demonstrated to be "biosimilar" to or "interchangeable" with an FDA-approved biological reference product. To advance efforts to share regulatory information broadly to stakeholders, the 2017 Biosimilar User Fee Negotiations and Commitment Letter (BsUFA II) and 2018 Biosimilars Action Plan (BAP) commit to providing patients, payors, and clinicians with timely, easy-to-use information about approved biologic products through an enhanced Purple Book.

To fulfill these commitments, FDA is expanding and digitizing the Purple Book by transitioning the current table format of the Purple Book to a searchable, public-facing database that will be accessible online. This initiative will provide the public with a dynamic, convenient, user-friendly online search engine with timely information about all FDA-licensed biological products, including biosimilar and interchangeable biological products. This expanded Purple Book will also offer more information about approved biological products, including information pertaining to exclusivity, and whether a product has demonstrated that it is biosimilar to, or interchangeable with, a reference product.

The new Purple Book online database will improve access to information about biological products and increase transparency for expert and patient stakeholders, providing an accessible, comprehensive view of approved biological product options. Such transparency is intended to help patients and industry track approval statuses of biosimilar and interchangeable biological products, and to aid prescribers and pharmacies in identifying innovative, life-saving, and potentially cost-effective medications. The new database could also provide scientific and regulatory clarity for the biosimilar product development community. Overall, providing stakeholders with more information about approved biological products through a modernized, interactive user experience may better facilitate the uptake of existing biosimilar products and development of new ones.

The initial Purple Book Version 1.0 (January 2020) will contain a limited data set, with simple search and advanced search functionality, that includes all approved biosimilars products and their related reference products. The goal of the initial release is to gather stakeholder feedback and conduct user testing on the new database to inform the next phases of development. FDA will release two additional enhancements to the database. These include Version 2.0 (Spring 2020) with Center for Biologics Evaluation and

Research (CBER) data, and Version 3.0, the final roll-out, that includes all Center for Drug Evaluation and Research (CDER) regulated products, including transition products, in addition to enhanced functionality as determined by user testing and stakeholder input, by August 2020.

Communications science tells us that we must test with our intended audiences before communicating them. Thus, FDA plans to test the Purple Book Version 1.0 using cognitive interviews with a small sample of 15 U.S. adults drawn from a diverse consumer panel.

This data collection is the 16th 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 Purple Book Version 1.0 with a small sample of target audience members to ensure the website 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, 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 and personal relevance for a higher public health impact. Specifically, FDA is asking Westat to gain insight to the following questions:

- How helpful is the Purple Book to participants in learning about their prescription biologic?
- How do participants locate background information on the Purple Book?
- How do participants use the search and the search results pages to locate information?
- How do participants access definitions for product delivery icons?
- How do participants locate full product information?
- How do participants interact with the Drugs@FDA information page?
- How do participants return to the Simple Search Results page from the FDA.gov information page?
- How do participants approach and locate the social media buttons to share information about the Purple Book site?

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

- What improvements do participants suggest for the Purple Book?

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 15 45-minute interviews with U.S. adults. Westat has partnered with Rare Patient Voice, LLC, a company specializing in patient recruitment. Rare Patient Voice 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, and client feedback. Rare Patient Voice monitors the quality of their data through various quality checks to save time and provide confidence in data accuracy. These quality checks include individual vetting of contact information, and review of IP addresses, and enrollment data, as well as review of screener questions and past survey response.

We will use a participant screener to recruit patients who have taken one of the following infliximab medications in the past 30 days: Remicade™, Inflectra™, or Renflexis™. These infliximab medications are biological products used to treat inflammatory bowel diseases, arthritis, and skin conditions, and thus the users of such medications may be inclined to visit FDA's Purple Book website in the future looking for information about their medication. To the extent possible, the participant pool will be diverse in terms of gender, education, age, race/ethnicity, and geography.

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

We plan to conduct interviews in February 2020.

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, and tablets. We will ensure that any materials provided to the participants for the test are compatible with these devices.

For each 45-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 Institutional Review Board (IRB) 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, Rare Patient Voice will provide $50 incentives to participants at the end of each 45-minute interview in the form of a check.

Rare Patient Voice 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. Rare Patient Voice's incentive scale is based on set time increments 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	30 min/$35	July 26, 2018

	about Safe Disposal of Opioids		
7	Nicotine Dialogue Campaign Branding	30 min/$35	August 23, 2018
8	Testosterone Medication Guide	45 min/$50	October 12, 2018
9	Asthma Fact Sheet	30 min/$35	February 12, 2019
10	Transmucosal Immediate Release Fentanyl Risk Evaluation Mitigation Strategy Program Patient-Prescriber Agreement Form	45 min/$50	April 4, 2019
11	BeSafeRx Campaign Messages	45 min/$50	May 17, 2019
12	Safe Drug Disposal Notecard	30 min/$35	June 28, 2019
13	Medical Countermeasures	45 min/$50	September 10, 2019
14	Warnings on Opioid Packaging	30 min/$35	October 22, 2019
15	Messages About Cannabidiol (CBD)	30 min/$35	January 2, 2020

8. **Questions of a Sensitive Nature**

We do not anticipate asking any sensitive questions in the interviews. Instead, the questions will focus on individuals' reactions to the messages and materials.

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.

Bibliography

Spencer, L., Ritchie, J., & O'Connor, W. (2003). Analysis practices, principles and processes. In *Qualitative research practice.* London: Sage Publications.

Guest, G., Bunce, A., & Johnson, L. (2006). How many interviews are enough? An experiment with data saturation and variability. Field methods, 18(1), 59-82.

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	90	3	5
Interviews	15	45	11
		Total	**16**

REQUESTED APPROVAL DATE: January 20, 2020

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