

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

TITLE OF INFORMATION COLLECTION: Rapid Message Testing with Consumers and Healthcare Professionals — Children’s Cough and Cold Consumer Update

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. Statement of need:

Consumer Updates are one of FDA’s flagship communications for providing the public with timely and easy-to-read articles containing the latest on FDA-regulated products and practical wellness and prevention information to empower consumers. Each Consumer Update article is distributed to more than a million listserv subscribers and social media followers, and is viewed thousands of times on the FDA [website](#) alone.

The purpose of this project is to conduct testing of a draft Consumer Update article about children’s cough and cold products. FDA will communicate the agency’s recommendation that parents and caregivers not use homeopathic cough and cold products in children under four years of age, that FDA has not evaluated any homeopathic drug for safety or effectiveness, and that FDA is not aware of any proven benefits of these products. FDA will also communicate that it recommends parents and caregivers not use over-the-counter (OTC) cough and cold products in children under two years of age. FDA plans to post and promote its messaging through the Consumer Update, targeted stakeholder outreach, and social media in September 2021 to align with the beginning of cough and cold season.

Communications science tells us that we must test messages with our intended audiences. Thus, FDA plans to test these communications using cognitive interviews with a small sample of 24 U.S. adults drawn from diverse consumer and healthcare professional (HCP) panels. The sample will include 16 parents/caregivers of children under 4 years old (primary audience) and eight pediatricians (secondary audience).

This data collection is the 23rd in a series of FDA rapid message tests submitted to OMB under generic clearance. These projects are part of FDA’s effort to make target audience testing part of its routine communication development processes. This project is in keeping with the spirit of the 2015 Executive Order¹ 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.

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

2. **Intended use of information:**

FDA's contractor Westat will test the PDF mock-up of the website 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, 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:

- What is the main message that participants get from the material?
- Do participants understand from the material that there is a difference between OTC and homeopathic products?
- Are the recommendations clear to participants for children's homeopathic cough and cold products? For children's OTC cough and cold products?
- Are the risks clear and understandable?
- What do participants recognize as the call to action?
- Do participants indicate that any of the material's information is new to them?
- Do participants find any of the warnings concerning?
- What information do participants find useful? Not useful?
- For pediatrician participants, how useful of a tool is the material for communicating with parents/caregivers?
- How well do participants think the visuals match the messages?
- Is there information that is missing or that would be helpful to add?
- How likely are parent/caregiver participants to give children under 4 homeopathic or OTC cough and cold products after reading?
- How likely are pediatrician participants to recommend for children under 4 homeopathic or OTC cough and cold products after reading?

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 24 45-minute interviews with U.S. adults. Westat has partnered with Plaza Research, a recruitment specialist to recruit 16 parents/caregivers from its general population panel. Westat has also partnered with WebMD Professional/Medscape, a specialist in healthcare professional recruitment, to recruit eight pediatricians from its user database. Both Plaza Research and WebMD Professional/Medscape track and store all database member activity and assign a unique ID number which stays with the member throughout their entire membership. These tracking records consist of profile

information provided during enrollment, profile updates, and past study involvement. Plaza Research and WebMD Professional/Medscape monitor 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 enrollment data, as well as review of screener questions and past study response.

We will use a participant screener to recruit 16 parents/caregivers, some of whom have given any OTC cough and cold medicine to a child younger than 4 years old in the past 12 months. We will primarily recruit lower education parents/caregivers (high school or less) for feedback on literacy and comprehension. We will also use a participant screener to recruit eight pediatric primary care physicians. To the extent possible, both participant pools will be diverse in terms of gender, age, race/ethnicity, and geography.

4. Date(s) to be Conducted:

We plan to conduct interviews in June 2021.

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, or tablets. We will ensure that any materials provided to the participants for the test are compatible with these devices. We will email materials to participants who do not have access to screen sharing technology.

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 will not be invited to participate in the interview.

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

Parents/Caregivers

For this project, Plaza Research will provide \$50 incentives to parent/caregiver participants at the end of each 45-minute interview in the form of a check. Plaza Research 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. Plaza’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 rapid message tests with consumers.

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
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
16	FDA's Purple Book Website	45 min/\$50	January 16, 2020
17	Storyboards about Safe Disposal of Opioids and Other Medicines	45 min/\$50	April 14, 2020
18	Medication Guide Template for Buprenorphine Products	30 min/\$35	May 13, 2020
19	Retest Warnings on Opioid Packaging	30 min/\$35	June 19, 2020
20	Drug Safety Communications About Misuse and Abuse of Over-the-Counter Medications	45 min/\$50	December 9, 2020
21	Additional Testing of Drug Safety Communications About Misuse and Abuse of Over-the-Counter Medications	45 min/\$50	March 12, 2021
22	Drug Safety Communication Landing Page and Format	45 min/\$50	April 14, 2021

Pediatricians

For this project, WebMD Professional/Medscape will provide \$100 to pediatrician participants at the end of each 45-minute interview in the form of a check. WebMD Professional/Medscape incentivizes respondents for any participation to maintain a quality-filled participant base. Members do not volunteer their time. FDA expanded its contract with Westat in 2020 to now include testing with HCPs. The table below details the previous incentives approved by OMB for rapid message tests with HCPs.

Project #	Communication Tested	Interview Length/Incentive	OMB approval date
1	Search and Rescue Website	45 min/\$100 (primary care) or \$150 (specialists)	September 23, 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 to 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

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.

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

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)
Parent/Caregiver Screener	1500	3	75
Pediatrician Screener	75	3	4
Interviews	24	45	18
		Total	97

REQUESTED APPROVAL DATE: June 8, 2021

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