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

TITLE OF INFORMATION COLLECTION: Studies to Enhance FDA Communications Addressing Biosimilar Drug Products: Focus Groups and Interviews with Healthcare Professionals

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. **Statement of need:**

   The purpose of this project is to (1) conduct focus groups with healthcare professionals (HCPs) to understand their experiences when communicating with patients about biosimilar and interchangeable drug products and (2) conduct in-depth interviews to gauge healthcare professionals' reactions to educational materials FDA developed as resources for HCPs about these products. FDA will use the finding to inform enhancements to these resources and development of other communications about these products.

   In 2010, the President signed into law The Patient Protection and Affordable Care Act, which amended the Public Health Service Act (PHS Act) to create an abbreviated licensure pathway for biological products that are demonstrated to be "biosimilar" to or "interchangeable" with an FDA-licensed biological product. FDA requires licensed biosimilar and interchangeable biological products to meet the Agency's rigorous standards for safety and efficacy. That means patients and healthcare professionals will be able to rely upon the safety and effectiveness of the biosimilar or interchangeable product, just as they would the original reference product. Developing evidence-based communications about drug products can be challenging, especially when an entirely new type of drug product becomes available as happened recently with the introduction of biosimilar drug products to U.S. HCPs and patients.

2. **Intended use of information:**

   FDA has determined further research is needed to better understand how to most efficiently and effectively focus resources to educate and communicate to various stakeholder audiences about biosimilars and interchangeables and their safe and appropriate use.

   FDA will use the results of this qualitative research to improve their understanding of healthcare professionals' communications about biological drug products, including biosimilars, and to inform revision of educational materials it developed about these products and development of other related communications. The study results will help ensure that the messages/materials communicate key information that HCPs need and desire about and biosimilars and interchangeables and address information that may be lacking or misunderstood. The data will not be used for the purposes of making policy or regulatory decisions.

3. **Description of respondents:**

On behalf of FDA/CDER, research company Fors Marsh Group will conduct 16, 90-minute online focus groups, each consisting of 5 – 8 participants, for a total of 80-128. We will conduct the groups with eight different prescriber types, all of whom who are currently or have in the recent past prescribed or dispensed a biologic or biosimilar product to patients. These specialty types were selected because they are the most likely to have prescribed or dispensed the biologic or biosimilar products that are currently on the market:

- Rheumatologists (3 groups)
- Oncologists/hematologists (3 groups, mixed cancer specialties)
- Dermatologists (3 groups)
- Nephrologists (3 groups)
- Gastroenterologists (3 groups)
- Nurse practitioners, physician assistants, and pharmacists (1 mixed group)

Following the focus groups, we will conduct 30, 90-minute in-depth online interviews with individuals who are healthcare professionals, all of whom will either currently prescribe or dispense biologic products or have in the recent past:

- Rheumatologists (6 individual interviews)
- Oncologists/hematologists (6 individual interviews)
- Dermatologists (5 individual interviews)
- Nephrologists (4 individual interviews)
- Gastroenterologists (5 individual interviews)
- Nurse practitioners (1 individual interview)
- Physician assistants (1 individual interview)
  Pharmacists (2 individual interviews)

Focus group and interview respondents will be recruited by Lightspeed Health, a subsidiary of the online panel company Lightspeed, which provides access to healthcare professionals from nearly 100 specialties across 44 therapeutic areas—a total of 2 million healthcare professionals worldwide (with approximately 40% of the total panel being U.S. based), including pharmacists, nurses, rheumatologists, oncologists, hematologists, nephrologists, dermatologists, gastroenterologists, physician assistants, and dozens of other specialists. In 2016, Lightspeed Health assisted market research companies in completing more than 200,000 physician interviews.

Lightspeed Health will initially reach out the appropriate healthcare professional specialties within their panel via email to inform them that there is an upcoming study they may qualify for (see email notification). Potential respondents will be able to click a link in the email to answer up to five initial screening questions. If respondents still qualify after those screening questions, a recruiter will contact the respondents via phone to complete the remaining screening questions and determine eligibility. If a respondent is qualified and selected for the study, the recruiter will schedule them over the phone. Recruiters will send out reminder emails with login information for the group or interview, as appropriate.

In screening for the focus groups and interviews, participants will answer general demographic questions (e.g., gender, practice), healthcare specialty information, and

about experience prescribing or dispensing biological products (see Screener for Healthcare Professional Focus Groups and In-Depth Interviews). We are aiming to recruit a mix of demographics to ensure adequate diversity.

4. **Date(s) to be conducted and location(s):**

   The HCP focus groups will be conducted over a 6-week period after OMB and RIHSC approvals have been obtained. The individual interviews will be conducted after the focus group data collection is completed.

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

   We will conduct 16 online focus groups with healthcare professionals to understand their experiences when communicating with patients about biologic products, including biosimilars and interchangeables. Each focus group will last 90 minutes and will consist of 5-8 participants.

   Following the completion of the focus groups, we will conduct 30 online in-depth (individual) interviews with healthcare professionals to examine their reactions to educational materials about biosimilar and interchangeable products created by FDA. Each interview will last 90 minutes.

   All focus groups and interviews will be conducted remotely via the FocusVision online platform, InterVu, which provides live, audio/video access for moderators and respondents in multiple locations to interact face-to-face. FocusVision InterVu is a secure, password protected system. With the InterVu remote set-up, members of the FDA team will be able to log in and view the session live, unobtrusively hearing the conversation and seeing what participants see in real time.

   For each 90-minute focus group or interview, a trained moderator/interviewer will lead the discussion using a semi-structured guide that ensures consistency in major topics but allows flexibility in probing each group/interviewee related to answers that may arise on particular questions (See the following 2 documents included as part of this package: (Healthcare Professional Semi-Structured Focus Groups Moderator's Guide and Semi-Structured Interview Guide).

   During the groups and interviews, a note taker will observe and document the major themes in each session. With the consent of participants, we will audio and video record each session, produce a written transcript of the discussion, and use the transcript to supplement the team's notes. We also will live video stream each focus group/interview using a secure, password-protected system (FocusVision InterVu) so that research staff from FMG and FDA can observe the sessions remotely). The recruiting coordinators will provide the participants with an honorarium following each session (see section 7).

6. **Confidentiality of respondents:**

As the groups and interviews are remote, a consent form will be emailed to each participant at the time of recruitment and scheduling. Participants will electronically sign a programmed version of the consent form, so that their typed signature is collected in FMG's survey system (see consent forms). No participants will be allowed to participate without a signed consent form.

The recruitment coordinators, Lightspeed Health, will store information obtained through the screening processes (see Screener for Healthcare Professionals Focus Groups and In-Depth Interview documents) in locked file cabinets (hardcopy) or on a password-protected computer (electronic) only in order to invite respondents and send them reminder letters or make reminder phone calls. Only the recruitment coordinators assigned specifically to this project will have access to this information. Once the screening and recruitment process is completed, the recruiting firm will provide FMG with screening data for participants that includes first names and phone numbers to facilitate outreach to participants who do not sign in for their sessions on time. FMG will keep this information on a password-protected computer and will delete the information at the completion of the project. Participant contact information will not be provided to FDA.

At the beginning of each group and interview, we will reiterate the information contained in the informed consent form participants signed previously: that participation is voluntary and they do not have to answer any questions they do not want to and can stop participating at any time. Participants will be instructed to use only their first names during the groups and interviews. We will also inform participants that no full names or any personally identifying information will be used in any notes, reports, or any materials; that only anonymized information reported in aggregate will be provided to the FDA; and that their information will be kept private to the extent possible given the study methods. As is the case in in-person focus groups, online participants will be able to see the moderator and each other only while the focus group is being conducted, and participants will be asked not to share anything that is discussed during the group with anyone outside of the group.

FDA will not have the full names or any contact information for any of the participants. FMG will have this information only to contact participants at the beginning of groups in the even they don't call in. Therefore, there will be no link between the data collected and the participants' identities. In addition, FMG will also put in place a non-disclosure agreement with Lightspeed to ensure this contact information is completely protected.

Recordings, electronic and written materials obtained during the focus groups and interviews will be stored on a password-protected server accessible only to the research team. FMG will retain these files for three years and then delete them. The information will be kept in a secured fashion that will permit access only by authorized project staff. All personally identifiable information will be removed from transcripts, audio/video files, reports, and all other materials before FMG provides them to FDA. FDA will store all study files and materials on password-protected computers for a period of 5 years. These confidentiality methods will be approved by FDA's Research Involving Human Subjects Committee (RIHSC) prior to collecting any information.

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

Healthcare professionals—and, in particular, specialists—are a notoriously difficult population to recruit and retain in qualitative research. Healthcare professionals are typically busy individuals who may work irregular shifts, be overcommitted, and need to respond to clinical emergencies. Despite being a highly sought after populations for research, response rates among healthcare professionals tend to be 10% lower compared to studies with the general public ([1]Cummings, Savitz, & Konrad, 2001). A systematic review of 66 peer-reviewed studies aimed at increasing response rates among healthcare professionals found that financial incentives are an effective strategy for maximizing participation ([2]VanGeest, Johnson, & Welch, 2007). Healthcare professionals are well paid and therefore are less apt to participate with lower incentive amounts. Consequently, we will offer meaningful financial incentives to ensure we can reach the desired segments and ensure adequate participation. If we offer lower incentives, we could not achieve the sample sizes required for this study. Because the focus groups and interviews take place over 90 minutes, healthcare professionals cannot easily fit them into a lunch break and thus must participate outside of typical business hours.

Healthcare professionals from different specialties will be recruited for these focus groups and interviews and will be provided different honorarium amounts based on their specialty. Oncologists and Nephrologists are considered to be more specialized physicians, and thus are offered a slightly higher honorarium. There are significantly fewer nurse practitioners and physician assistants practicing generally as well in these specialties specifically, and in the LightSpeed Health's healthcare provider panel; therefore they are harder to recruit and so will be offered a higher honorarium to better ensure we are able to recruit from these key health care practitioner populations.
Based on past experience recruiting participants from this highly specialized population and recent consultation with market research firms, the following honorariums will be provided for the focus groups, by specialty:

- Rheumatologists, dermatologists, gastroenterologists, pharmacists – $184
- Oncologists/hematologists, nephrologists – $208
- Nurse practitioners and physician assistants – $250

Lightspeed Health, has specialized in qualitative research for 16 years, during which healthcare professionals in the panel have become accustomed to the honorarium amounts proposed and decreasing these traditional amounts would result in a drop in response rates that could increase the time needed for conducting these focus groups and interviews, thereby increasing the cost to the government to recruit and field groups of the size and number necessary to complete this research, and delaying the completion of the study, which could also result in increased costs for the work for which the government contracted.

For the individual interviews we will offer $250 to all participants, because each will spend 90 minutes providing direct input.

All focus group and interview participants will receive their honorariums per the usual process they agree to when they agree to participate in the LightSpeed Health healthcare professional panel via their personal All Global Circle accounts within one week of

completing the focus group or interview (see consent forms). Within their All Global Circle accounts, participants are given the option to receive their honorarium via PayPal, SWIFT (Virtual Visa Reward Card, E-Vouchers (e.g., Amazon, iTunes, Department Stores), Gift Cards, or Unicef Donations—depending on each participant's preference. All of the available payment options are processed through their individual All Global Circle account.

8. **Questions of a sensitive nature:**

We do not anticipate asking any sensitive questions in the focus groups or interviews. Participants will be informed during the screening process that the research relates to biologic and biosimilar products, so they so they will know about these topics in advance and have the opportunity to decline to participate. The questions in the focus groups will focus primarily on respondents' experiences communicating about and prescribing/dispensing biological and biosimilar products to patients and what they think patients will need to know about them. Questions in the interviews will focus primarily on obtaining respondents' opinions about educational materials related to biosimilars and interchangeables. All participants 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 (i.e., sample size & method of selection):**

Qualitative methods in the form of human and machine coding via software program will be used to analyze the data from both the focus groups and from the interviews.

Specifically, organizational coding schemes will be developed based on the verbatim transcripts for the focus groups and for the interviews. Two team members will then independently code approximately 20% of the transcripts for each (up to four transcripts for focus groups; up to 6 transcripts for interviews). Once reliability is established (i.e., kappa coefficient of >.70 is reached for all double coded transcripts), coders complete coding transcripts individually.

The resulting coded content will be used to facilitate a systematic, thematic review of the qualitative data. Our analysis procedure includes coding transcripts within nodes to extrapolate key themes and, as appropriate and necessary, utilizing analytical features (e.g., text searches, word frequency, coding queries) within NVivo. These results will ultimately guide the research team's efforts to identify insights and representative quotes, draw conclusions, make actionable recommendations, and complete its reporting.

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

Type/Category	No. of Respondents	Participation	Burden

of Respondent		Time (minutes)	(hours)
Screening for Focus Groups (Healthcare Professionals)	256	5	21.3
Focus Group (Healthcare Professionals)	128	90	192
Screening for Interviews (Healthcare Professionals)	60	5	5
Interview (Healthcare Professionals)	30	90	45
TOTAL			263.3

REQUESTED APPROVAL DATE: April, 2018

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FDA CENTER: Center for Drug Evaluation and Research (FDA/CDER)

References

[1]Cummings, S. M., Savitz, L. A., & Konrad, T. R. (2001). Reported Response Rates to Mailed Physician Questionnaires. *Health Service Research, 35*(6), 1347 – 55.

[2]Vangeest, J. B., Johnson, T. P., & Welch, V. L. (2007). Methodologies for Improving Response Rates in Surveys of Physicians. *Evaluation & the Health Professions, 30*(4), 303-321. doi:10.1177/0163278707307899