FDA DOCUMENTATION FOR THE GENERIC CLEARANCE, "TESTING COMMUNICATIONS ON BIOLOGICAL PRODUCTS" (0910-0687)

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TITLE OF INFORMATION COLLECTION: Focus Group Study of Healthcare Provider Knowledge of Biosimilar Biological Products

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. **Statement of need:**
   The purpose of this project is to (1) conduct focus groups with healthcare providers to identify their knowledge, perceptions, attitudes, and information needs related to biosimilar biological products (Phase 1) and (2) conduct individual interviews with healthcare providers to test campaign messages and materials (Phase 2). OMB approved Phase 1 activities on December 23, 2014. This is a request for OMB approval of Phase 2 activities.

   Through comments received to the various biosimilar guidance and public hearing dockets and through other mechanisms, many stakeholders emphasized the importance of FDA engaging in public and healthcare provider educational outreach on biosimilars in order for these products to be successfully adopted by the U.S. community. FDA learned from companies marketing biosimilars in Europe, among others, that the level of positive support from local governments and regulatory decision makers was one of the stronger influences on the uptake of biosimilars in some areas of the European market. To develop the messages and materials for a biosimilar education campaign targeted to healthcare providers, FDA conducted focus groups to understand the gaps in healthcare providers' knowledge regarding biosimilars (OMB approval received for Phase 1 activities on December 23, 2014). What was learned from these focus groups then guided the development of biosimilar educational messages and materials.

   For Phase 2, we are seeking OMB approval to conduct 27 in-person interviews with healthcare providers at two multisite medical facilities. Each interview will last 60 minutes. Fourteen of the interviews will take place at Baylor Scott & White Health (BSWH) in Dallas, TX, and the remaining 13 interviews will take place at the University of California, Irvine (UCI) in Irvine, CA.

2. **Intended use of information:**
   FDA will use the results of this research to refine its education and outreach campaign targeting physicians, pharmacists, and other healthcare providers. The study results will ensure that the campaign's messages/materials communicate key information, address any misperceptions about biosimilar products, and utilize communication channels trusted by the target audiences. 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:**
   We will conduct 27 one-hour interviews with healthcare providers at medical facilities in Dallas, TX, and Irvine, CA. We will conduct the interviews with five different audience segments:
   - Rheumatologists (n=4)
   - Oncologists / Hematologists (n=6)
   - Dermatologists (n=6)
   - Nephrologists (n=6)
   - Pharmacists (n=5)

4. **Date(s) to be Conducted:**
   We plan to conduct interviews in October and November 2015.

5. **How the Information is being collected:**
   For each 60-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.

   With the consent of participants, we will audio and video record each interview, produce a written transcript of the discussion, and use the transcript to supplement the interviewer's notes. We will also live video stream each interview using a secure, password-protected system (e.g., Adobe Connect) so that research staff can observe the interviews remotely. We will provide cash incentives to participants at the end of each interview.

6. **Confidentiality of Respondents:**
   At the beginning of each interview, we will ensure participants understand that their participation is voluntary and that they can skip questions or stop participating at any time. We will protect participants' confidentiality by not using full names in our notes, recordings, or transcripts and by storing all notes or recordings in a locked filing cabinet in the project director's office (hardcopy) or on a password-protected server (electronic). We will assure participants that research findings and reports will not contain any personal information.

   The recruitment coordinators at each medical facility will store screening information in locked file cabinets (hardcopy) or on a password-protected computer (electronic) in order to invite respondents and send them reminder letters / calls. Only the recruitment coordinators will have access to this information; FDA and its contractor (RTI) will be provided de-identified screening data for participants (i.e., first names only, no other contact info). Names of participants will be used solely to facilitate contact. After the study is completed, the coordinators will destroy the screening information.

   FDA and RTI will not have the full names or any contact information for any of the participants. Therefore, there will be no link between the data collected and the participants' identities.

7. **Amount and justification for any proposed incentive**
Healthcare providers—and, in particular, specialists—are a notoriously difficult population to recruit and retain in qualitative research. Providers are typically busy individuals who may work irregular shifts, be overcommitted, and need to respond to clinical emergencies. Consequently, we will offer meaningful financial incentives to ensure adequate participation.

Based on the guidance OMB provided to FDA on June 24, 2014 (see attached email), we plan to offer incentives of $175 for pharmacists and $250 for physicians for 60-minute interviews.

8. **Questions of a Sensitive Nature**
We do not anticipate asking any sensitive questions in the interviews. Instead, the questions will focus on individuals' knowledge and attitudes toward biological and biosimilar products, and their reactions to campaign messages and materials. We also will ask generally about their experience prescribing/dispensing biological products.

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.

Specifically, we will obtain verbatim transcripts of the interviews based on the audio and video recordings. We will then review each transcript, have two team members independently code participant responses, and organize responses into a meta-matrix that segments responses by topic and audience segment (e.g., knowledge of biosimilars x rheumatologists). This step serves to reduce and summarize the data, while also facilitating the recognition of patterns within it (Gale, Heath, Cameron, Rashid, & Redwood, 2013).

At this point, the research team will note regularities, patterns, and other explanations in the data (Miles & Huberman, 1994). 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.

References:

Gale, N. K., Heath, G., Cameron, E., Rashid, S., & Redwood, S. (2013). Using the framework method for the analysis of qualitative data in multi-disciplinary health research. *BMC Medical Research Methodology*, 13(1), 117.

Miles, M. B., & Huberman, A.M. (1994). *Qualitative Data Analysis*. Thousand Oaks, CA: 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)
Screening (Healthcare Providers)	54	2	1.8
Individual interviews (Healthcare Providers)	27	60	27
TOTAL			**28.8**

REQUESTED APPROVAL DATE: August 7, 2015

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