# Request for Approval under the "Data to Support Drug Product Communications and Biosimilar Prescribing" (OMB Control Number: 0910-0695)

**A. TITLE OF INFORMATION COLLECTION:** HHS/FDA Biosimilars Prescribing Survey

**DESCRIPTION OF THIS SPECIFIC COLLECTION**

1. **Statement of Need:**

   The purpose of this survey is to provide HHS and FDA with key information on healthcare professionals' likely prescribing habits for biosimilar biological products. HHS and FDA would like to understand the factors that influence their prescribing decisions and how they expect to communicate with their patients about prescriptions for biological products. The survey presents physicians with hypothetical prescribing scenarios and hypothetical products and examines factors including FDA's naming convention for biological products, product formulary status, patient treatment history, product indications, and product delivery system. Research that taps directly into providers' decision-making processes is critical to understanding how FDA can achieve its public health goals through effective education and information.

   As described in the supporting statement for generic clearance 0910-0695, one of the purposes of information collection under this generic clearance is to understand the general beliefs of physicians and healthcare adjuncts and to determine their informational needs, identify any communication challenges, and understand the most effective formats for reaching and educating them. The specific collection described in this memo aims to understand the decision-making processes and information needs that physicians encounter in ordering and prescribing biosimilar biologic products.

2. **Intended Use of Information**:

   The biosimilar pathway is still in its early years and the information obtained will be used to help HHS and FDA attain a baseline understanding of how healthcare professionals are likely to order and prescribe biosimilar products and the information that factors into prescribing decisions. The information will inform development and dissemination of educational materials about FDA's regulation of biosimilar products and support communication with healthcare professionals about biosimilar products. The data collected will not be statistically representative of population segments characterized by the physician specialty groups. In addition, the data will not be used for making policy or regulatory decisions.

3. **Description of Respondents:**

The targeted group is 500 healthcare providers in the United States working in specialties with experience prescribing biological products. Eligible respondents must be a physician, licensed nurse practitioner or physician's assistant. There are six groups of respondents practicing in the specialties of oncology, rheumatology, dermatology, gastroenterology, hematology, and nephrology. Potential survey participants will be identified by the contractor for this work, Fors Marsh Group, LLC, using the online panel provider SurveyHealthcare (SHC) to recruit physicians in these specialties. SHC samples from a population of 2 million plus physicians and allied healthcare professionals. They regularly update and validate their panel from standard core sources (AMA, hospital books/directories, medical directories and verified healthcare internet sites as original sample sources). In addition, SHC requests and collects copies of medical credentials and call enrollees to verify them. Participants will be contacted through this panel for survey participation.

4. **How the Information is Being Collected:**

The survey link will be distributed by email. It is a web-based, self-administered survey with closed-ended questions and is estimated to take 23 minutes for each participant to complete. The purpose of the pretest survey is to conduct the survey with a small sample of participants to ensure that the survey functions properly. In both the pretest and the main study, screening questions will confirm each respondent's eligibility and specialty. Eligible respondents will then be presented with hypothetical prescribing scenarios using two biological products, a reference product and a biosimilar, relevant to their specialty. Depending on the respondent's specialty, the survey will be populated with a fictitious brand name and nonproprietary name, information about patient treatment history, product indications, product delivery systems, and product formulary status. In the main study, half of the respondents within each specialty will receive the survey with the nonproprietary name of the biosimilar biological products identified with a four-letter suffix. For the other half of respondents, the nonproprietary name of all biological product identified in the survey will include a four-letter suffix.

5. **Dates to Be Conducted:**

September 2019 – December 2019

6. **Confidentiality of Respondents:**

Personally identifiable information will not be collected. The survey will request general demographic information (age, gender race/ethnicity) only. Information will be kept secure to the extent provided by law.

7. **Amount and Justification for any Proposed Incentive:**

   According to available research,[1] surveys involving health care providers are characterized by low and declining response rates (RRs), and researchers have utilized various strategies to increase survey RRs among health professionals. It has been noted that those subgroups receiving monetary incentives were more likely to respond, while nonmonetary incentive groups were not significantly different from non-incentive groups.

   For this study, participating healthcare professionals will receive an honorarium for completion of the survey. Particularly in the case of healthcare professionals, incentives need to be high enough to entice them to make time in their busy schedules to participate in a survey collection. Low participation can cause a difficult and lengthy recruitment process, that in turn can cause delays in launching the research or result in inadequate data collection.

   The following honoraria, differentiated by specialty, will be awarded to respondents who complete the survey:

   Dermatology: $30.00
   Gastroenterology: $35.00
   Hematology: $60.00
   Nephrology: $30.00
   Nurse Practitioner - Physical Assistant: $25.00
   Oncology Cancer: $35.00
   Rheumatology: $40.00

8. **Questions of a Sensitive Nature:**

   There will be no questions of a sensitive nature asked of participants during the screening or the surveys.

9. **Description of Statistical Methods:**

   A qualitative analysis will be conducted on the data collected from the survey. Data will be analyzed using descriptive statistics. The resulting content will be used to facilitate a systematic, thematic review of the qualitative data. This analytic approach will allow us to determine what knowledge and decision processes are consistent across healthcare providers and to identify whether any of these elements differ by medical specialty or other factors.

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

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[1] *Enhancing Surveys of Health Care Professionals: A Meta-Analysis of Techniques to Improve Response*, Young Ik Cho, Timothy P. Johnson, Jonathan B. VanGeest, Internet publication, August 23, 2013.

| Type/Category of Respondent | No. of Respondents | Participation Time (minutes) | Burden (hours) |
|---|---|---|---|
| Pretest screener | 40 | 3 | 2 |
| Pretest participants | 30 | 20 | 10 |
| Main study screener | 650 | 3 | 33 |
| Main study participants | 500 | 20 | 165 |
| TOTAL | | | 210 |

**REQUESTED APPROVAL DATE:** July, 2019

**NAME OF PRA ANALYST & PROGRAM CONTACT:**

Ila S. Mizrachi
Paperwork Reduction Act Staff
Ila.Mizrachi@fda.hhs.gov
301-796-7726

Beverly Friedman
Beverly.Friedman@fda.hhs.gov
301-796-3468.

Zahava Hurwitz and Sandy Benton
Zahava.Hurwitz@fda.hhs.gov; Sandra.Benton@fda.hhs.gov
301-796-5257

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