FDA DOCUMENTATION FOR THE GENERIC CLEARANCE, "FOCUS GROUPS ABOUT DRUG PRODUCTS" (0910-0677)

Focus groups do not yield meaningful quantitative findings. They can provide public input, but they do not yield data about public opinion that can be generalized. As such, they cannot be used to drive the development of policies, programs, and services. Policy makers and educators can use focus groups findings to test and refine their ideas, but should then conduct further research before making important decisions such as adopting new policies and allocating or redirecting significant resources to support these policies.

TITLE OF INFORMATION COLLECTION: Generic Drug Substitution in Special Populations

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. **Statement of need:**

The Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER), Office of Generic Drugs (OGD) is seeking OMB approval under the generic clearance 0910-0677 to conduct focus groups for the project "Generic Drug Substitution in Special Populations".

Based on the supporting statement for generic clearance 0910-0677, the purpose of information collection under this generic clearance is to gather information about drug products regulated by the FDA that "will be used as a first step to explore concepts of interest and assist in the development of quantitative study proposals, complementing other important research efforts in the agency. This information may also be used to help develop communication messages and campaigns."

The proposed research will identify research needs, monitor, and improve generic drug substitution in special populations (i.e., pediatric patients, older adults who take multiple medications, women, racial/ethnic minorities, individuals with impaired kidney or liver function, and individuals residing in different geographic regions/settings). We propose to use a mixed-methods approach including a systematic review of the literature, primary data collection (focus groups) and secondary data analysis of Medicare and Medicaid data to fully explore practice patterns and existing barriers to generic drug substitution in special populations.

The specific collection described in this memo will use focus groups to understand the alignment between clinical practice and labeled drug administration information discussed among practitioners and special patient populations in order to identify factors that raise issues for safety and effectiveness with generic substitution among special populations. Focus groups with individual physicians, pharmacists, and patients associated with targeted special populations will be conducted to gain an in-depth understanding of the communication taking place between patients and their physicians and pharmacists about drug risks and instructions based on the unique needs of their population group identified.

Bioequivalence studies that compare a reference formulation to an investigational generic formulation typically are conducted in healthy adult volunteers and occasionally are conducted in patients. Some patient populations have unique physical, biological, and

physiological considerations that are not reflected by healthy volunteers or by the typical patient for whom a drug is indicated. Furthermore, there is a paucity of evidence on barriers to and patterns of generic substitution in special populations whose experiences with a drug are not represented by those in whom bioequivalence studies are conducted.

To address this information gap, OGD has funded a cooperative agreement with Auburn University and IMPAQ International (U01FD005875). Through this cooperative agreement, focus groups will be conducted with individuals (i.e., prescribers, pharmacists, older adult patients and pediatric patient proxies) to gain an in-depth understanding of the alignment between clinical practice and labeled drug administration information among a selection of special patient populations.

2. Intended use of information:

Data collected from these focus groups will support the project's purpose of identifying research needs and monitoring generic drug substitution in special populations by discussing current communication regarding generic drug substitution or administration with members of specific special populations (i.e., pediatric patients, older adults who take multiple medications). This project also may help improve generic drug labeling and guidance regarding use of generic drugs in special populations. Depending on the findings, this information may support additional research studies or guide internal FDA analyses that could support actions such as labeling changes or guidance development. Information obtained from these focus groups will not be used to directly support any policy making or regulatory decisions.

3. Description of respondents:

A maximum of 28 focus group participants will be interviewed. Participants will be recruited from each of the following 4 groups:

- Patients, aged 65 years or older (n=9)
- Pediatric patient proxies (for patients aged 17 years or younger) (n=9)
- Prescribers, including physicians, nurse practitioners, and physician assistants (n=5)
- Pharmacists (n=5)

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

September 15, 2017 – March 14, 2018

Baltimore Research Headquarters
8320 Bellona Ave, Towson, MD 21204

5. How the information is being collected:

Recruitment

A marketing research firm, Baltimore Research, will assist with recruitment and scheduling. Baltimore Research will utilize privately purchased marketing lists to recruit prescribers, pharmacists, patients, and/or pediatric patient proxies. Participant eligibility differs by group (see Table 1). Participants who meet the eligibility requirements (see below) will be contacted via telephone by Baltimore Research. Participants will be asked if they wish to participate in the study provided they are able to during the designated date and time yet to be determined (see Appendix A). Participants who are available and wish to participate in the focus group will be mailed an electronic or hard copy of the informed consent letter (see Appendix B) within 48 hours of enrollment in the study and will receive a reminder via email or phone of their scheduled focus group two days prior to their scheduled discussion date and time.

Table 1. Eligibility for Focus Groups

Group	Eligibility
Prescribers	Prescribed a generic drug in a community/institution setting in the past month
Pharmacists	Practicing pharmacists who have dispensed a drug at a pharmacy in any setting (chain, independent, or hospital) in the past month
Older Adult Patients	Are 65 years or older, and have taken a generic drug/or serves as a proxy to a patient who is 65 or older and has taken a generic drug in the past month
Pediatric Patient Proxies	Are 19 years or older, and serve as a proxy to a patient who is 17 years or younger and has taken a generic drug in the past month

Focus Groups

Skilled moderators from IMPAQ International will conduct up to three focus groups with no less than six participants and no more than nine participants from each of the three groups: Prescribers/Pharmacists, older adult patients, and pediatric patient proxies. Each sixty (60) minute focus group will be based on a pre-specified list of questions (see focus group guides attached at Appendix C), with additional probing and discussion. Focus groups will be audio recorded and transcribed.

Participation will be voluntary. Before each focus group begins, the moderator will review study information, review participants' rights and responsibilities, and obtain signed consent from the participant to participate in the study. Participants will be provided an electronic or hard copy of the informed consent letter prior to the scheduled focus group. This document will be reviewed with the participants prior to the start of the focus group and participants will be asked to sign the letter in order to participate. Participants may mail back the signed document or bring it with them on the day of the scheduled focus group. The informed consent letter provided to participants prior to

participating in the focus group also describes the purpose of the audiotaping and protection of participants' data. The interviewer will review the highlights of the informed consent letter at the start of the focus group in case there are any questions. The interviewer will also request permission to audio record the discussion prior to the start of the focus group interview.

Transcription of the audio recordings will be used to analyze participant responses.

6. Number of focus groups:

There will be three focus groups:
1. Prescribers and Pharmacists
2. Patients aged 65 or older or their proxy
3. Pediatric patient proxies

7. Amount and justification for any proposed incentive:

The proposed compensation for each group may be found in Table 2. The proposed compensation or "incentive" is not a reward or salary. Rather, it is a stimulus to participate in the focus group. Proposed incentive rates are in accordance with standard practice and based on several factors including education and training, level of expertise, access to participants, and willingness to participate. Incentive amounts are based on Baltimore Research's experience. Offering an incentive below these rates may result in increased costs exceeding the amount saved with a lower incentive. Consequences of insufficient incentives include increased time and cost of recruitment, increased "no-show" rates, and increased probability of cancelled or postponed focus groups.

Table 2. Respondent Compensation

Group	**Incentive Amount**
Prescribers*	
Primary Care Providers	$175
Specialist	$250
Pharmacists†	
Retail	$150
Hospital	$200
Patients/Pediatric Patient Proxies	$50

*Incentives are based on physician specialty, level of expertise, years in school and average salaries. The more schooling and training, the higher the incentive. Incentives are also based on willingness to participate.

†The $150 incentive is for retail pharmacists. The incentive for hospital pharmacists is $200. These incentives are based on the pharmacist, availability, specialty and willingness to participate. More specifically, retail pharmacists are more prevalent than hospital-based pharmacists, making hospital pharmacists more difficult to recruit.

Incentives will be distributed upon completion of the focus groups. All incentives will be distributed in a check paid by Baltimore Research. The name and address of the recipient and date mailed will be the only information noted. Patients and pediatric patient proxies participating in the focus groups will receive an incentive of $50 via check. Prescribers participating in the focus group will be issued a check for $175 (Primary Care) or $250 (Specialists). Participating pharmacists will receive a check for $150 (retail pharmacists) or $200 (hospital pharmacists). For those participants to whom an annual amount of $600 or more is expected to be issued by Baltimore Research for participation in this and other studies, they will be given a W9 to complete before payment is issued. These participants will also be mailed a 1099 at the end of the year for tax purposes. All financial records will be kept confidential and stored on a secure server. Personal information will not be shared with anyone outside of the IMPAQ financial staff. Upon completion of this project all confidential participant information not pertinent to financial record keeping will be destroyed.

8. Questions of a Sensitive Nature:

There will be no questions of a sensitive nature asked of participants.

9. Description of Statistical Methods (I.E. Sample Size & Method of Selection):

This is a qualitative study using a convenience sample. As such, the analyses do not entail the use of statistics.

Qualitative analyses will be conducted using NVivo 10 software, in which initial themes from the transcripts will be identified and then discussed until all team members agree on major themes and a final code book. Team members' coded data will be compared for variations and periodically discussed as needed until consensus is reached.

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

A burden of approximately 28 hours in total is estimated based on 1 hour focus group discussions for a maximum of 28 participants across 4 types of participants in 3 focus groups. It should be noted that the anticipated total number of participants is 27, but we have included the maximum number of respondents and burden in order to allow the researchers the flexibility to include an additional pharmacist or prescriber to the Prescriber/Pharmacist focus group.

Table 3. Estimated Reporting Burden

Type/Category of Respondent	**No. of Respondents**	**Participation Time** (minutes)	**Burden** (hours)
Older Adult Patients	9	60	9
Pediatric Patient Proxies	9	60	9
Pharmacists	5	60	5
Prescribers	5	60	5
Total	28		28

REQUESTED APPROVAL DATE: August 15, 2017.

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