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: Educating Groups Influencing Generic Drug Use

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,[1] 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 help understand roles of key groups and the extent of their influence on generic drug use in order to provide additional and effective educational outreach to meet their informational needs. To this end, we propose to study key groups, determine the extent of their influence and informational needs regarding generic drugs overall and by specific drug class, and develop generic drug educational materials using a mixed-methods approach including systematic reviews of clinical and observational studies, robust empirical analyses of publicly available datasets and surveys, and qualitative key informant interviews and focus groups.

The specific collection described in this memo will use focus groups to gain feedback on the content, format, channel, and satisfaction of educational materials developed for different stakeholder groups. Focus groups with individuals representing three key groups (including patients/caregivers, prescribers/pharmacists, and formulary managers/large purchasers of drugs/policymakers) will be conducted to help develop educational materials which will be tested among a larger sample of these key groups.

Evidence shows that generic drug use is largely impacted by certain key groups' behaviors and perceptions towards generic drugs. These key groups include patients/caregivers, prescribers, pharmacists, insurance formulary managers, state health policy makers, and large purchasers of drugs. While believed to be influential, the extent

[1] https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201604-0910-008

of each groups influence is heterogeneous and dependent on factors such as experiences and perceptions with generic drugs and the changing costs of certain drugs or therapeutic classes. Other key groups or factors might also influence generic drug use. It is important for consumers, health care providers, researchers, policy makers and other stakeholders to understand the drivers of generic drug prescribing and use, in order to design policy or programs that promote the "triple" aim of better care, smarter spending, and healthier people. Thus, effective educational efforts to target all types of barriers that may limit generic drug use are a critical need.

To address this information gap, OGD has funded a cooperative agreement with Auburn University and IMPAQ International (U01FD005486). As part of this cooperative agreement, focus groups with individuals representing one of the following three key groups (including patients/caregivers, prescribers/pharmacists, and formulary managers/large purchasers of drugs/policymakers) will be conducted to help develop educational materials for these key groups.

2. **Intended use of information:**
Data collected from these focus groups will support the project's primary purpose of developing, testing, and revising educational materials to address key groups' informational needs regarding generic drugs (Aim 3). The development and evaluation of each set of materials will be directed by the Auburn project PI in accordance with current best practices in the field of instructional design. A rapid prototyping approach will be used in which the first iteration of the educational material will be quickly developed and reviewed by all members of the project team. The focus groups will then provide individualized feedback on iterations of the materials to ensure they adequately account for variations in target audience, content, format and channel. With the portfolio of educational materials created through the focus group and rapid prototyping process, the Auburn/IMPAQ research team will then use a mixed-methods approach including key informant interviews and surveys among key groups to conduct a formative evaluation of the educational materials. A separate information collection request will be submitted to OMB for these interviews and surveys.

3. **Description of respondents:**
A total of 4 focus groups for the following 3 groups will be conducted:
    - Patients/caregivers, aged 19 years or older (2 focus groups)
    - Prescribers/pharmacists, aged 19 years or older (1 focus group)
    - Formulary managers/large purchasers of drugs/policymakers, aged 19 years or older (1 focus group)

4. **Date(s) to be conducted and location(s):**
November 3, 2017 – November 20, 2017

Auburn University, Auburn, AL 36849

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

Recruitment

Auburn research team will recruit prescribers, pharmacists, patients/caregivers, formulary managers, large purchasers of drugs, and policymakers from Auburn University and Edward Via College of Osteopathic Medicine (VCOM) students, faculty, and staff. Participant eligibility differs by group (see Table 1 below and participant email recruitment invitation at Appendix A). Participants who meet the eligibility requirements (see below) 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. Participants who are available and wish to participate in the focus group will receive a reminder via email of their scheduled focus group two days prior to their scheduled discussion date and time.

Table 1. Eligibility for Focus Groups

Group	**Eligibility**
Prescribers	Is 19 years or older, can be physicians or nurse practitioners from the Edward Via College of Osteopathic Medicine (VCOM) and Auburn University School of Nursing, respectively
Pharmacists	Is 19 years or older, can be pharmacists from the Auburn University Harrison School of Pharmacy
Patient/caregivers	Is 19 years or older, can be Auburn University students, faculty, and staff
Formulary managers, large purchasers of drugs, and policymakers	Is 19 years or older, who serves as these roles and also be Auburn University students, faculty, and staff

Focus Groups

Participation will be voluntary. Before each focus group begins, the moderator will review study information, review participants' rights and responsibilities, and obtain written informed consent (Appendix B) from the participants to participate in the study. Written consent will be obtained in order to document each participant's permission to participate in the study. The written informed consent also describes the purpose of the audiotaping and protection of participants' data. Personal identifiable data such as name, address, and Auburn University badge ID will only be collected in connection with honorarium payments and tax withholding (employee only) and will be saved in a password protected folder on a secure server at Auburn University main campus at Auburn, AL. No PHI will be used or disclosed. The moderator will review the informed consent in detail and request permission to audio record the focus group prior to the start of the focus group. Transcription of the audio recordings will be used to analyze participant responses.

Skilled moderators from the Auburn research team will conduct four focus groups among the three groups, with no less than three participants and no more than six participants in each focus group: patients/caregivers (2 focus groups), prescribers/pharmacists (1 focus group), and formulary managers/large purchasers of drugs/policymakers (1 focus group). Each sixty (60) minute focus group will be based on a pre-specified list of questions (see focus group protocols at Appendix C), with additional probing and discussion. Focus groups will be audio recorded and transcribed.

Focus groups for prescribers/pharmacists and formulary managers/large purchasers of drugs/policymakers will review and discuss educational materials developed by the research team in collaboration with FDA. (See Appendix D). We will use FDA-developed generic drug educational materials for the patients/caregivers focus groups. (See Appendix E).

6. Number of focus groups:

There will be a total of four focus groups:

1) Patients and caregivers aged 19 and older (2 focus groups)
2) Prescribers and Pharmacists aged 19 and older (1 focus group)
3) Formulary managers/large purchasers of drugs/policymakers (1 focus group)

7. Amount and justification for any proposed incentive:

The proposed compensation for each participant from each group will be a $25 check. The proposed compensation or "incentive" is not a reward or salary. Rather, it is a stimulus to participate in the focus group. Incentive amount is based on Auburn research team's experience. Consequences of insufficient incentives include increased time and cost of recruitment, increased "no-show" rates, and increased probability of cancelled or postponed focus groups.

Incentives will be distributed upon completion of the focus groups. All incentives will be distributed in a check paid by Auburn University. Personal identifiable data such as name, address, and badge ID will only be collected in connection with honorarium payments and tax withholding (employee only) and will be saved in a password protected folder on a secure server at Auburn University main campus at Auburn, AL. Information will not be shared with anyone outside of the Auburn research team and Auburn University 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.

The focus group recordings will be transcribed verbatim and independently crosschecked by a second researcher. Data saturation will be defined as the point in data collection when no new relevant information or themes had emerged from the focus groups conducted. Content analysis methodologies will be used to analyze results. Two researchers will independently perform data coding and crosscheck thematic analyses.

Data will be analyzed using line-by-line analysis and assigning codes to key thoughts and ideas. The team will analyze the data using Atlas.ti qualitative analysis software. Using Atlas.ti qualitative analysis software, 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 24 hours in total is estimated based on 1 hour focus group discussions for a maximum of 24 participants in 4 focus groups. It should be noted that the maximum of anticipated total number of participants is 24. The minimum of anticipated total number of participants is 12 (3 participants in each group for a total of 4 focus groups).

Table 2. Estimated Reporting Burden

Type/Category of Respondent	**No. of Respondents**	**Participation Time** (minutes)	**Burden** (hours)
Patients and/or caregivers	12	60	12
Pharmacists and prescribers	6	60	6
Formulary managers, large purchasers of drugs, and policymakers	6	60	6
Total	24		24

REQUESTED APPROVAL DATE: November 3, 2017.

NAME OF PRA ANALYST & PROGRAM CONTACT:

Ila S. Mizrachi
Paperwork Reduction Act Staff

301-796-7726
ila.mizrachi@fda.hhs.gov

Mitchell M. Frost
OMPT/CDER/OGD/ORS/DTP
301.796.8624
Mitchell.Frost@fda.hhs.gov

FDA CENTER: Center for Drug Research and Evaluation