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: Focus groups to assess the post-marketing safety of authorized generic drug products

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 "Assessing the post-marketing safety of authorized generic drug products."

Congress passed the Generic Drug User Fee Amendments (GDUFA, Title III of the Food and Drug Administration Safety and Innovation Act (Public Law 112-144)) in July 2012. Under GDUFA, FDA obtains industry and public input to create regulatory science initiatives regarding research on generic drugs that advance public health.[1] Based on this input, post-market evaluation of generic drug**s** was identified as a research priority for fiscal year 2014.[2] One of the research studies funded under this priority was a cooperative agreement with the Brigham and Women's Hospital (U01FD005279) to assess the post-marketing safety of authorized generic drug products; focus groups for which we are seeking approval are being conducted as one part of this cooperative agreement.

More than 8 out of every 10 prescriptions dispensed in the US are for generic drugs.[3] Generic medications contain the same amount of the same active ingredient as their brand-name counterparts and must demonstrate bioequivalence to approved brand-name products. Generic drugs are much less costly than their brand-name counterparts and therefore reduce overall health system spending.[4] Despite potential financial savings associated with generic drug use, negative perceptions of generics are prevalent and patients do not always use generic drugs when they are available.[5]

An "authorized generic drug" is a listed drug as defined in § 314.3 that has been approved under subsection 505(c) of the Food, Drug, and Cosmetic Act and is marketed, sold, or distributed directly or indirectly to retail class of trade with either labeling, packaging (other

[1] GDUFA Regulatory Science. http://www.fda.gov/ForIndustry/UserFees/GenericDrugUserFees/ucm370952.htm
[2] FY 14 GDUFA Regulatory Research Priorities. http://www.fda.gov/Drugs/NewsEvents/ucm367997.htm
[3] IMS Institute for Healthcare Informatics. Medicines use and spending shifts: A review of the use of medicines in the U.S. in 2014. April 2015.
[4] Haas JS et al. Potential savings from substituting generic drugs for brand-name drugs: medical expenditure panel survey, 1997-2000. Ann Intern Med 2005;142:891-7.
[5] Shrank WH et al. Physician perceptions about generic drugs. Ann Pharmacother 2011;45:31-8.

than repackaging as the listed drug in blister packs, unit doses, or similar packaging for use in institutions), product code, labeler code, trade name, or trade mark that differs from that of the listed drug.[6] However, the role of authorized generics in the marketplace is not well understood. Authorized generic drugs are produced by the brand-name manufacturer and are identical to brand-name drug not only chemically, but typically also in appearance. Authorized generics may be priced more like generics and may therefore have the financial benefits of generic drugs. The extent to which physicians and pharmacists are knowledgeable about the role of authorized generic drugs is not known. Moreover, it is not known what value healthcare providers place on the different features of authorized generic products. These focus groups are intended to address these knowledge gaps regarding generic drugs.

2. **Intended use of information:**

Information from these focus groups will be used to assess physicians' and pharmacists' knowledge of and beliefs about authorized generic drug products. Specifically, we aim to:

(1) Assess physicians' and pharmacists' knowledge of and experience with authorized generics;
(2) Elicit their opinions about whether, when, and why they would prefer that patients use authorized generics over brand-name or other generic products; and
(3) Determine the price premium they would place on authorized generics relative to other products.

This information will then be considered as part of the larger research project, which also includes analyses of healthcare databases and the FDA's Adverse Event Reporting System, to better understand how authorized generics might be used in post-marketing surveillance of generic drug products. For example, we expect that focus group results will shed light on how physicians and pharmacists perceive authorized generics as compared to brand-name and other generic products. These perceptions will aid in interpreting the results of other aspects of the larger project by helping us understand the extent to which observed findings in use and outcomes of generic drugs may be related to differing perspectives of authorized generic products as compared to other types of products.

This project is the first to examine the role of authorized generic drugs in the U.S. health care system, and will inform future projects that evaluate and compare generic, authorized generic, and brand name drug products. If this information is not collected, an important piece of the regulatory science research program will be lost, which may prevent or delay the development of future research projects in this area.

3. **Description of respondents:**

Focus groups will include physicians and pharmacists. Eligible physicians are those who spend at least 50% of their time practicing primary care to ensure reasonable opportunity for exposure to authorized generic products. Physicians will be recruited from the practices of

[6] FDA List of Authorized Generic Drugs.
http://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/abbreviatednewdrugapplicationandagenerics/ucm126389.htm

the Brigham and Women's Hospital Primary Care Practice-based Research Network (BWHPC PBRN) and other primary care practices in the Boston, Massachusetts area.

Eligible pharmacists are those who practice in a retail pharmacy setting. Pharmacists will be recruited from local retail pharmacies in Boston, Massachusetts.

Eligible participants may represent a variety of demographic backgrounds and shall not be excluded on the basis of race, gender, or age.

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

All focus groups will be conducted at Brigham and Women's Hospital in Boston, Massachusetts. The focus groups will be held in July 2016.

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

Recruitment

Physicians will be recruited from primary care practice sites that are members of the Brigham and Women's Hospital Primary Care Practice-based Research Network.[7] Letters will be mailed to each office to recruit physicians who spend >50% of their time practicing primary care (See Appendix A). Since physicians will receive recruitment materials via mail to the office, individual identities will not be known to the research team until interested physicians opt in by calling or emailing the study coordinator. The study coordinator will screen interested physicians by telephone or by email, depending on the physician's preference, to determine eligibility (See Appendix B).

Pharmacists will be recruited by letters sent to local retail pharmacies within a 10-mile radius of the office where focus groups will be conducted. As with the physicians, pharmacists will receive recruitment materials via mail to the pharmacy, so the individual identities will not be known to the research team until interested pharmacists opt in by calling or emailing the study coordinator. The study coordinator will screen interested pharmacists by telephone or by email, depending on the pharmacist's preference, to determine eligibility.

Physicians and pharmacists screened by telephone will be told during the initial phone call of their eligibility based on their responses to the screening questions. Physicians and pharmacists screened by email will receive a follow-up email to notify them of their eligibility. All eligible physicians and pharmacists will be re-contacted via telephone or email, based on their preference, to schedule the focus group. All participants will receive an email confirmation with details on the specific time and location of the focus group. A reminder email will be sent to participants three days prior to their focus group (See Appendix B).

Focus Groups

Each focus group will be facilitated by Joshua Gagne, PharmD, ScD, and Michael Fischer, MD. Drs. Gagne and Fischer are investigators on the cooperative agreement under which these focus groups are being conducted (U01FD005279). At the beginning of the focus

[7] Brigham and Women's Primary Care Practice-Based Research Network. http://www.brighamandwomens.org/Research/depts/Medicine/General_Medicine/PBRN/ParticipatingPractices.aspx

group, verbal consent will be obtained from each participant and participants' consent as a whole will be noted in the research record by Drs. Gagne and Fischer (See Appendix C). Individuals who do not give verbal consent will not be able to participate in the focus group.

For the purposes of qualitative data analysis, each focus group will be recorded using a digital audio recording device. Neither personal identifiers nor Protected Health Information (PHI) will be included in any recordings. These recordings will be transcribed for subsequent qualitative analysis. The focus group moderators may also take notes during the focus groups. These notes will not contain personal identifiers or PHI for any focus group participants.

All focus groups will be organized to promote general discussion of the following topics (See Appendix C):

- Concept and definition of an authorized generic
- Knowledge of frequency with which patients use authorized generics
- Preferences regarding patient use of an authorized generic instead of another generic product
- Values assigned to brand-name drugs, authorized generics, and non-authorized generics
- Relative safety and effectiveness of authorized generics, non-authorized generics, and brand-name drugs
- Importance of consistency in pill appearance across refills
- Importance of consistency in manufacturer across refills

6. **Number of focus groups:**

The research team will organize two, two-hour, in-person focus groups for pharmacists and two, two-hour, in-person focus groups for physicians, for a total of four focus groups.

7. Amount and justification for any proposed incentive:

A monetary incentive will be given for participation in a single focus group to pharmacists ($150.00 cash) and physicians ($250.00 cash). This proposed incentive is intended to stimulate participation in focus groups. The incentive also helps reduce the possibility of having to cancel the focus groups, if pharmacists or physicians volunteer to participate but do not actually attend the focus group.[8] Canceling and rescheduling the focus group would result in a much higher cost, in time and in money, than the proposed incentive.

The proposed amounts are based on the Brigham and Women's Hospital investigators' prior experience with focus groups. These incentives are in accordance with standard practice for physicians and pharmacists and take into account their education, training, and experience in patient care.[9] Offering an incentive that is below this accepted rate may result in project costs exceeding the amount saved using a lower incentive.

8. Questions of a Sensitive Nature:

[8] Centers for Disease Control and Prevention: General Guidelines for Focus Groups. http://www.cdc.gov/nccdphp/dnpa/socialmarketing/training/pdf/focusgroupguidelines.pdf

[9] Krueger RA, Casey MA. Focus Groups: A practical guide for applied research. Fourth Edition. SAGE, 2009.

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, and therefore the analyses do not entail the use of statistics. The qualitative analytical methods are described below.

Transcribed recordings and notes from all focus groups will be analyzed using standard qualitative methodologies. As notes and transcripts are read, sections of text that indicate or suggest key themes will be marked and provisionally labeled. The labels will form the basis for a coding scheme, for which each code is defined and illustrated. The process of code development will be iterative and will take place over time. The set of codes accumulated during data review will be repeatedly revisited and revised to produce the final coding scheme. Actual data coding will then consist of reviewing the set of notes and transcripts and assigning codes to the sections of text to which they correspond. Data will be coded using NVivo, a software program for analyzing qualitative data. The findings will be summarized in manuscripts and presentations and shared with stakeholders.

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)
Physicians	16	120	32
Pharmacists	16	120	32
Total	32	--	64

REQUESTED APPROVAL DATE: June 2016

NAME OF PRA ANALYST & PROGRAM CONTACT:

Domini Bean
Paperwork Reduction Act Staff
(301) 796-5733
Domini.Bean@fda.hhs.gov

Saeid Raofi
Office of Generic Drugs
(240) 402-3926
Saeid.Raofi@fda.hhs.gov

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