FDA DOCUMENTATION FOR THE GENERIC CLEARANCE, "TESTING COMMUNICATIONS ON DRUGS PRODUCTS" (0910-0695)

TITLE OF INFORMATION COLLECTION: Educating Groups Influencing Generic Drug Use (Interviews and Surveys)

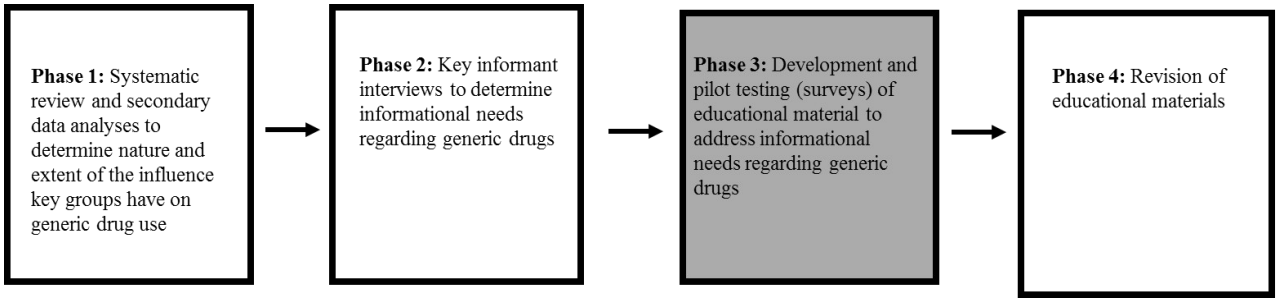
DESCRIPTION OF THIS SPECIFIC COLLECTION

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 0910-0695 to conduct key informant interviews (KII) and surveys for the project "Educating Groups Influencing Generic Drug Use."

Based on the supporting statement for generic clearance 0910-0695,[1] the purpose of information collection under this generic clearance is "to provide tools to assess the need for communications on specific topics and to assist in the development and modification of communication messages to promote public health and compliance with regulations." The specific collection described in this memo aims to determine the informational needs of a variety of groups influencing generic drug use in order to develop communications addressing gaps in knowledge regarding generic drugs and promoting generic drug use. Phase 1 was a systematic review and secondary data analyses and Phase 2 was approved on October 25, 2017. Exhibit 1 illustrates the full set of research phases for this project; please note that this information collection request concerns only Phases 3.

Exhibit 1. Overview of Research Phases



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, the FDA obtains industry and public input to create regulatory science initiatives regarding research on generic drugs that advance public

[1] http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201509-0910-002

health.[2] Once marketed, certain generic drugs are often not preferred over brand drugs[3] [4] [5] [6] even though generic drugs generally cost less than brand drugs.[7] Research to characterize the key influencers of generic drug use (particularly for drug classes with low generic drug use), including their knowledge base and perceptions toward generic drugs, is needed to effectively design and deliver communications about generic drugs to the key groups influencing consumer acceptance and use of generic drugs. To address this regulatory science need regarding generic drugs, the FDA entered into a cooperative agreement with investigators at Auburn University (Auburn) and IMPAQ International (IMPAQ) (Grant Number U01FD005486).

In addition to prescribers, other groups such as pharmacists, patients and their caregivers, formulary managers / pharmacy and therapeutics (P&T) committees, federal and state policy makers, and large purchasers of drugs (group purchasing organizations, pharmacy chains, etc.) also influence the nature and extent of generic drug use.[8,9]

Through a cooperative agreement with Auburn and IMPAQ, the informational needs of these key groups regarding generic drugs will be explored and educational materials targeting these key groups will be assessed through feedback received by participants in key informant interviews (Policymakers, Large Purchasers, and Formulary Managers) and surveys (Prescribers, Pharmacists, and Patients/Caregivers).

2. Intended use of Information:

Data collected from these key informant interviews and surveys will be used to inform the development and revision of educational materials to address the key groups' knowledge gaps regarding generic drugs (Aim 3).

---

[2] http://www.fda.gov/ForIndustry/UserFees/GenericDrugUserFees/ucm370952.htm

[3] Scher, S. (2013) The Branded Advantage. *Ophthamol Mgmt*. July: p18 http://www.ophthalmologymanagement.com/printarticle.aspx?articleID=108618

[4] Alloway, RR, Isaacs R, Lake K, Hoyer P, First R, Helderman H, Bunnapradist S, Leichtman A, Bennett MW, Tejani A, Takemoto SK. (2003) Report of the American Society of Transplantation Conference on Immunosuppressive Drugs and the Use of Generic Immunosuppressants. *A J Transpl* 3: 1211.

[5] Liow K, Barkley GL, Pollard JR, Harden CL, Bazil CW. (2007) Position statement on the coverage of anticonvulsant drugs for the treatment of epilepsy. *Neurology* 68: 1249.

[6] American Thyroid Association, The Endocrine Society, and American Association of Clinical Endocrinologists. (2004) Joint Statement on the U.S. Food and Drug Administration's Decision Regarding Bioequivalence of Levothyroxine Sodium. *Thyroid* 14: 486.

[7] IMS Institute for Healthcare Informatics. (2013) Avoidable Costs in U.S. Healthcare: The $200 Billion Opportunity from Using Medicines More Responsibly. http://www.imshealth.com/deployedfiles/imshealth/Global/Content/Corporate/IMS Institute/RUOM-2013/IHII_Responsible_Use_Medicines_2013.pdf

[8] Tang Y, Gellad WF, Men A, Donohue JM. (2014) Impact of medicare part D plan features on use of generic drugs. *Medical care*. 52(6):541-548.

[9] Berg MJ, Gross RA, Haskins LS, Zingaro WM, Tomaszewski KJ. (2008) Generic substitution in the treatment of epilepsy: patient and physician perceptions. *Epilepsy & behavior* 13(4):693-699.

3. Description of Respondents:

Key informants in each of the following three groups will be interviewed:

- Formulary managers
- Policymakers (federal and state)
- Large purchasers of drugs (group purchasing organizations, pharmacy chains, etc.)

Surveys will be conducted with representatives from the following three groups:

- Prescribers, including physicians, nurse practitioners, and physician assistants
- Pharmacists
- Patients/Caregivers

4. Date(s) to be Conducted:

FDA's contractor for this work, Auburn University/IMPAQ, plans to conduct interviews between March, 2018– June, 2018.

5. How the Information is Being Collected:

Key Informant Interview Recruitment

The Auburn University/IMPAQ research team will develop a list of formulary managers, policymakers, and large purchasers of drugs for recruitment. Participants for these three groups will be identified in collaboration with the FDA and AAM (Association for Accessible Medicines) and no formal screeners will be utilized in identifying members for these three groups. More targeted, informal recruitment will be conducted with these three groups in order to allow the research team to better identify participants from various stages of generic drug utilization (e.g. large purchasers) or across different levels of policy (e.g. state or federal levels of policymaking). Please see Appendix A for the recruitment emails and flyer.

Survey Recruitment

The Auburn University/IMPAQ research team will develop a list of prescribers, pharmacists, and patients/caregivers for recruitment (Appendix A). Participants for the pharmacist and prescriber groups will be identified in collaboration with the Auburn University Harrison School of Pharmacy's Continuing Education (CE) program and the University of Alabama at Birmingham (UAB) Continuing Medical Education (CME) program. Email list-serves targeted to these two groups will be used to recruit participants for these electronic surveys. Participants for the patient/caregiver group will be identified in collaboration with Auburn University's pharmacy services clinics. Pharmacy students and technicians who contact these

patients and their caregivers during routine care will recruit these participants for face-to-face versions of the survey.

Table 1. Eligibility of Participants

Group	**Eligibility**
Formulary Managers	Current member of a P&T committee at the hospital or health plan level
Policymakers	Current federal or state government employee with jurisdiction over generic drug policy
Large Purchasers of Drugs	Bulk purchaser of drugs for large retail chains (e.g., with more than 10 pharmacies) or group purchasing organization
Prescribers	Current physician, nurse practitioner, or physician assistant; US prescriptive authority; works in outpatient or community settings; involved in direct patient care at least 2 days per week
Pharmacists	Current pharmacist licensed to practice in the US; works in outpatient or community settings; involved in direct patient care at least 2 days per week
Patients/Caregivers	Patient: Adult who self-reports taking at least 1 prescription medication in the last 6 months; at least 19 years of age Caregiver: Adult who self-reports being an unpaid caregiver for family or friends during the last 6 months; self-reports helping family/friends manage at least 1 prescription medication in the last 6 months; at least 19 years of age

Key Informant Interview Approach

Skilled interviewers from Auburn and IMPAQ will conduct up to eighteen (18) phone interviews with no less than six participants each from the formulary managers, policymakers, and large purchasers of drugs groups. Each thirty (30) minute interview will be based on a list of questions (interview guides in Appendices D, E, and F for the three key groups, respectively), with additional probing and discussion. Prior to the interview participants will receive a hard or soft copy of the educational materials. Participants will be required to review the educational material at the beginning of the scheduled interview. The review should take no more than 15 minutes, bringing the time commitment total to 45 minutes. Interviews will be audio recorded and transcribed verbatim (see below).

Participation is voluntary. Before the interview begins, the facilitator will obtain verbal consent (Appendix B: informed verbal consents (information letters) for key informant interviews) from the participant to record the session. The consent form also mentions the audiotaping. The interviewer will review the consent form and request permission to audio record the interview prior to the start of the interview.

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

Survey Approach

Prescribers and pharmacists
Survey invitations will be emailed to participants from each of the provider groups (prescribers and pharmacists). A sample of 100 participants per provider group is targeted, for a total sample size of 200 providers. Based on the investigators' previous survey research with these participant groups, a survey response rate of 40% is expected. Accordingly, a random sample of 250 participants from each list-serve group will be sent survey invitations (250 x 40% = 100). Response rate will be increased with provision of incentives for survey completion and email reminders.

The email invitations will contain embedded links to the survey information letter, hosted on Qualtrics. Participation is voluntary. Prescribers and pharmacists who indicate willingness to proceed after viewing the information letter (Appendix C: consents for surveys) will be directed to the survey. Prescribers and pharmacists will first be shown an electronic version of the education material for their review (approximately 5 minutes), followed by the remainder of the survey (approximately 15 minutes), for a total time commitment of 20 minutes. Attention filters will be used to exclude participants who may not have reviewed the entire education material. Survey protocols for prescribers and pharmacists are presented in Appendices G and H, respectively.

Patients and caregivers
Patients and caregivers who are clients of Auburn University's pharmacy services clinics will be recruited in-person by pharmacy students and technicians at the conclusion of routine patient appointments. Pharmacy students and technicians will identify patients/caregivers who meet the eligibility criteria, explain the purpose of the study, and review the informed consent document with these potential participants. Written informed consent will be obtained at this time. Recruitment will be increased with provision of incentives for survey completion.

Those who consent and meet the eligibility criteria will be guided through the face-to-face survey by the pharmacy student or technician at the point of recruitment. Participation is voluntary. Investigators will first show consenting patients/caregivers a paper copy of the education material for their review (approximately 5 minutes), and will then administer the survey (approximately 25 minutes), for a total time commitment of 30 minutes. Pharmacy students/technicians will be present to answer any questions the patients/caregivers may have as they take the survey. Survey protocol for patients/caregivers is presented in Appendix I.

6. Confidentiality of Respondents:

Key Informant Interviews
Auburn, IMPAQ, and FDA will comply with safeguards for ensuring participant information is kept private to the extent permitted by law. The interviewees will be informed about how the recordings are used in the analyses, and assured that the recorded data are kept private to the extent permitted by law.

Recordings will be saved on a secure webserver prior to being stored on a secure server at the IMPAQ headquarters. Once recordings are downloaded to the IMPAQ server, they will be deleted from the webserver. Audio recordings will be transcribed, and transcriptions will be saved and stored in a de-identified format on the IMPAQ server. Verbatim quotes included in the final report will not be attributed to any individual.

Surveys
Electronic survey data (prescribers and pharmacists) will initially be housed on the Qualtrics servers and then completely de-identified data files will be downloaded and stored on the Auburn University SPIRIT server. Qualtrics' datacenters are access restricted and require authorization. All computer equipment (servers, SANS, switches, routers, etc.) is redundant and is located in secure, environmentally controlled data centers with 24/7 monitoring. Web traffic does not directly access the database and database requests are sent reverse proxy via an application server to the database. Paper surveys (patients/caregivers) will be stored in a locked cabinet within the investigator's locked office at the Auburn site. After electronic data entry of the paper copies, all paper copies will be destroyed and electronic copies stored on Auburn's SPIRIT server. Auburn's secure SPIRIT server is housed in the OIT building. This datacenter is staffed 24/7 and is protected by video systems and biometric access. The SPIRIT datacenter also provides two independent power distribution systems, data system environmental controls, a one megawatt power protection battery array, and a pair of diesel generators for backup power. The SPIRIT server contains restricted access only to project personnel and the server administrator.

Data from this study may be used in publications and/or presentations. Participant names and other identifying information will be removed before the data is used. Identifying information will not be used in publications unless written consent from participants is obtained.

7. Amount and Justification for any Proposed Incentive:

Key Informant Interviews

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 interview. 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.

Incentives are based on the Auburn-IMPAQ team's previous experience conducting key informant interviews with these particular groups. 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 interviews.

Incentives will be distributed upon completion of each interview. All incentives will be distributed in a check paid by IMPAQ International. The name and address of the recipient and date mailed will be the only information noted. For those participants in which an annual amount of $600 or more is expected to be issued by IMPAQ International 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 private to the extent permitted by law and stored on a secure server. Information will not be shared with anyone outside of the IMPAQ financial staff. Upon completion of this project all participant information that were kept private to the extent permitted by law not pertinent to financial record keeping will be destroyed.

Surveys

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 survey. 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.

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, decreased survey response rate, and decreased participant engagement with survey content.

Table 2. Respondent Compensation

Group	**Incentive Amount**
Formulary Managers	$75
Policymakers	$75 (If Applicable)
Large Purchasers of Drugs	$75
Prescribers	$50
Pharmacists	$50
Patients/Caregivers	$25

Incentives will be distributed upon completion of each survey. All incentives will be distributed in a check paid by Auburn University. The name and address of the recipient and date mailed will be the only information noted. All financial records will be kept private to the extent permitted by law and stored on a secure server. Information will not be shared with anyone outside of the Auburn 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 during the key informant interviews or surveys.

9. Description of Statistical Methods:

Key Informant Interviews

The key informant interviews are a qualitative component of the study using a convenience sample. As such, the analyses do not entail the use of statistics. Using NVivo 11 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.

Surveys

Data will be analyzed using descriptive statistics. Means responses and percentages will be calculated. Statistics will include means/standard deviations and numbers/ percentages. Comparisons will be made with t-tests, ANOVA, and chi-square tests. Analyses will use SPSS version 24 survey software.

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

Key Informant Interviews

Approximately 20.25 hours in total based on 45 minute (formulary managers, policy makers and large purchasers of drugs) interviews for a maximum of 27 participants across 3 groups. It should be noted that the anticipated total number of interviews is only 18, but we have included the maximum number of respondents and burden in order to allow the researchers the possibility to conduct additional interviews to reach qualitative data saturation.

Survey

Approximately 117 hours in total based on 20 minute surveys (prescribers and pharmacists) or 30 minute (patients/caregivers) for a maximum of 300 participants across 3 groups.

A total of 327 respondents will participate in the study; 300 participants for the survey and 27 participants for the key informant interviews.

Table 3. Estimated Reporting Burden Hours

Type/Category of Respondent	**No. of Respondents**	**Participation Time** (minutes)	**Burden** (hours)
Key Informant Interviews			
Formulary managers	9	45	6.75
Policy makers (federal and state)	9	45	6.75
Large purchasers of drugs (group purchasing organizations, pharmacy chains, etc.)	9	45	6.75
Sub Total	27	--	20.25
Surveys			
Patients /Caregivers	100	30	50
Prescribers	100	20	33.3
Pharmacists	100	20	33.3
Sub Total	300	--	116.6
Total Reporting Burden Hours	327		136.85

REQUESTED APPROVAL DATE: March, 2018.

NAME OF PRA ANALYST & PROGRAM CONTACT:

Ila S. Mizrachi
Paperwork Reduction Act Staff
Ila.Mizrachi@fda.hhs.gov
301.796.7726

Murewa Oguntimein M.H.S, CHES
LCDR- USPHS
Social Scientist
Division of Therapeutic Performance
Office of Research and Standards
301.796.4869
Oluwamurewa.oguntimein@fda.hhs.gov

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