FDA DOCUMENTATION FOR THE GENERIC CLEARANCE OF FOCUS GROUPS AS USED BY THE FOOD AND DRUG ADMINISTRATION (0910-0497)

TITLE OF INFORMATION COLLECTION: Focus Groups on FDA's Accelerated Approval Process

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. Statement of need:

FDA may grant accelerated approval to a drug under Subpart H**:** Accelerated Approval of New Drugs for Serious or Life-Threatening Illnesses (see 21 C.F.R. §§ 314.500, 314.510) or Subpart E: Drugs Intended to Treat Life-Threatening and Severely-Debilitating Illnesses (see 21 C.F.R. §§312.80-88). Direct-to-consumer promotion of prescription drugs granted accelerated approval does not always disclose this approval status. These focus groups are the first step in a research project that will help determine whether including a disclosure explaining the drug's accelerated approval status is useful for consumers and if so, the best way to present it in consumer-friendly language.

2. Intended use of information:

These focus groups will provide FDA with information about how consumers understand information about the accelerated approval process. We will also use the qualitative data gathered here to create stimuli for a future quantitative study of accelerated approval information. The long-term objective is to ensure effective communication of prescription drug information.

3. Description of respondents:

We will recruit participants for eight focus groups. Participants will be recruited by local focus group facilities that may use a combination of web prescreening and telephone screening to screen and recruit participants. Facilities will recruit 12 participants for nine completes per focus group (total $n = 72$). The target population for this study is English-speaking adults, 18 years old and over. Individuals will be excluded from participating if (1) they work in certain professions (i.e., market research firm, pharmaceutical company, FDA, or medical profession), (2) they haven't visited a doctor or hospital for a medical condition in the past two years, or (3) they participated in a focus group within the past three months. We will use questions about age, gender, race/ethnicity, education, income, and health experiences (i.e., "Have you or someone in your close family ever suffered from a serious medical condition?) to recruit a range of participants. Finally, we will ask questions related to health literacy. Based on the health literacy responses, participants will be recruited into one of two focus group compositions — four groups composed of low health-literacy participants or four groups of average/high health-literacy participants.

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

We will conduct eight focus groups between February, 2018 and April, 2018 (pending OMB approval), across four geographic regions: South, Mid-Atlantic, Midwest, and Southwest.

The locations will be Baltimore, MD; Oklahoma City, OK; Albuquerque, NM; and Little Rock, AK, with an additional focus group conducted in Arlington, VA, at Fors Marsh Group's office.

Through public-use data sets, we identified and located these study sites to maximize the desired population characteristics. In order to capture a significant low-literacy segment of the population, we considered several variables: educational attainment, socio-economic status, racial demographics, as well as certain variables related to health.

5. How the Information is being collected:

Recruitment Procedures

FDA's contractor, Fors Marsh Group, will conduct recruitment procedures in collaboration with focus group facilities in four cities across the United States. Facilities will be responsible for (1) contacting potential participants, (2) screening potential participants, (3) scheduling participants, and (4) confirming participants' appointments. Facilities will recruit potential focus group participants from their database, and recruitment procedures may involve telephone- or web-based methods. All participants will be required to go through a screener (attached) to ensure their eligibility for the focus groups. Facilities will recruit 12 participants for nine completes per focus group (total $n = 72$), after which they will be scheduled and confirmed into a focus group time and date.

Method

Eight focus groups (two in each of the four locations across the United States) will be conducted. When participants arrive at the facility, they will be provided with an informed consent form (attached). The focus group moderator will use a discussion guide and associated materials (stimuli and worksheets; attached) to guide and conduct the focus group sessions. The focus group moderator will explain the accelerated approval process to participants and ask for their perceptions and reactions. The focus groups will explore the types of information participants would like to have when making decisions about prescription drugs.

Focus group sessions will be audio recorded, and remote login information will be provided to study staff to observe the focus groups in real time.

Focus groups will last approximately 60 minutes.

6. Confidentiality of Respondents:

Participants will view an informed consent form before proceeding to the study. Participants will not be asked for any personal identifying information besides their first name (full names and contact information are only used in the recruiting process and are not shared with the researchers). Although moderators will address focus group participants by their first name to create rapport and facilitate discussion, names will be redacted from transcripts of the sessions. Participants' responses will not be linked to their name or other identifying information. Participants will be provided with a unique ID (e.g., AK5) that they will use

when they complete the group worksheets, which will protect participant privacy and confidentiality. The findings from this research will be evaluated in aggregate.

Focus group sessions will be audio recorded and livestreamed for reporting purposes. Only FDA personnel and other study team members who are directly involved in the research will view the livestream and have access to the audio files. Livestreaming connections will be secure, using industry-standard firewalls and security practices. All data will be encrypted in transit using secure hypertext transfer protocol (HTTPS). All equipment will be operated and maintained according to industry-standard practices, and all software will be validated using industry-standard, quality-assurance practices. The consent forms will notify participants of both the audio recording and livestreaming. At the beginning of the focus group, the moderator will confirm consent by receiving verbal affirmation from the participants to audio record and livestream the session.

The contractor will not share personal information regarding participants with any third party without the participant's permission unless it is required by law to protect their rights or to comply with judicial proceedings, court orders, or other legal processes. If a participant makes a direct threat of harm to himself or herself, or others, the contractor reserves the right to take action out of concern for him or her and for others.

All data will also be maintained in consistency with the FDA Privacy Act System of Records #09-10-0009 (Special Studies and Surveys on FDA Regulated Products). All identifying information, including information collected during screening and audio recordings, will be kept on a separate password-protected computer and/or in locked cabinets for a period of three years and will only be accessible by the contractor, after which they will be destroyed by securely shredding the documents or permanently deleting electronic information.

7. Amount and Justification for Any Proposed Incentive:

Participants will receive a $75 incentive for participating in the focus groups. Following OMB's "Guidance on Agency and Statistical Information Collections," we offer the following justification for our use of this incentive.

Burden on the respondent: This data collection involves in-person focus groups. As participants often have competing demands for their time, incentives are used to encourage participation in research. When applied in a reasonable manner, incentives are not an unjust inducement and are an approach that acknowledges respondents for their participation.[1] The use of incentives treats participants justly and with respect by recognizing and acknowledging the effort that they expend to participate. Incentives must be high enough to equalize the burden placed on respondents with respect to their time and cost of participation,[2] as well as to provide enough motivation for them to participate in the study rather than another activity.

Data quality/Improved coverage of specialized respondents, rare groups, or minority populations: This data collection involves recruiting participants with low and high health literacy. Previous research suggests that providing incentives may help reduce sampling bias

1 Halpen, S.D., Karlawish, J.H., Casarett, D., Berlin, J.A., & Asch, D.A. (2004). Empirical assessment of whether moderate payments are undue or unjust inducements for participation in clinical trials. *Archives of Internal Medicine, 164*(*7*), 801–803.

2 Russell, M.L., Moralejo, D.G., & Burgess, E.D. (2000). Participants' perspectives. *Journal of Medical Ethics*, *26*(*2*), 126–130.

by increasing rates among individuals who are typically less likely to participate in research (such as those with lower education).[3] Furthermore, there is some evidence that using incentives can reduce nonresponse bias in some situations by bringing in a more representative set of respondents.[4]

Reduced survey costs: If the incentive is not adequate, participants may agree to participate and then not show up or drop out early. Low participation may result in inadequate data collection or, in the worst cases, loss of government funds associated with moderator and observer time.[5] Additionally, low participation can cause a difficult and lengthy recruitment process that in turn, can cause delays in launching the research, both of which lead to increased costs.

8. Questions of a Sensitive Nature:

The discussion will often revolve around the context of serious illness, given that accelerated approval is for drugs that treat serious or life threatening conditions. This topic may be distressing to participants who have experienced serious illness themselves or who have had a close family member experience a serious illness. The discussion guide is not designed to encourage personal recounts of serious illness, and the moderator will be trained to deal with these recounts sensitively if they occur. Participants will also be reminded that their participation is voluntary, that they may withdrawal without penalty, and that they do not have to answer any questions they do not wish to answer.

9. Description of Statistical Methods (i.e., Sample Size and Method of Selection):

No statistical methods will be used.

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

Table 1 shows the estimated annual reporting burden.

	No. of Respondents	**No. of Responses per Respondent**	**Total Annual Responses**	**Average Burden per Response (in Hours)**	**Total Hours**
Number to complete the screener	400	1	400	.08 (5 min.)	32
Number to complete the study	72	1	72	1.00 (60 min.)	72
Total			472		104

3 Guyll, M.., Spoth, R.., & Redmond, C. (2003). The Effects of Incentives and Research Requirements on Participation Rates for a Community-Based Preventive Intervention Research Study. *Journal of Primary Prevention*, vol. *24*(1), pp. 25-41.

4 Castiglioni, L., & Pforr, K. (2007). The effect of Incentives in Reducing Non-Response Bias in a Multi-Actor Survey." Presented at *The 2nd Annual European Survey Research Association Conference*, Prague, Czech Republic; Singer, E., (2006). Nonresponse Bias in Household Surveys. *Public Opinion Quarterly*, vol. 70(5), pp. 637-645.

5 Morgan, D.L. & Scannell, A.U. (1998). *Planning focus groups*. Thousand Oaks, CA: Sage.

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