FDA DOCUMENTATION FOR THE GENERIC CLEARANCE OF FOCUS GROUPS (0910-0497)

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 on Perceptions of Prescription Drug Promotion and Approval Review Process (Formative Research)

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. **Statement of need:**

The Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER), Office of Prescription Drug Promotion is seeking OMB approval under the generic clearance 0910-0497 for the focus group project, "Perceptions of Prescription Drug Promotion and Approval Review Process (Formative Research)."

The U.S. Food and Drug Administration (FDA; 2018[1]) regulates the approval process for prescription drugs. Although it has broad regulatory authority over prescription drug promotion, FDA does not pre-approve prescription drug promotional material (e.g., print and television advertisements, websites, digital ads) except in certain circumstances (e.g., Subpart H products). The Agency may provide advisory comments if requested by the sponsor, and all promotional material must be submitted to FDA at the time they are initially disseminated; however, pharmaceutical companies can also disseminate promotional material without prior FDA review or comment (Prescription-drug advertisements, Title 21 eCFR §202.1). Despite efforts to explain and clarify this process to the public, confusion remains. Surveys of consumers conducted over the past 20 years show little change in the misconceptions associated with FDA's role in reviewing and approving prescription drug promotions. For example, Bell, Kravitz and Wilkes (1999)[2] found that 43% of consumers in a telephone survey thought that only "completely safe" drugs could be advertised. Another survey of patients conducted in 1999 and 2002 found that between 21% (2002) and 31% (1999) agreed that "only the safest prescription drugs" were allowed to be advertised to the public (Aikin, Swasy, & Braman, 2004)[3]. More recently, O'Donoghue and colleagues (2016)[4] found that 25.8% of consumers indicated that only drugs that were "extremely effective" could be advertised to the public, and 68.8% indicated that FDA must approve prescription drug ads *before* they appear to the

[1] U.S. Food and Drug Administration (FDA). (2018, June 13). *Development and approval process (Drugs).* https://www.fda.gov/drugs/developmentapprovalprocess/default.htm

[2] Bell, A. B., Kravitz, R. L., & Wilkes, M. S. (1999). Direct-to-consumer prescription drug advertising and the public. *Journal of General Internal Medicine, 14*(11), 651–657. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1496757/pdf/jgi_01049.pdf

[3] Aikin, K. J., Swasy, J., & Braman, A. C. (2004). Patient and physician attitudes and behaviors associated with DTC promotion of prescription drugs: Summary of FDA survey results. Silver Spring, MD: FDA.

[4] O'Donoghue, A. C., Sullivan, H. W., Williams, P. A., Squire, C., Betts, K. R., Fitts Willoughby, J., & Parvanta, S. (2016). Consumers' understanding of FDA approval requirements and composite scores in direct-to-consumer prescription drug print ads. *Journal of Health Communication, 21*(8), 927–934. doi:10.1080/10810730.2016.1179367

public. This suggests that many people continue to believe that FDA is involved in reviewing promotional content in advance, which may influence the trust they put in the information contained in promotional materials.

Information about the status of FDA review of promotional materials could be disseminated through use of a disclosure but the literature on disclosures is mixed. Studies have reported low levels of recall for warnings and disclosures for a variety of products (Bhalla & Lastovicka, 1984[5]; Houston & Rothschild, 1980[6]; Jacoby & Witherspoon, 1982[7]; Scammon, 1977[8]). Surveys of consumer attitudes have found that many people (40%+) believe that supplements are approved by FDA (Pillitteri et al., 2008[9]), despite awareness of the Dietary Supplement Health and Education Act (DSHEA) disclaimer[10] (Mason & Scammon, 2011[11]). A study by Asher et al. (2008)[12] found that after exposure to an advertisement for a weight-loss supplement, 10% thought the product was FDA-approved and 7% thought the ad itself was FTC-approved. In the context of prescription drug promotion, there is initial evidence that—when noticed—disclosures may effectively convey important information (Betts et al., 2017[13]; Betts et al., 2018[14]; Sullivan, O'Donoghue, David & Patel, 2018[15]); however, whether disclosures (or signals like those indicated in the current study) can educate or correct misunderstanding warrants further investigation.

Consumer understanding of the prescription drug approval process is lacking, and many misconceptions about the process and requirements persist. Although healthcare professionals (HCPs) may have a deeper understanding than consumers of the approval required for prescription drugs, it is unclear to what extent they understand the details of FDA's oversight role with regard to promotion or the best way to communicate this information in the context of a promotional piece. To our knowledge, no research has examined these issues with HCPs or compared HCPs to consumers.

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[5] Bhalla, G., & Lastovicka, J. L. (1984). The impact of changing cigarette warning message content and format. *ACR North American Advances*.

[6] Houston, M. J., & Rothschild, M. L. (1980). Policy-related experiments on information provision: a normative model and explication. *Journal of Marketing Research*, 432-449.

[7] Jacoby, L. L., & Witherspoon, D. (1982). Remembering without awareness. *Canadian Journal of Psychology*, *36*(2), 300.

[8] Scammon, D. L. (1977). "Information load" and consumers. *Journal of Consumer Research*, *4*(3), 148–155.

[9] Pillitteri, J. L., Shiffman, S., Rohay, J. M., Harkins, A. M., Burton, S. L., & Wadden, T. A. (2008). Use of dietary supplements for weight loss in the United States: results of a national survey. *Obesity*, *16*(4), 790-796.

[10] "This statement has not been evaluated by the Food and Drug Administration (FDA). This product is not intended to diagnose, treat, cure, or prevent any disease."

[11] Mason, M. J., & Scammon, D. L. (2011). Unintended consequences of health supplement information regulations: the importance of recognizing consumer motivations. *Journal of Consumer Affairs*, *45*(2), 201-223.

[12] Asher, B.H., Miller, R.G., Pichard, C.P., Levine, R., & Wright, S.M. (2008). Patients' Understanding of the Regulation of Dietary Supplements. *Journal of Community Health*, *33*, 22-30. doi 10.1007/s10900-007-9063-7

[13] Betts, K. R., Aikin, K. J., Boudewyns, V., Johnson, M., Stine, A., & Southwell, B. G. (2017). Physician response to contextualized price-comparison claims in prescription drug advertising. *Journal of Communication in Healthcare*, *10*(3), 195-204.

[14] Betts, K. R., Boudewyns, V., Aikin, K. J., Squire, C., Dolina, S., Hayes, J. J., & Southwell, B. G. (2018). Serious and actionable risks, plus disclosure: Investigating an alternative approach for presenting risk information in prescription drug television advertisements. *Research in Social and Administrative Pharmacy*, *14*(10), 951-963.

[15] Sullivan, H. W., O'Donoghue, A. C., David, K. T., & Patel, N. J. (2018). Disclosing accelerated approval on direct-to-consumer prescription drug websites. *Pharmacoepidemiology and Drug Safety*, *27*(11), 1277-1280.

A. Objectives

This project phase will explore HCP and consumer beliefs about FDA's role in review and approval in DTC and professional promotion and drug approval status.

2. **Intended use of information:**

The qualitative information collected from this study will contribute to subsequent quantitative experimental research.

3. **Description of respondents:**

A total of nine focus groups are planned; five with adult consumers (aged 18 and over) and four with HCPs (general practice Primary Care Physicians and advanced practitioners [nurse practitioners and physicians assistants]). No more than 10 participants will participate in a group. FDA has contracted with RTI International to conduct these in-person focus groups.

Eligible participants for the **Healthcare Provider** groups will be in general practice (PCPs and advanced practitioners), who engage in direct patient care at least 50% of the time, and we will ensure reasonable diversity of number of years in practice. We will exclude individuals who work in the marketing, advertising, or pharmaceutical industries or people that work for the Department of Health and Human Services because they may have specialized knowledge of FDA regulatory policies.

Eligible participants for the **Consumer** groups will be general population adults (divided by education level). We will exclude individuals who work in the health care, marketing, advertising, or pharmaceutical industries or people that work for the Department of Health and Human Services because their knowledge and experiences may not reflect those of the average consumer.

In addition to the above screening criteria, we will exclude individuals who have participated in an interview or focus group during the previous 3 months to minimize the threat of trained responses or social desirability bias.

Our participant segments are as follows:

Healthcare Providers (4 groups; n=36):

- PCPs (2 groups; n=18)
  - 1 group each in Atlanta and Washington, DC
- Advanced Practitioners (Nurse Practitioners and Physicians Assistants) (2 groups; n=18)
  - 1 group each in Atlanta and Washington, DC

Consumers (5 groups; n=45)

- Less than High School education (n=2 groups; n=18)

- 2 groups in Atlanta

- High School or more education (n=3 groups; n=27)
  - 1 group in Atlanta; 2 groups in Washington, DC

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

   Focus groups will be conducted approximately one month from the date of OMB approval. The focus groups will be conducted Washington, DC and Atlanta, GA. The selected locations offer suitable focus group facilities and recruitment capabilities that will enable us to recruit groups who meet the criteria described in Section 3 above.

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

   Recruitment Information
   Selected market research facilities and recruiters will identify potential participants in their respective cities through existing contact databases and social media advertisements (Attachment A). The market research facilities and recruiters will contact potential participants by telephone or email and screen them for eligibility using the participant screener (Attachment B). The facilities' staff will provide all necessary information and instructions to ensure participants arrive at the proper location on the agreed upon date and time. Facilities will conduct recruitment and ensure that the needed number of participants show up for their scheduled time slot. The facilities will send confirmation and reminder correspondences to recruited participants to help ensure attendance (Attachments C and D).

   Focus Group Discussions
   RTI staff members will serve as moderators for all focus groups. RTI staff members will administer the informed consent prior to the beginning of the focus groups and provide a hard copy of the informed consent (Attachments E and F) to participants. FDA staff members will observe most, if not all, of the sessions from the observation rooms at the focus group facilities or remotely using streaming technology.

   The moderator will use the attached moderator guides (Attachments G and H) to ensure that all relevant topic areas are addressed, including discussion about disclosure signals in promotional materials. The focus group facilities will make audio and video recordings to ensure a verbatim record of the proceedings is captured.

   The Contractor will comply with safeguards for ensuring participant information is kept secure to the extent permitted by law. The last names of the participants will not appear on any focus group materials. Verbatim quotes included in the final report will not be attributed to any individual.

6. **Number of focus groups:**

   A total of nine focus groups of eight to 10 participants will be conducted.

7. **Amount and justification for any proposed incentive:**

To prepare for these focus groups, we consulted with facilities that recruit and host focus groups to determine appropriate amounts as tokens of appreciation for participants' time. Based on these consultations, we propose $100 for consumers and $300 for HCPs for 90 minutes to ensure that we are able to attract a reasonable cross section of consumers and HCPs.

Significant time and other burdens accompany participation in research, as well as the process of conveying importance to participants. Incentives or honorariums are intended to help defray these "costs" (i.e., burdens) in order to encourage individuals to participate (Klabunde et al., 2012[16]). Numerous empirical studies have established that incentives can significantly increase participation rates among both consumers and HCPs (see, for example, Abreu & Winters, 1999[17]; Aikin et al., 2016[18]; Dykema et al., 2011[19]; Medway & Tourangeau, 2015[20]; Mercer et al., 2015[21]; Shettle & Mooney, 1999[22]; Thorpe et al., 2008; VanGeest et al., 2007). As a result, incentives have become a standard facet of market research across a variety of audience groups. The importance of monetary compensation for focus group participation has been discussed by Krueger and Casey (2014), who indicate that offering monetary compensation can help ensure that sufficient numbers of participants will attend, thereby yielding more useful research results.[23] Further, in a meta-analysis of 38 experiments and quasi-experiments, Church (1993) found that providing cash incentives for participation was far more effective than nonmonetary gifts in generating survey response, and prepaid monetary incentives yielded an average increase of 19.1 percentage points over comparison groups.[24] When applied in a reasonable manner, incentives are not an unjust inducement and are an approach that acknowledges respondents for their participation and treats them justly and with respect by recognizing and acknowledging the effort they expend to participate.[25]

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[16] Klabunde, C. N., Willis, G. B., McLeod, C. C., Dillman, D. A., Johnson, T. P., Greene, S. M., & Brown, M. L. (2012). Improving the quality of surveys of physicians and medical groups: a research agenda. *Evaluation & the Health Professions*, *35*(4), 477-506.

[17] Abreu, D. A., & Winters, F. (1999). Using monetary incentives to reduce attrition in the survey of income and program participation. In *Proceedings of the Survey Research Methods Section, American Statistical Association.* Baltimore, MD (pp. 533-538).

[18] Aikin, K.J., Betts, K., Boudewyns, V., Stine, A., & Southwell, B. (2016). Physician responsiveness to survey incentives and sponsorship in prescription drug advertising research. *Annals of Behavioral Medicine*, 50(Supp. 1): S1-S335.

[19] Dykema, J., Stevenson, J., Day, B., Sellers, S. L., & Bonham, V. L. (2011). Effects of incentives and prenotification on response rates and costs in a national web survey of physicians. *Evaluation & the health Professions*, *34*(4), 434-447.

[20] Medway, R. L., & Tourangeau, R. (2015). Response quality in telephone surveys: do prepaid cash incentives make a difference? *Public Opinion Quarterly*, *79*(2), 524-543.

[21] Mercer, A., Caporaso, A., Cantor, D., & Townsend, R. (2015). How much gets you how much? Monetary incentives and response rates in household surveys. *Public Opinion Quarterly*, *79*(1), 105-129.

[22] Shettle, C., & Mooney, G. (1999). Monetary incentives in US government surveys. *Journal of Official Statistics*, *15*(2), 231.

[23] Krueger, R.A. & M.A. Casey. (2014). Focus groups: A practical guide for applied research. (5th ed.). Thousand Oaks, CA: Sage Publications, Inc.

[24] Church, A.H. (1993). Estimating the effect of incentives on mail survey response rates: A meta-analysis. *Public Opinion Quarterly*, 57, 62-79.

[25] 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.

Finally, the importance of monetary incentives has been corroborated in experiences related to the National Adult Literacy Survey by Berlin and colleagues (1992)[26].

Our experience in conducting focus group research indicates that offering nonmonetary incentives or an incentive that is below the commonly accepted rate will result in increased costs that exceed the amount saved on a reduced incentive. The consequences of an insufficient incentive include the following:

- Increased time and cost of recruitment
- Increased likelihood of "no-shows" (which may result in methodologically unsound focus groups with small numbers of participants)
- Increased probability that a focus group may need to be cancelled or postponed due to insufficient numbers recruited by the scheduled date of the focus group, which not only incurs additional costs, but also puts additional burden on the recruited participants who have to reschedule their participation in the focus group.

Consumers

We plan to offer a $100 incentive for adult consumers who complete their participation in one of the 90-minute in-person focus groups to be held (in Atlanta, GA and the Washington, DC area). RTI has consulted with several research firms with experience recruiting and hosting qualitative research across multiple markets (Schlesinger Group, L&E Research, Focus Pointe Global, Plaza Research, Fieldwork), including those indicated for the current study (Atlanta, GA and the Washington, DC area). All of the contacted research firms have extensive experience working with government-funded studies and understand the processes for working within the parameters of these studies, including incentive parameters. All research firms confirmed that the incentive amount of $100 is consistent with what consumers require for participation in 90- to 120-minute in-person studies. The firms' feedback also reflected the concerns over insufficient incentives noted above.

In addition, this $100 incentive amount is consistent with other research conducted by RTI, including recent and current studies with FDA, where $75 has been used as the incentive for **60-minute interviews** with consumers, including *Hearing, Aging, and Direct-to-Consumer Television Advertisements* (OMB Control number 0910-0818), *Disclosure Regarding Additional Risks in Direct-to-Consumer Prescription Drug Television Advertisements Study* (under generic OMB Control Number 0910-0695), the *Experimental Study of Comparative Direct-to-Consumer (DTC) Advertising* (OMB Control Number 0910-0707), and the *Risk and Benefit Perception Scale Development* (under generic OMB Control Number 0910-0497). Increasing the participation time to *90 minutes* warrants the higher incentive rates because of the longer time commitment. This project includes **90-minute interviews** to collect in-depth data that will inform subsequent study phases to ensure their effectiveness and efficiency.

Other important considerations include the ability to attract a reasonable cross-section of participants, reflecting diversity in age, income, and education, as well as prevent a low

[26] Berlin, M., L. Mohadjer, J. Waksberg, A. Kolstad, I. Kirsch, D. Rock, & K. Yamamoto. (1992). An experiment in monetary incentives. In *Proceedings of Survey Research Methods Section, American Statistical Association*. Alexandria, VA. (pp. 393–398).

show rate. The $100 incentive will help to facilitate sample diversity and sufficient show rates.

Healthcare Providers

Considering the time and burden associated with participation in research is also important when the study includes HCPs who are more difficult to recruit than are members of the general population. For example, many HCPs work irregular hours and must respond to clinical emergencies, making them less available to participate in research that must be scheduled in advance (Asch, Connor, Hamilton, & Fox, 2000[27]). The amount of time required for data collection also limits HCPs' participation in research. These time constraints are particularly salient for qualitative data collections like focus groups because they tend to be more time consuming than surveys and may require travel to an offsite location.

For this study, we will provide all HCP participants with a $300 honorarium for their participation in the 90-minute focus group. Past experience on other projects RTI has conducted, and our recent consultation with several research firms across multiple markets (Schlesinger Group, L&E Research, Focus Pointe Global, Plaza Research, Fieldwork), show that offering the $300 incentive is consistent with what HCPs require to take time out of their already time-constrained clinical practices to participate in these types of research projects. Honorariums of similar rates for HCPs have also been supported by research showing that monetary incentives result in higher response rates than do nonmonetary incentives, and higher incentives (up to or exceeding $500) yield greater participation than do lower incentives (Krueger & Casey, 2015).

In addition, the $300 incentive amount is consistent with other studies OMB has approved for several FDA research projects, including the current *Healthcare Providers' Understanding of Opioid Analgesic Abuse-Deterrent Formulations (ADF) Study* (under generic OMB control number 0910-0847), and previous FDA studies, including *Testing Communications on Biological Products* approved in 2014 (under generic OMB Control Number 0910-0687).

Our proposed incentive amounts will help ensure that respondents honor their commitment of participating in the focus group focus groups.

8. **Questions of a Sensitive Nature:**

None.

9. **Description of statistical methods (i.e., sample size & method of selection):**

Facilities will contact prospective participants by telephone and screen them for eligibility to participate (Attachment B). The facilities' staff will provide all necessary information and instructions to ensure participants arrive at the proper location on the

[27] Asch, S., Connor, S. E., Hamilton, E. G., & Fox, S. A. (2000). Problems in recruiting community-based physicians for health services research. *Journal of General Internal Medicine*, *15*(8), 591-599.

agreed upon date and time. Facilities will conduct recruitment and ensure that the needed number of participants show up for their scheduled time slot. This study employs qualitative methods and does not entail the use of any statistical methods.

Table 1 shows the estimated annual reporting burden for the groups, assuming 10 participants per group.

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

Table 1.

Type/Category of Respondent	No. of Respondents	Participation Time (minutes)	Burden (hours)
Screener	200	5	50
Focus group discussion	90	90	135
Total			185

REQUESTED APPROVAL DATE: August, 2019

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Attachments:
Attachment A: Recruitment Advertisements
Attachment B: Consumer and HCP Screeners
Attachment C: Consumer Reminder Script and Email
Attachment D: HCP Reminder Script and Email
Attachment E: Consumer Informed Consent
Attachment F: HCP Informed Consent
Attachment G: Consumer Moderator's Guide
Attachment H: HCP Moderator's Guide