DEPARTMENT OF HEALTH & HUMAN SERVICES
Administration

Public Health Service
Food and Drug

Memorandum

Date February 16, 2011

From PRA Specialist, Paperwork Reduction and Records Management Staff, Office of Information Management

Subject Request for Approval of FDA Focus Group, "Investigation of Issues Related to Direct-to-Consumer (DTC) Advertising"; OMB Control No. 0910-0497

To Human Resources and Housing Branch
Office of Information and Regulatory Affairs, OMB
Through: HHS Reports Clearance Officer_____

The Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER)/Division of Drug Marketing, Advertising, and Communications (DDMAC) is seeking OMB approval under the generic clearance 0910-0497 to conduct a focus group, "Investigation of Issues Related to Direct-to-Consumer (DTC) Advertising," to explore how consumers feel about various aspects of direct-to-consumer (DTC) advertising of prescription drugs. This information will be critical in our development of future quantitative research studies.

Purpose of the Focus Group

The qualitative focus group is a valuable tool for developing a future research agenda. Currently, DDMAC has an active research program with funds committed for important projects. In order to maximize resources and anticipate future needs, it is necessary for DDMAC to explore avenues for future research so that a solid research plan is in place. These focus groups will allow us to investigate five areas of interest to DDMAC and to sharpen the focus of the research questions for later quantitative studies.

DDMAC proposes five focus group sets of consumers with an incentive of $75. According to Karen Sollod of OMR Market Research and Focus Groups based in Washington, DC, in the fall of

2010, $75 had been the industry standard until two or three years ago. At that time, facilities in Washington, DC, Philadelphia, Dallas, and Seattle began to offer a $100 incentive for consumers. According to these facilities, with the current cost of gas and other travel expenses, $100 is the new standard for ensuring participation in qualitative research. Given this information, we propose a $75 incentive to ensure that we are able to attract a reasonable cross-section of consumers.

Each set of focus groups is explained below.

1. The role of information-seeking and new technologies in consumers' processing of DTC advertising

The methods and tools that people use to access information about their health have changed in the last decade. FDA has not evaluated these changes and their impact on the perceptions and comprehension of DTC advertising during this time. The proposed focus groups are designed to update our knowledge of the information-seeking behaviors of consumers, with particular focus on traditional and new technologies such as television, internet, hand-held devices, and social media. This set of groups will be separated into four different age groups. FDA recognizes that the future of communications to consumers likely involves electronic media but also that several generations remain committed to hardcopy materials. This set of groups is designed to assess the way consumers in different generations look for health information and their reactions to DTC advertising. The groups will enable FDA to determine whether quantitative measures such as surveys to further assess these issues are warranted to improve the implementation of the regulations governing advertising and labeling in the next several years.

For this part of the study, we propose to run 16 in-person focus groups, split into four age categories: older adults (age 71+), sandwich generation (age 41-70), established adults (age 26-40), and young adults (age 18-25). Two groups within each age group shall contain individuals with a college degree or higher and two groups shall contain individuals with some college education or less. These groups will take place in the metropolitan Washington, DC area and in other cities across the country to obtain some level of geographic representation.

2. Consumers' perceptions of regulatory concepts

FDA's prescription drug regulations specify that ads must present a fair balance between information relating to risks and benefits, which is achieved when the treatment of risk and benefit information in a promotional piece is comparably thorough and complete throughout the piece (21 CFR 202.1(e)(5)(ii)). These regulations also provide illustrations of the factors FDA considers in determining whether promotional pieces comply with the above requirements relating to risk disclosure. Specifically, these regulations identify twenty types of advertising communications that FDA considers "false, lacking in fair balance, or otherwise misleading" (21 CFR 202.1(e)(6)). Both healthcare providers and consumers have expressed concerns to FDA about the effectiveness of its regulation of manufacturers' prescription drug advertising directed to consumers (DTC), especially as it relates to ensuring balanced communication of risks compared with benefits. DDMAC has an interest in assessing both: 1) consumers' current sense of how truthful and fairly balanced DTC ads are, and 2) how providing information on the rationale behind the regulations

would influence consumer attitudes toward DTC advertising and toward FDA regulation of them. Findings from these groups will determine whether future quantitative surveys or outreach are warranted.

For this part of the study, we propose to run eight groups of the general population 18 years of age and greater. We will split the groups by education level and run half of the groups in the Washington DC metropolitan area and the other half in other US cities.

3. Consumers' attitudes toward disease information in DTC ads

Some branded DTC prescription drug ads contain information about the disease condition in general. We are planning to conduct a quantitative study about consumers' perceptions of this information, including their perceptions of the approved indication of the drug product, the consequences of the untreated disease state, and potential links between the two concepts. Before we conduct this quantitative study, however, we need to explore qualitatively how consumers perceive this information in branded pieces.

For this part of the study, the Contractor shall recruit and run a total of eight in-person groups of the general population age 18 and older, including a mix of gender and age. These eight groups shall be split into four groups with a college degree or higher and four groups with some college education or lower and these education groups shall be further split between the Washington, DC area and one or more U.S. cities.

4. Attitudes toward DTC in low-incidence populations

Special considerations may come into play when assessing advertising directed at special populations of individuals. In particular, people who have been diagnosed with cancer or people living with HIV/AIDS may be particularly vulnerable to certain types of advertising claims and they may find DTC advertising more or less useful than members of the general population. We do not know how these particular patients perceive or interpret DTC ads directed at them. This part of the study will provide some initial information about these populations and their responses to and perceptions of DTC advertising.

For this part of the study, we propose a total of eight in-person groups:

• Two groups of women who (a) have been diagnosed with breast cancer in the last five years and (b) who have a college degree or higher;
• Two groups of women who (a) have been diagnosed with breast cancer in the last five years and (b) who have some college education or less;
• Two groups of individuals who (a) have been diagnosed with HIV/AIDS and (b) who have a college degree or higher; and
• Two groups of individuals who (a) have been diagnosed with HIV/AIDS and (b) who have some college education or less.

All participants shall be 18 years of age or older. The groups shall be evenly split between the

Washington, DC area and one or more other U.S. cities.

5. Consumers' understanding of composite scores in DTC ads

FDA is currently designing quantitative studies to examine the addition of quantitative information to DTC ads. One issue that has surfaced repeatedly is how to convey to consumers the concept of composite scores, in which multiple study endpoints are combined into one overall score. These focus groups will assist us in determining what questions to ask and what issues must be addressed before embarking on quantitative research on the specifics of communicating composite scores.

For this part of the study, the Contractor shall recruit and run a total of four in-person groups of the general population age 18 and older, including a mix of gender and age. Two groups shall contain individuals with a college degree or higher and two groups shall contain individuals with some college education or less. These groups shall be evenly split between the Washington, DC area and one or more other U.S. cities.

Summary

The purpose of this project is to assess consumer focus group participants' thoughts and perceptions about the role of DTC advertising in five specific areas of interest, as outlined above. These issues will be explored with consumer focus group participants in 44 focus groups of 9 individuals each. The objective of this focus group project is to apply social science techniques to elicit information about DTC advertising in different areas of interest to better understand how consumer focus group participants view such information. Partially from these discussions, FDA will determine whether quantitative research further delving into these five areas is necessary to fulfill the needs of the Division. The consumer responses gained through the focus groups will be used to help the FDA team develop dependent measures for subsequent studies.

Table 1. Participant populations and group breakdown.

	Participants	# Groups	# Participants per Group
Ia	Young Adults (age 18-25)	4	9
Ib	Established Adults (age 26-40)	4	9
Ic	Sandwich Generation (age 41-70)	4	9
Id	Older Adults (age 71+)	4	9
II	General population (18+)	8	9
III	General population (18+)	8	9

IVa	Breast cancer survivors	4	9
IV b	Diagnosed with HIV/ AIDS	4	9
V	General population (18+)	4	9
	Total	44	396

Table 2. Estimated Annual Reporting Burden for Selected Respondents

Number of respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
792 (screener)	1	792	2/60	26
396 (focus groups)	1	396	90/60	594
				620

Depending on the results of the focus group, we plan to develop up to five quantitative study series on: 1) DTC in emerging technologies, 2) how to facilitate consumers' ability to discuss the risk/benefit tradeoff with their physicians, 3) the understanding of FDA's role in regulating prescription drug advertising, 4) the role of DTC advertising in low incidence and seriously ill populations, and 5) how to best convey complex clinical trial information to consumers.

We plan to conduct these focus groups during fiscal year 2011.

If you have any questions, please contact Elizabeth Berbakos at 301-796-3792.

Attachments