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 Group Testing of Consumer Fact Sheet and Website Outreach Card on Medication Use during Pregnancy

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. **Statement of need:**
   In support of FDA's mission to provide the public with accurate, science-based information related to the safe use of FDA-regulated products, the FDA Office of Women's Health (FDA OWH) developed a consumer fact sheet that provides general tips on medication use during pregnancy and a website on pregnancy exposure registry studies that collect information from women who take medicines or vaccines during pregnancy. The fact sheet was approved by DHHS and is currently being distributed in English and Spanish. The website has been reviewed by the relevant FDA Product Reviewer Centers (CDER and CBER). In 2014, FDA released new guidance regarding the inclusion of information on pregnancy and lactation in product labeling. Given recent policy updates and increased public interest related to medication use during pregnancy, the FDA OWH would like to update the fact sheet and other web-based messaging related to medication use during pregnancy.

   FDA OWH proposes conducting a series of four (4) focus groups to obtain consumer feedback on the readability and usability of the OWH 'Medicine and Pregnancy' fact sheet and learn more about consumer knowledge and opinions about pregnancy exposure registries. The focus groups will be conducted by Bixal Solutions, Inc. – a Contractor for the FDA Office of Women's Health

2. **Intended use of information:**
   The information gathered in the focus groups will be used to refine the messaging and layout of the FDA OWH print and electronic resources on medication use during pregnancy and pregnancy exposure registries.

3. **Description of respondents:**
   The participants will be women over age 18 who are pregnant, who had a baby within the last 5 years, and women who currently take prescription medications and are planning to get pregnant.

4. **Date(s) to be conducted and location(s):**
   Two of the focus groups will be conducted in Rockville, MD (one in English on March 26, 2015 and one in Spanish on April 22 or 23, 2015). One focus group will be conducted in English in Chicago, IL on April 2 or 3, 2015 and one focus group will be conducted in Spanish in Miami, FL on April 9 or 10, 2015. Dates are tentative pending approval and facility availability.

5. How the Information is being collected:

The attached participant screener and moderator's guide, prepared by FDA OWH, will be used by the Contractor to recruit the focus group participants and facilitate the guided discussion. A trained facilitator will moderate the focus group discussions. Discussion begins on or near the prearranged time, when most or all of the participants have arrived. After short introductions, the moderator eases the participants into a discussion of the specific topics related to the materials being tested. The facilitator does not pose any questions of a sensitive or private nature. The moderator continues to facilitate the discussion until all of the topics in the moderator's guide have been addressed. Time is allowed to address ideas and questions spontaneously generated from the discussion. Reliability and validity are assessed iteratively by revisiting respondents' verbalizations and asking for clarifications. This is done both within the course of individual discussions and between separate group discussions.

Contractor and FDA staff will observe the groups in real time behind a one-way mirror. The participants will be informed that they are being observed. The groups will also be audiotaped. Before the group discussion begins, the facilitator will obtain verbal consent from the participants to audiotape the sessions. The consent forms also mention the audiotaping. The consent forms will be reviewed with each participant and signed prior to them joining the discussion group. Transcriptions of the audio recordings will be used by the Contractor to analyze participant responses and prepare the Final Report. The focus group participants will be informed about how the tapes are used in the analyses, and assured that the recorded data are kept in a locked storage cabinet in a secure room, and that the recordings are destroyed after five years.

The Contractor will comply with additional safeguards for ensuring participant confidentiality. Participants will not have to use their last names during group discussions, and the last names will not appear on any focus group materials (typed lists of participants, name placards, transcripts, draft or final reports). Participants will also have the option of using a pseudonym. Verbatim quotes in the final report will not be attributed to an individual participant. Data will be used in the aggregate.

Focus group participants will provide their reactions to the FDA OWH fact sheet and provide suggestions as to ways the layout and messaging could be improved. The focus groups will be conducted to answer the following general questions:

- Where do pregnant women get information about the benefits and risks of medication use during pregnancy and how do they prefer to get this information?

- What do pregnant women think about the readability and layout of FDA plain language materials on medication use during pregnancy?

- What do pregnant women know about pregnancy exposure registries? What are the best ways to educate pregnant women about the benefits of participating in pregnancy exposure registries?

Following the four groups, the Contractor will listen to the audiotapes and read the transcripts for each session. The Contractor will develop an independent top line summary of each group. The Contractor will draft a report within three weeks after the

completion of the last focus group, and will submit this draft report to FDA OWH for review. The report will include an Executive Summary, Key Findings, Summary and Recommendations, and Appendices. Within one week following receipt of the report, FDA OWH will forward comments on the draft to the Contractor. The Contractor will then submit the final report within five weeks after the completion of the last focus group.

6. **Number of focus groups:**
   4

7. **Amount and justification for any proposed incentive:**
   Each focus group participant will be provided a $75 incentive. The incentive is designed to offset the cost of transportation to the group and childcare. These factors have been identified as challenges to participation for women

8. **Questions of a Sensitive Nature:**
   The groups will not ask any questions of a sensitive or private nature.

9. **Description of Statistical Methods (I.E. Sample Size & Method of Selection):**
   A total of 32 women will be recruited to participate to ensure that there are 6-8 women per group. Participants will be drawn from the general population of women using the criteria stipulated in the participant screener. The contractor will work with a market research facility to use their database of potential respondents to identify participants for the focus groups.

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)
General Consumer	32	2. (90 minutes)	64

Each respondent will participate in one (1) focus group.

REQUESTED APPROVAL DATE: March 9, 2015

NAME OF PRA ANALYST & PROGRAM CONTACT: PRA Specialist - Amber Sanford **/ Program Contact -** Kimberly A Thomas, MPH

FDA CENTER: Office of the Commissioner