FDA DOCUMENTATION FOR THE GENERIC CLEARANCE OF REQUEST FOR DATA TO SUPPORT SOCIAL AND BEHAVIORAL RESEARCH (0910-0847)

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TITLE OF INFORMATION COLLECTION: Improving FDA Health Communications with Older Women Regarding FDA-Regulated Products

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. **Statement of need:**

   This study is designed to support the critical efforts of FDA and FDA's Office of Women's Health (OWH) to improve the quality of FDA health communications to older women. In order to help women and their health care professionals make informed health-related decisions, OWH develops, evaluates, and uses tools and methods to create accessible, clear, and useful information about FDA-regulated products that are used by women. This study is designed to explore health-information-seeking needs, intentions, and behaviors of older women, as well as barriers they face in their attempts to access this information.

   Current evidence suggests that interventions to optimize FDA's health communications should be based on human behavior and theoretical science. Additional behavioral and social science research would strengthen FDA's design and implementation of its health communications among the uniquely vulnerable population of older women.

   This proposal also addresses several Center-specific regulations and initiatives.

   The conceptual framework of this proposed study is based on the Health Belief Model. We will use this model to elicit responses from older women to specific questions regarding consumer- or patient-focused communications.

   Our study objectives are to: (1) identify older women's perceptions about FDA's health communications; and (2) assess older women's health information seeking behaviors and intentions. This study will also examine whether older women's perceptions, intentions, and behaviors about FDA's health communications vary by about FDA's health communications FDA-regulated products and by generation.

   This study will collect information from focus groups about the perceptions and opinions of older women regarding the adequacy, appropriateness, usefulness, and relevance of FDA's health communications about FDA-regulated products.

   Results from this cross-Center study will provide data that FDA can use to develop better health communications for older women. Specifically, the findings of this study can help FDA Centers develop science-based messages that are clearer and more relevant to this population, and may be more likely to help older women make more informed health decisions.

2. **Intended use of information:**

We expect this study to provide evidence the four participating FDA Centers can use to support development of health communications that encourage consumers to adopt healthy behaviors. This effort will involve all stakeholders, including specific patient and consumer populations, to clarify goals and effective messages based on sound research and broadly accepted, evidence-based behavioral theories. The findings from this study will enable the Centers to create health communications that enable older women in the U.S. to most effectively use FDA-regulated products.

The investigators will also share the findings of this study through peer-review publications or other means with our partner governmental agencies and other stakeholders, such as, pharmaceutical industries, healthcare providers, medical professional societies, and food industry members. The goal is to ensure that their communications regarding FDA-regulated products will also meet the needs of older women.

The results from this proposed study will contribute to fulfilling critical missions of FDA and OWH, as well as regulatory and programmatic priorities of each center, including some provisions of the 21st Century Cures Act important to the Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research.

3. **Description of respondents:**

In this proposed focus groups, the target study participants are U.S. women who are 39 years of age and older (in 2019). As women age, they face two significant burdens. First burden: development of chronic health conditions. Older adults, therefore, must exert substantial effort to maintain and control these conditions through medical treatment and preventative health measures. Further, among adults aged 65 years and older, women are significantly more likely to use one or more medications. Second burden: increase in caregiving responsibilities. Among caregivers, 60% are women and 53% of them are age 50 or older. The burden of this dual role of patient and caregiver compounds the challenges older women face when making health-related decisions.

Older women in the U.S. are potential consumers of health information, including FDA communications. Thus, some of them could be at risk for serious, but preventable, negative health outcomes if they lack access to, or understanding of, information about the availability, proper use, and potential adverse effects associated with FDA-approved healthcare products. In one study of older adults, 71% had difficulty using print materials, 80% had difficulty using documents such as forms or charts, and 68% had difficulty with interpreting numbers and performing calculations. Such limited health literacy leads to health disparities, worse health outcomes, increased healthcare use, and more medication errors among older adults.

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

The focus groups will be conducted during January 2019 and December 2020.

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

The investigators will conduct up to twenty four (24) exploratory focus groups among U.S. women aged 38 years and older (8-10 women per group). The plan is to stratify this study population by generation and rural/urban setting. It is important that FDA finds effective ways to reach out to older women, while balancing financial constraints of information dissemination. Stratifying by generation will help elucidate modes of communication preferred by older women of these different age groups, as well as identify any generation-specific values, beliefs, and predispositions that assist in developing targeted messages. These focus groups will take place in the four regions of the nation (North-East, Midwest, South, and West) at times that best accommodate participants' availability. The investigators will strive for socioeconomic and demographic diversity among participants in these focus groups.

Focus groups will respond to the research questions regarding perceptions, motivations, attitudes, and behavior concerning use of FDA-regulated materials. Some questions will also address the role some of these older women play as caregivers to help the investigators better understand whether the health information needs vary between older women who seek health information for self-care, compared with those who seek health information to care for others. The investigators will identify themes from the focus groups and report any trends that emerge.

6. **Confidentiality of respondents:**

All focus group participants are subject to University of Maryland School of Pharmacy's privacy policy. University of Maryland does not share personally identifiable information ("Personal Information"). Respondent identity and information will remain confidential to the extent permitted by law.

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

As participants often have competing demands for their time, a token of appreciation is an approach that acknowledges respondents for their participation. The use of a token of appreciation treats participants justly and with respect by recognizing and acknowledging the effort they expend to participate.

A token of appreciation for each focus group participant's time, effort, and travel will be $40. The participant's time and effort will be recognized at a rate of $15 for each hour. Since the focus group will take approximately 2 hours of each participant's time, the token of appreciation for each participant's time and effort would be $30 per focus group session. In addition, $10 will be provided to each participant's in recognition of travel cost (i.e., mileage, bus, taxi) associated with her participation of the focus group Specifically for this proposed study population of women 38 years and older, many of them are either busy working or have many other responsibilities and activities. For older women, it will take much deliberate efforts for them to attend the focus group since many of them may have difficulty walking, dressing, or driving. The token of appreciation of $40 is a reasonable amount to acknowledge the time, effort, and travel they expend to participate.

The token of appreciation must be high enough to equalize the burden placed on respondents with respect to their time and cost of participation. If the token of appreciation 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. 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 focus groups will not ask questions of a sensitive nature.

9. **Description of Statistical Methods**

A total of 192 respondents are intended to be sampled for the focus groups. The sampling will deliberatively separate seniors into three generations in order to examine different perspectives based upon participants' age. Those three generations are:

- Generation A: Born 1965 to 1980; 39 to 54 years old in 2019
- Generation B: Born 1946 to 1964; 55 to 73 years old in 2019
- Generation C: Born 1928 to 1945; 74 to 91 years old in 2019

This proposed focus group is designed to explore whether older women's perceptions differ by generation and if so, how these perceptions differ. This information will help FDA to develop and tailor its health communications to different generations of older women to better meet their specific needs. Older women in different generations might have different perceptions about the same health communications materials because of the differences in their pre-existing beliefs. Because different generations can have different health beliefs and perceptions, it is reasonable to expect that different generations of older women also have different perceptions of FDA health communications.

Women in generation B and C are the study population of interest as they are older women. Generation A is included in the focus group as a comparison group. The targeted sample size is 40 each for each generation. Since this focus group is a qualitative study and no formal statistical analysis will be needed, it is not applicable to determine whether we have enough power to detect meaningful group differences. Instead, we will try to identify and summarize the most commonly reported perceptions and health-information seeking intentions and behaviors for each generation.

The convenient sampling approach is mainly based upon geography. With established collaborations with University of Maryland's research partners across the United States, they will engage academic collaborators, women's health centers, and rural health centers in our recruitment efforts. These partners will be well-versed in the most appropriate methods and venues to reach potential participants across the United States. University of Maryland will work with our collaborators and use a screening guide to ensure that we are able to enroll participants that represent the characteristics of interest to CBER and CDER. A liaison from the research team will work closely with the partners to create a system to track enrolled participants' characteristics and to identify additional subgroups

that are needed. The partners will also be able to assist us with securing locations for the focus groups that are in convenient locations and held at times that best accommodate participants' availability to recruit women in generations A, B, and C for the focus group. Many of those women have dual role of caring for herself and caregiver to others. At the screening phase, potential focus group participants will self-report their caregiver status.

BURDEN HOUR COMPUTATION:

Type/Category of Respondent	No. of Respondents	Participation Time (minutes)	Burden (hours)
Focus group respondent	192	120	384

REQUESTED APPROVAL DATE: January, 2020

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