OWH/FDA Health Communication towards older women project
Summary of the 2018 Focus Groups Conducted

The FDA Centers who collaborated in this research entitled "Improving FDA Health Communications with Older Women Regarding FDA-Regulated Products" are: Center for Biologics Evaluation and Research (CBER), Center for Drug Evaluation and Research (CDER), Center for Devices and Radiologic Health (CDRH), and Center for Food Safety and Applied Nutrition (CFSAN). The research is conducted in two phases. The focus group which is Phase 1 is to elicit health information seeking needs, intentions, behaviors, and barriers and experiences with health communication materials about FDA-regulated products. Phase 2 is to develop and administer a national survey based on the Phase 1 findings to further understand older women's perceptions of FDA's health communications and their health-information seeking behaviors and intentions (expect to be conducted in year 2020). Phase 1 is the exploratory step needed for the development of Phase 2. Results from this unique cross-center study will support the FDA's mission to ensure the quality of health communications for older women using science-based messages that are clear and most relevant to this population.

What was the problem to be investigated? The U.S. Food and Drug Administration (FDA) Office of Women's Health (OWH) develops, evaluates, and uses tools and methods to create accessible, clear, and useful information about FDA-regulated products that are used by women. Given that nearly 70% of older women have difficulty interpreting technical health-related information, it is important that health-related information is readily available and provided in an easy-to-understand format. To date, there has been limited research to evaluate the effectiveness of FDA communications to older women. The goal of this study is 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 via a range of FDA modes of communication.

The method used to obtain the convenience sample. Using a convenience sampling strategy, the University of Maryland CERSI staff and community liaisons collaborated with community partners across the state of Maryland to recruit for and host the thirteen focus groups. Eligible women were recruited via personal communications (e.g., face-to-face outreach), distributing flyers, and placing advertisements in community partners' newsletters. The research team used the participant screeners to confirm eligibility and identify focus group venues and times that were convenient to participant locations and schedules. The team aimed to include a balance of younger and older women within each generational group.

Burden imposed. Each focus group was set up as 1.5 hours. The total time for each participant was estimated as 2.5 hours including the commute time. This estimate was based on FDA's and University of Maryland's expertise and the knowledge that the focus group sites were selected based on convenience to participants. The total burden for this collection of information was estimated to take 272.5 hours (109 participants x 2.5 hours).