

“Focus Groups on Perceptions of Prescription Drug Promotion and Approval Review Process (Formative Research)”

(OMB Control Number 0910-0497)

CHANGE REQUEST (83-C)

Date: November 18, 2019

This request proposes a change to the moderator’s guide based on the first set of focus groups. We received OMB approval for ICR [0910-0497] - **Focus Groups on Perceptions of Prescription Drug Promotion and Approval Review Process (Formative Research)** on 8/20/19. No change to the burden is requested.

The purpose of this project phase will explore HCP and consumer beliefs about FDA’s role in review and approval of DTC and professional promotion and drug approval status. 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]). Our participant segments are as follows:

Healthcare Providers (4 groups; n=36):

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

Consumers (5 groups; n=45)

- o Less than High School education (n=2 groups; n=18)
 - 2 groups in Atlanta
- o High School or more education (n=3 groups; n=27)
 - 1 group in Atlanta; 2 groups in Washington, DC

We have completed the four Atlanta focus groups. Based on information we gathered from those focus groups, we propose to add several questions to the moderator’s guide to explore certain aspects of understanding about review terminology that are not currently addressed in the moderator’s guide. Questions about attitudes toward the pharmaceutical company or advertiser will be deleted in order to keep the length of the guide the same; thus, there will be no change in burden. The revised moderator’s guide will be used for the remaining 3 groups to be conducted in Washington, DC. This change will involve no additional cost to the federal government.