

“Healthcare Professional Interviews:
Risk Processing for Newly Promoted Prescription Drugs”
(OMB Control Number 0910-0695)

June 14, 2019

The Food and Drug Administration is submitting this generic request to make minor modifications to our approved project, *Healthcare Professional Interviews: Risk Processing for Newly Promoted Prescription Drugs* (#0910-0695). We conducted pilot testing in order to assess the materials and procedures prior to main study administration. We are now proposing minor modifications to these materials and procedures based on findings from this pilot testing. We made no revisions to the consent forms or reminder email relative to the original submission. There is no change to the burden hours for this project.

The proposed changes are outlined below:

1. We will recruit from MedStar Washington Hospital Center, MedStar Georgetown University Hospital, Medstar Montgomery Medical Center, MedStar Medical Groups, and MedStar St. Mary’s Hospital. Interviews will be conducted at MedStar Institute for Innovation, Montgomery Medical Center, and MedStar St. Mary’s Hospital.
2. Data collection will be extended through the fall of 2019.
3. Language in the screener and moderator guide have been updated slightly to improve the clarity of the instructions and procedures.
4. Items have been added to the screener to address the usage of eyeglasses during study participation; center of employment, and race and ethnicity.