Educating Groups Influencing Generic Drug Use:
Non-Substantive Change Request

OMB Control No.: 0910-0695

Date: July 26, 2016

FDA is requesting the following, non-substantive/non-material changes to the above referenced study, approved March 22, 2016:

A. **Informed consents: Minor revision**. Since Auburn University IRB has determined that a signed consent form can be waived for the conduct of this Aim of the funded project, we use information letter to consent participants. The letter also provides additional information about the study as well as their rights as a participant. Per the request of Research Involving Human Subject Committee (RIHSC), we:

highlighted the purpose of the study in the letter;

clarified the distribution of incentive and information collected for the purpose of distributing incentives in the letter; and

explained how their data will be used and protected, and who will have access to the data.

B. **Interview guides: Minor revision**. Prior to beginning to pose any interview questions, the interviewer will provide the participant with an opportunity to ask any clarifying questions. That means, when participants call in, the interviewer will revisit the information letter to confirm participation. To serve this purpose, we:

inserted a condensed version of the information letter at the beginning of the interview guides.

C. **Addition of invitation e-mail script**. The purpose of the invitation email script is to reach out to possible respondents identified as representatives of the policymaker, large purchaser, and formulary management groups. As the email script only represents an additional avenue for recruiting potential study respondents, it has no impact on the amount of time participants will be asked to invest in the study.

Please note that while these changes may include more text, the burden remains unchanged.