

Pretests for a Study on Quantitative Information in Direct-to-Consumer Television Advertisements

(OMB NO: 0910-0695)

December 22, 2015

We are requesting an amendment for the study, “Pretests for a Study on Quantitative Information in Direct-to-Consumer Television Advertisements” (ICR reference number: 201509-0910-002). In the time since we submitted our pretest questionnaires to OMB, we received comments from the public (via the 60-day federal notice for FDA-2015-N-3543) and peer reviewers on the main study design and materials. We subsequently revised the pretest questionnaires based on these comments so that the pretest questionnaires will align with the main study questionnaires. These changes include adding new questions, deleting or revising previous questions, and re-ordering questions (see attached). We also revised the consent form based on feedback from FDA’s Research Involving Human Subjects Committee. All other aspects of the pretests, including participant burden, remain unchanged.