

U.S. Food and Drug Administration

Assessment of Terms and Phrases Commonly Used in Prescription Drug Promotion

OMB Control Number 0910-0895

Non-substantive Change Request:

This information collection supports section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)), which authorizes the Food and Drug Administration (FDA) to conduct research relating to health information. Section 1003(d)(2)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 393(d)(2)(C)) authorizes FDA to conduct research relating to drugs and other FDA-regulated products in carrying out the provisions of the FD&C Act.

FDA's Office of Prescription Drug Promotion's (OPDP) mission is to protect the public health by helping to ensure that prescription drug promotion is truthful, balanced, and accurately communicated. OPDP's research program provides scientific evidence to help ensure that its policies related to prescription drug promotion will have the greatest benefit to public health. We have consistently conducted research to evaluate the aspects of prescription drug promotion that are most central to our mission. The study in this information collection pertains to the three topic areas: (1) advertising features, (2) target populations, and (3) research quality.

The present research involves assessment of how consumers and primary care physicians interpret terms and phrases commonly used in prescription drug promotion, as well as those used to describe prescription drugs and prescription drug promotion more generally. This includes both what these terms and phrases mean to each population (e.g., definitions) and what these terms and phrases imply (e.g., about efficacy and safety). Understanding the most prevalent interpretations of these terms and phrases can help OPDP determine the impact of specific language in prescription drug promotion. For example, certain terms and phrases, when used without additional contextual information, might overstate the efficacy or minimize the risk of a product. Additionally, from a health literacy perspective, it is helpful to ascertain general understanding of such terms and phrases because this may help FDA develop best practices to communicate these concepts.

Proposed Changes

FDA is proposing modifications to Phase 2 survey materials based on findings from the approved Phase 1 interviews. The revised Phase 2 survey materials are attached, and the changes to these materials are summarized below. FDA is not requesting changes to the burden hours for this project.

(1) We deleted the following:

- Questions that seemed unnecessary or repetitive.
- Answer options that seemed irrelevant based on interview data.

- Medical terminology like “incidence” from consumer version.
 - Drug names to avoid biasing the audience and removed context statements that were deemed unnecessary.
- (2) We added the following:
- “Don’t know” options to some questions.
 - Clarifying language to some instructions.
 - Answer options heard in interviews that were not already represented in the questionnaire.
- (3) We tailored language to the specific audience based on responses in the interviews.
- (4) We edited the language to reduce redundancy in answer options; ensured no double-barreled questions or lists that were not mutually exclusive (these changes were made in response to review by a survey methodologist).
- (5) We revised language to better match the answer task (e.g., used “which” instead of “what” for multiple choice options).