United States Food and Drug Administration

Study of Disclosures to Health Care Providers Regarding Data That Do Not Support Unapproved Use of an Approved Prescription Drug

OMB Control Number 0910-0900

No Material or Non-Substantive Change to a Currently Approved Collection (83-C)

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. This study in this information collection pertains to the two topic areas: (1) advertising features; and (2) target populations. Our purpose for the information collection is to examine how physicians process information about unapproved new uses of approved prescription drugs when made aware of other unsupportive information and how they evaluate the effectiveness of various disclosure approaches for this information. This study has provided and continues to provide FDA with empirical information of the effects that these variables have on physician perceptions and has informed and continues to inform FDA's regulatory approach to materials of this type.

Proposed Changes

Results of the first round of cognitive testing revealed that the stimuli for one of the study conditions, diabetes, was not functioning as intended. We determined that a change to the study stimuli was warranted and noted this in the 30-day *Federal Register* notice for this study, published June 11, 2021 (86 FR 31318).

FDA is requesting to conduct an additional nine cognitive interviews to ensure that physicians successfully operate the revised stimuli in this arm of the study and so that FDA can proceed with the pretesting and main study. We are requesting the proposed changes: (1) an amendment to conduct additional cognitive testing on the stimuli for the insomnia condition; and (2) an adjustment to the total estimated annual reporting burden to reflect additional cognitive testing. We are not requesting to change the study procedure.

The Office of Management and Budget (OMB) has approved a total estimated annual reporting burden of 812 hours for FDA to pretest and conduct a main study. We are proposing to increase the total number of hours by 9 hours, which results in a total estimated annual reporting burden of 821 hours. Our request to increase the burden hours will allow FDA to conduct an additional round of cognitive testing with nine primary care physicians.

Furthermore, we propose to offer physicians $200 to conduct interviews with them for 60 minutes. OMB previously approved this amount for the interview phase of this project, entitled "Healthcare Professional Interviews: Data Disclosures in Communications About Prescription Drugs," which is covered under OMB control number 0910-0695, approved 10/30/2019.

A revised burden table is presented below.

Table 1.--Estimated Annual Reporting Burden[1]

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response (in hours)	Total Hours
Pretest screener	290	1	290	0.08	23
Pretest completes	180	1	180	0.33	59
Main study screener	2,526	1	2,526	0.08	202
Main study completes, Medical Condition 1	510	1	510	0.33	168
Main study completes, Medical Condition 2	1,090	1	1,090	0.33	360
Cognitive testing	9	1	9	1	9
Total	4,605				821

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: October 13, 2021