"Physician Interpretation of Information About Prescription Drugs in Scientific Publications vs. Promotional Pieces"
(OMB Control Number 0910-0875)

Change Request (83-C)

June 1, 2020

The Food and Drug Administration is submitting this nonmaterial/non-substantive change request (83-C) for this project. The purpose of this project is to examine how physician perception of professional prescription drug communications is influenced by variations in information context, methodologic rigor of the underlying clinical study, and time pressure. This study will provide FDA with empirical information of the effects of these variables on physician perceptions and inform FDA's regulatory approach to promotional materials of this type. We are requesting: (1) an amendment to adjust the number of participants by adding a second pretest; and (2) an adjustment to the estimated burden based on experience with the first pretest. We are not seeking to change the study procedure.

The estimated annual reporting burden, formerly estimated as 267 hours, has increased by 131 hours to a new total estimated annual hourly burden of 397 hours. We are requesting an increase in the burden hours in order to conduct a second pretest and to reflect the experience of the first pretest. In the first pretest, a larger number of individuals were screened than estimated to achieve the final pretest sample size. We have adjusted the estimated screening burden for Pretest 1 and the Main study to reflect this experience.

Results of the first pretest revealed that one of the independent variables, time pressure, was not effective as operationalized; participants did not report perceiving to be under time pressure. Based on the results of the pretest, FDA is requesting an additional pretest to test other variations of the time pressure variable to ensure this variable is being successfully operationalized prior to proceeding with the main study, and to examine the appropriate amount of time pressure to apply in the main study.

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	Total Hours
Pretest 1 screener	443	1	443	.03 (2 minutes)	13
Pretest 2 screener	850	1	850	.03 (2 minutes)	26
Completes, Pretest 1	158	1	158	.33 (20 minutes)	52
Completes, Pretest 2	252	1	252	.33 (20 minutes)	83
Main Study screener	1,200	1	1,200	.03 (2 minutes)	36
Completes, Main Study	566	1	566	.33 (20 minutes)	187
Total	3,469		3,469		397

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

Table 2.—Adjustments to Total Hours		
Activity	Adjustment to Total Hours	Notes
Pretest 1 screener	7 additional hours	Adjustment based on experience
Pretest 2 screener	26 additional hours	New requested hours
Pretest 2 completes	83 additional hours	New requested hours
Main study screener	15 additional hours	Adjustment based on application of Pretest 1 experience
Total	131 additional hours	