U.S. Food and Drug Administration

Medical Conference Attendees' Observations About Prescription Drug Promotion

OMB Control Number: 0910-0901

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 two topic areas: (1) advertising features and (2) target populations. Our purpose for the information collection is to provide information to inform FDA generally about the landscape of medical conferences and specifically about promotional prescription drug booths, where considerable promotion occurs. This knowledge will assist FDA in understanding a common venue for prescription drug promotion.

Proposed Changes

The program is requesting two changes based on pretest results:

A. An increase in sample size

Based on previous studies with WebMD and our pretest results, we anticipate about 7 percent of completed participants will be low quality (e.g., speeders, laggards). Consequently, we recommend increasing our sample size to 396 completed participants (originally *n*=368). This number breaks down to approximately 99 participants per experimental condition and 33 participants per medical conference. The original burden numbers included all those screened and who participated in the pretest (total respondents =1,326; total hours = 204). The new total number is 1,427 and total hours is 219.

Original Table 1:

Table 1. Estimated Annual Reporting Burden[1]

	No. of respondents	No. of responses per respondent	Total annual respondents	Average burden per response	Total hours
Screener	933	1	933	.08 (5 min)	74.64
Pretest	25	1	25	.33 (20 min)	8.25
Main test	368	1	368	.33 (20 min)	121.44
Total					204.33

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

Revised Table 1:

Table 1. Estimated Annual Reporting Burden[1]

	No. of respondents	No. of responses per respondent	Total annual respondents	Average burden per response	Total hours
Screener	1,006	1	1,006	.08 (5 min)	80.48
Pretest	25	1	25	.33 (20 min)	8.25
Main test	396	1	396	.33 (20 min)	130.68
Total					219.41

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

B. Small changes to the questionnaire

Based on an analysis of the pretest data, we propose minimal differences to the questionnaire that will not change the amount of time required to complete it.

1. We moved one question from the questionnaire to the screener to ensure that we are recruiting prescribers.

S0. Which of the following best describes your role as a healthcare provider?

(1) Physician
(2) Nurse practitioner
(3) Physician assistant
(4) Pharmacist
(5) Other (please specify)

2. We added two follow-up questions (17-A and 17-B) to achieve better data.

[Recent Conference – Virtual Exhibit Hall Description]

17. [If selected "Yes" for Q16] Please answer the following questions about the exhibit hall or setting where virtual attendees were able to interact with industry representatives. Be as specific as possible.

17-A. [If selected "Yes" for Q16] When were virtual attendees able to interact with industry representatives (e.g., between sessions, during social hours)?

[Open-ended text format]

17-B. [If selected "Yes" for Q16] What interface did virtual attendees use to interact with industry representatives (e.g., video chat, special software)?

[Open-ended text format]

3. We deleted one question.

31. [Typical Priority Conferences]

1. **Please list the top three medical conferences you try to attend each year, schedule permitting.**

Conference #1: _____
Conference #2: _____
Conference #3: _____