

“Market Claims in Direct-to-Consumer Prescription Drug Print Ads”

(OMB Control Number 0910-0824, expires 09/30/2019)

CHANGE REQUEST (83-C)

Date: January 13, 2017

We received OMB approval for ICR [0910-0824] - **Market Claims in Direct-to-Consumer Prescription Drug Print Ads** on 9/21/16. This request proposes a change to the sampling procedure to accommodate a lower than expected incidence rate and wording updates to the questionnaire.

The purpose of this research is to examine the impact of market claims and quantitative efficacy information in direct-to-consumer (DTC) print advertising for prescription drugs. The eligible study population is U.S., non-institutionalized adults age 18 and older that have been diagnosed with diabetes (as measured by self-report). The selected sample is drawn from Ipsos’s opt-in online survey panel, i-Say. Panelists identified as having been diagnosed with diabetes are invited to participate in the survey via email. Panelists who agree to participate are screened to confirm they have been diagnosed with diabetes. During the pretest, the incidence rate was lower than expected, meaning that fewer people qualified for the study than anticipated. The reason is that there are a non-trivial number of individuals who self-identified as having diabetes at some point in the past but who no longer self-identify as having diabetes. This is most likely because the panel data is out of date, an issue the contractor is taking steps to correct as a result of these findings.

To address the potential shortfall, we propose to broaden the survey invitation to members of the i-Say panel who have not pre-identified themselves as having been diagnosed with diabetes in an effort to identify more individuals who meet the screening criteria for Pretest 3 and the follow-up study. Panelists who agree to participate will complete the same screener as pre-identified panelists, to ensure they have been diagnosed with diabetes. Thus, the final sample for Pretest 3 and the follow-up study will still be comprised of individuals who self-identify as having been diagnosed with diabetes. The revised estimated burden is 692.8, an increase from the original estimated burden of 629.1. A revised burden chart follows (see Table 1). Of note, re-collecting this data will involve no additional cost to the federal government.

Second, we have recently completed work to develop standardized scales for measuring risk and benefit perceptions in prescription drug advertising (OMB control number 0910-0784). We would like to update the wording in several of the questions to reflect that work. The new wording is described in Table 2.

Table 1: Estimated Burden¹

Activity	Number of respondents	Number of responses per respondent	Total annual respondents	Average burden per response	Total hours
Sample outgo (pretests and main survey)	16,384	==	==	==	==
Screeners completes	3,062	1	3,062	.03 (2 minutes)	91.9
Eligible		==	==	==	==
Completes, Pretest 1	293	1	293	0.5 (30 minutes)	146.5
Completes, Pretest 2	252	1	252	0.5 (30 minutes)	126.0
Completes, Main Study	495	1	495	0.5 (30 minutes)	247.5
Completes, Pretest 3	108	1	108	0.25 (15 minutes)	27.0
Completes, Follow-up Study	216	1	216	0.25 (15 minutes)	54.0
Total	==	==	==	==	692.8

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

Table 2: Updated Question Wording

Question Number	Original Wording	Updated Wording
7	In your opinion, what is the <u>ad's message</u> about how much relief [drug] gives people from diabetic nerve pain?	What is the <u>ad's message</u> about how much [drug] would improve your [condition]?
10A	In your opinion, what is the <u>ad's message</u> about how serious the side effects of [drug] would be, if it did cause side effects?	What is the <u>ad's message</u> about how serious [drug]'s side effects are?
10B	In your opinion, what is the <u>ad's message</u> about how many side effects [drug] might cause, if it did cause you to have side effects?	What is the <u>ad's message</u> about how likely it is that you would experience at least one side effect if you took [drug]?
13	In <u>your</u> opinion, how much relief does	In <u>your</u> opinion, how much would [drug]

	[drug] actually give people from their diabetic nerve pain?	improve your [condition]?
16	In your opinion, if 100 people take [drug] how many will have side effects? Please enter a number in the box below.	In <u>your</u> opinion, how likely is it that you would experience at least one side effect if you took [drug]?
17	In <u>your</u> opinion, how serious would the side effects of [drug] be, if it did cause you to have side effects?	In <u>your</u> opinion, how serious are [drug]'s side effects?
18	In <u>your</u> opinion, how many side effects might [drug] cause, if it did cause you to have side effects?	In <u>your</u> opinion, do you think [drug]'s side effects would be short lived or long lasting?
25	How much relief do you think <u>doctors</u> believe [drug] gives people from their [condition]?	How much do you think <u>doctors</u> believe [drug] would improve your [condition]?
25A	How serious do you think <u>doctors</u> would rate the side effects of [drug], if it did cause you to have side effects?	How serious do you think <u>doctors</u> believe [drug]'s side effects are?
25B	How many side effects do you think <u>doctors</u> believe [drug] might cause, if it did cause you to have side effects?	Do you think <u>doctors</u> believe that [drug]'s side effects would be short lived or long lasting?