

U.S. Food and Drug Administration

A Survey on Quantitative Claims in Direct-to-Consumer Prescription Drug Advertising

OMB Control Number 0910-0929

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

Request for Non-Substantive Change

The Food and Drug Administration (FDA) Center for Drug Evaluation and Research (CDER) is seeking Office of Management and Budget (OMB) approval of non-substantive changes to OMB control number 0910-0929. The purpose of this survey is to collect insights on consumer understanding of quantitative claims in direct-to-consumer prescription drug advertising. We anticipated 1,100 participants would respond to the survey from our initial recruitment of 2,993 individuals. However, the response rate was lower than expected due to declining survey response rates seen across Federal surveys, resulting in 480 survey responses. The purpose of this change is to increase the number of respondents to get closer to the previously estimated survey response and therefore increase the power to detect differences among subgroups.

We request an additional recruitment of 1,500 individuals, with the intent to yield an additional 214 completed surveys and allow us to detect differences of 14.4 percentage points. Based on the initial recruitment, we are assuming a 15 percent response rate and a 5 percent postage non-deliverable rate for the additional sample. We updated the burden chart to reflect the revised estimated burden for the survey (table 1). We also revised (1) the informed consent form to note that the sample is now about 4,500 people and (2) the official FDA announcement of the survey to provide new survey dates for the additional sample (see revised Informed Consent and revised Appendix F).

Because we did not reach the full survey response with our initial recruitment efforts, the second wave of data collection is intended to collect more responses to add to the full final sample. The second wave will field the survey instrument approved by OMB on June 10, 2024. It is therefore critical that the survey is the same for both waves so that the data can be combined as planned. We therefore request an exemption from collecting the revised Statistical Policy Directive No. 15 (SPD 15) detailed data on race and ethnicity. If we revised the survey to include the detailed race and ethnicity categories, we would have different race and ethnicity information for the new participants, which would mean that we could not combine the data from the new participants with the data we have already collected. Combining the data from different race and ethnicity items would not be methodologically sound for this study because it would add imprecision to our measure of race and ethnicity. In addition, SPD 15 states that the seven minimum race and ethnicity categories shall be treated co-equally; however, the original survey item which 480 participants have already completed had five categories.

Accordingly, we have adjusted the estimated burden in by 1,500 responses and 156 hours.

Table 1.--Estimated Annual Reporting Burden¹

| Activity | No. of Respondents | No. of Responses per Respondent | Total Annual Responses | Average Burden per Response | Total Hours |
|--|--------------------|---------------------------------|------------------------|-----------------------------|-------------|
| Read prenotification letter | 4,493 | 1 | 4,493 | 0.08 (5 min.) | 359 |
| Read web survey invitation letter ² | 4,268 | 1 | 4,268 | 0.08 (5 min.) | 341 |
| Read reminder postcard | 3,880 | 1 | 3,880 | 0.03 (2 min.) | 116 |
| Respond to survey (web and paper) | 1,314 | 1 | 1,314 | 0.33 (20 min.) | 434 |
| Total | | | | | 1,250 |

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

2 The numbers assume a response rate of around 5 percent postal non-deliverables from the prenotification letter and estimate nonrespondents for the subsequent mailings.

Dated: December 2024