“Experimental Study of Risk Information Amount and Location in Direct-to-Consumer Print Ads”

(OMB Control Number 0910-0861)

CHANGE REQUEST (83-C)

Date: July 24, 2019

We received OMB approval for ICR [0910-0861] - **Experimental Study of Risk Information Amount and Location in Direct-to-Consumer Print Ads** on 9/17/18. This request proposes a change to the estimated burden to accommodate a higher than expected no-show and cancellation rate amongst recruited participants.

The purpose of this project is to investigate, through empirical research, various combinations of the important safety information (ISI) and brief summary in consumer-directed prescription drug print ads to examine the positive or negative impact of including the same warnings in both the ISI and again in the brief summary. Data were collected at five sites: Chicago, IL, Tampa, FL, Phoenix, AZ, Houston, TX, and Marlton, NJ. A total of 347 participants have completed the study at those locations, out of 422 recruited. The contractor has experienced 46 no shows and 29 cancellations. This has resulted in a shortfall of 53 participants. To address this shortfall, we propose to expand data collection to one of two additional sites, Ft. Lauderdale, FL or Paramus, NJ. This will require screening an additional 210 participants. A revised burden chart follows with changes highlighted. This data collection will involve no additional cost to the federal government.

Table 1.--Estimated Annual Reporting Burden with Change

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours	Change in Burden Hours
Pilot Screener	120	1	120	.03 (2 minutes)	4	0
Study 1 Screener	696	1	696	.03 (2 minutes)	21	3
Study 2 Screener	714	1	714	.03 (2 minutes)	21	3
Completes, Pilot	40	1	40	1	40	0
Completes, Study 1	200	1	200	1	200	0
Completes, Study 2	200	1	200	1	200	0
Total					486	6