

UNITED STATES FOOD & DRUG ADMINISTRATION

Study of Oncology Indications in Direct-to-Consumer Television Advertising

OMB Control Number: 0910-0885

Non-substantive Change Request:

Based on cognitive interviews and pretesting, we made several revisions to the study materials.

1. We revised the screener to include a “prefer not to answer” option for the questions about sex, ethnicity, race, and education (see revised Appendix G).
2. We revised the Study 1 questionnaire: we revised the wording for the instructions and several items (Q2, Q3_E, Q5, Q7-Q10a, Q11, Q11b, Q20, and Q23) and deleted several others (Q10b, Q19, Q21, and Q22; see revised Appendix C).
3. We revised the Study 2 questionnaire: we revised the wording for the instructions and several items (Q2b-Q4, Q10, Q11, Q13, and Q22a) and deleted several others (Q2, Q5-Q8, Q12b, Q101a, Q101b, Q19, and Q22c; see revised Appendix D).
4. We revised the consent form to reflect the change from an estimated 20-minute survey to an estimated 15-minute survey (see revised Appendix A and revised burden chart below).

In addition to these revisions, we updated the burden chart to reflect the actual pretest burden and the revised estimated burden for the main studies. We revised the main study estimates based on (1) shorter survey time seen in the pretest (an average burden of 15 minutes per person); and (2) an anticipated increase in the number of respondents to be screened and to complete the main studies. Together, the revisions add 15.4 hours to the total estimated burden time (see Tables 1 and 2).

Table 1.--Estimated Annual Reporting Burden¹

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Cognitive Interview screener	30	1	30	0.08 (5 minutes)	2.4
Cognitive Interviews	18	1	18	1 (60 minutes)	18
Pretests 1 and 2 screener	298	1	298	0.08 (5 minutes)	23.84
Pretests 1 and 2	149	1	149	0.25 (15 minutes)	37.25
Study 1 screener	1,610	1	1,610	0.08 (5 minutes)	128.8
Study 1	805	1	805	0.25 (15 minutes)	201.25
Study 2 screener	1,196	1	1,196	0.08 (5 minutes)	95.68
Study 2	598	1	598	0.25 (15 minutes)	149.5
Total					656.72

Table 2.—Adjustments to Total Hours

Activity	Adjustment to Total Hours	Notes
Pretests 1 and 2 screener	7.84 additional hours	Based on screening more participants than expected
Pretests 1 and 2	2.35 fewer hours	Based on more participants but shorter survey length than expected
Study 1 screener	35.44 additional hours	Adjustment based on application of pretests 1 and 2 screener experience
Study 1	29.75 fewer hours	Adjustment based on application of pretests 1 and 2 experience
Study 2 screener	26.32 additional hours	Adjustment based on application of pretests 1 and 2 screener experience
Study 2	22.1 fewer hours	Adjustment based on application of pretests 1 and 2 experience
Total	15.40 additional hours	

