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Comment On: FDA-2012-N-0892-0001
Agency Information Collection Activities; Proposals, Submissions, and Approvals: Communicating Composite Scores in Direct-to-Consumer Advertising

Document: FDA-2012-N-0892-DRAFT-0004
Michelle C. Carras - Comment

Submitter Information

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General Comment

Thanks for your thoughtful consideration of consumer understanding of composite measures. I appreciate what the agency does to ensure the public is aware of limitations in drug advertising. Regarding your study design, I have a few questions:

The respondents identified as screeners (n=3200 and n=3400), whose participation time will be about 2 minutes, do not seem clearly identified in the docket submission. Who are these respondents?

If you are doing a population-based survey, why would you not want to ensure adequate power for hypothesis testing? If the agency feels it is necessary to examine these questions, it is a waste of resources to perform this type of survey without ensuring power and an adequate sample size. In addition, you do not address the idea of expected nonresponse, which is likely to be at least 50% for an internet-based sample.

Is the concern about understanding of composite variables more applicable to print or video ads? It may be useful to make sure you are delivering the sample ad in the medium that consumer will be more likely to use.

I have the same concerns regarding power with the experimental condition; please do not use the agency's resources without ensuring you will have an adequate sample size, taking dropout into consideration.

Thank you for your attention to my comments.

Michelle Colder Carras