TESTING COMMUNICATIONS ABOUT FDA-REGULATED PRODUCTS: QUALITATIVE FEEDBACK ON FDA-GENERATED SUNSCREEN VIDEOS
(0910-0695)

TITLE OF INFORMATION COLLECTION: Testing Communications about FDA-regulated Products: Qualitative Feedback on FDA-generated Sunscreen Videos

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. Statement of need:

The Food and Drug Administration (FDA) is responsible for ensuring that products that FDA approves for marketing are safe and effective when used properly. Risks and benefits are inherent in all FDA-regulated products. FDA plays a critical oversight role in mitigating and preventing negative consequences of FDA-regulated product use. However, the users of FDA-regulated products ultimately determine which products are purchased and whether they are used according to package directions. For this reason, it is critical that the public understand the risks and benefits of FDA-regulated products to a degree that allows them to make rational decisions about product use. These responsibilities are authorized by Section 1003(d)(2)(D) of the Federal Food Drug and Cosmetic Act (21 U.S.C. Section 393) and by Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)).

Effective two-way communication with audiences who use FDA-regulated products is critical in preserving the overall balance between product benefits and risks. Besides communicating to the public, we also must effectively listen to those who prescribe and/or purchase and use the products, to determine whether the information being disseminated both by FDA and by the manufacturers and distributors we regulate appropriately reaches our targeted audiences so that they understand them. This is not just a matter of determining whether the public is satisfied with FDA's communications-related performance, but whether purchasers and users of our regulated products understand the information and are willing to act on it. Unless the public is able to employ FDA communications to make appropriate choices, FDA will not be fulfilling our mission to the public.

Modified sunscreen regulations were put into place in 2011, and FDA initiated a communications campaign to introduce to consumers new information on sunscreen labels that manufacturers will be required to use in 2012. Part of the campaign included videos of varying styles to show consumers how to use the new products. Testing messages is a critical step in sound and strategic risk communication (see, for example, the *NCI Pink Book: Making Health Communication Programs Work*) In preparing consumer communications and educational materials, FDA needs to ascertain whether the public understands the messages as intended, or where we need to modify or clarify the messages for better user understanding.

In the production of videos to support a communications campaign, there are limited funds available, and the goal of video production is to enhance the consumer's ability to absorb the messages of the campaign while remaining within limited budgets for video production. The topic of this study will be the comparative effectiveness of three sunscreen videos that use different approaches to inform the public about the new labels and new sunscreen guidance. This data collection will help FDA understand how to maximize its use of videos within budgetary constraints to communicate with the public to achieve FDA's public health objective of ensuring safe and effective use of FDA regulated products.

2. Description of respondents:

The sample will consist of approximately 300 Americans aged 18 or older who will be drawn randomly from a representative online panel with an oversample of approximately 100 low literacy (less than 8th grade education) adults. Stratification factors include age (under 35 years, 35-54 years, and 55 years or older), sex, race (White, Black, Asian), ethnicity (Hispanic or not Hispanic), education (completed years of education), and geographic area (West, Midwest, Northeast, and South).

Six groups shall be designated to watch and compare two of three videos, and respondents will be randomly assigned according to stratification factors. The sample size shall be large enough for results of questions asked of all respondents to be reported with a margin of error no greater than +/- 7%..

3. Date(s) to be Conducted:

June 18, 2012 – August 31, 2012

4. How the Information is being collected:

Data will be collected via online access to the survey. Access to the online survey shall be controlled through a process of enrollment and ID/password distribution.

5. Confidentiality of Respondents:

Respondents shall be promised that the information they provide will be kept private to the extent permitted by law. Respondents shall be identified only by numeric code. The Contractor shall destroy all records relating to the personal identity of the participants in the interviews, to ensure their anonymity and to protect the personal identity of the participants, prior to forwarding any data to FDA.

The Contractor shall put in place procedures to ensure quality control, including supervisor training, random validation checks, and daily feedback as needed to identify problems and their resolution. Representatives from the Government may visit the site to verify quality control. Educational or communication efforts described in this proposal are typically considered exempt from the "Regulations for the Protection of Human Subjects" in accordance with paragraph (b) (3) of 45 CFR Sec. 46.101. FDA researchers have obtained an exemption or a full approval for all research from FDA's IRB, the Research Involving Human Subjects Committee.

6. Questions of a Sensitive Nature

There are no questions of a sensitive nature in the questionnaire.

7. Description of Statistical Methods

The Contractor is responsible only for data collection. Data will be analyzed at FDA using weighted bivariate and multivariate techniques.

BURDEN HOUR COMPUTATION:

Respondent	No. of Respondents	Participation Time (minutes)	Burden (hours)
U.S. population	200	0:15	50
Low-literacy U.S. Population	100	0:15	25
TOTAL			75

REQUESTED APPROVAL DATE: June 13, 2012

NAME OF PRA ANALYST & PROGRAM CONTACT: Juanmanuel Vilela

FDA CENTER: Office of the Commissioner