CAMPAIGN for TOBACCO-FREE Kids®

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Office of Information and Regulatory Affairs, OMB
Attn: FDA Desk Officer

RE: Pretesting of Tobacco Communications – 0910–NEW
Docket No. FDA-2010-N-0084

To Whom It May Concern:

The Family Smoking Prevention and Tobacco Control Act (FSPTCA) gives the Food and Drug Administration (FDA) broad regulatory authority over the marketing of tobacco products and imposes important responsibilities on the FDA to communicate effectively with the public about tobacco products and the dangers of tobacco use. Among the fundamental purposes of the FSPTCA is to prevent underage smoking initiation and one of the essential purposes of the Act is to reduce "the number of children and adolescents who use cigarettes and smokeless tobacco and [to] prevent [] the life-threatening health consequences associated with tobacco use." Sec. 2(31). In fulfilling its regulatory role, FDA will be called upon to evaluate the effect of various regulatory and communications strategies on the actual consumption of tobacco products by both youth and adults. The aim of the pretesting program for which FDA seeks authority is to increase the agency's understanding of the factors that influence decision making about tobacco use by various target audiences. Development of such an understanding is an essential element in determining the content of an effective communications and regulatory strategy. Research about the actual effect of potential communications should greatly improve the efficacy of such communications and inform regulatory decisions. We commend FDA for taking a rigorous approach in its research to ensure that its communications have their intended effect. FDA's plan to conduct pretests to assess which messages will be most effective as well as the effectiveness of its specific communication efforts will play a critical role in the success of these campaigns.

The agency's communication strategy should be informed by an accurate understanding of the effect of such communications on its various target audiences and the factors that influence decisions on smoking initiation and cessation. We agree with FDA that it must conduct such research among *all* its targets, including adolescents, in order to develop an effective communications strategy. Conducting research with young people is not at all uncommon, and it has been absolutely critical to the success of campaigns to reduce tobacco use in states and nationally, like the truth® campaign. Since 90 percent of all adult smokers begin before the age of 19[1], the FDA must be able to know that it is effectively

[1] Calculated using SAMHSA's online data analysis tool using data found in Substance Abuse and Mental Health Services Administration (SAMHSA), Results from the 2007 National Survey on Drug Use and Health (NSDUH), 2008. U.S. Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, Office of Applied Studies.

reaching young people in its communications if it is to succeed in preventing young people from starting to smoke.

In addition, granting generic clearance for FDA to collect this information is essential to ensure that this research can be conducted in timely fashion. FDA cannot conduct effective campaigns without this kind of formative research, and it is not in the interest of public health to delay such communications unduly because of the clearance process.

We urge OMB to approve the request for generic clearance, so that FDA is able to assure that its communications will effectively reach the target audience and have their intended effect.

Sincerely,

Matthew L. Myers
President
Campaign for Tobacco-Free Kids