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American Academy of Pediatrics
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The Massachusetts Chapter

American Cancer Society®

Cancer Action Network℠ American Cancer Society®

American Heart Association.

AMERICAN LUNG ASSOCIATION.

CAMPAIGN for TOBACCO-FREE Kids®

truth initiative
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January 22, 2019

Office of Information and Regulatory Affairs
Office of Management and Budget
Attn: FDA Desk Officer

Re: OMB Control number 0910-NEW
Experimental Study of Cigarette Warnings

Docket No. FDA-2018-N-3552

Ladies and Gentlemen:

The undersigned medical and public health organizations and practicing pediatricians submit these comments with regard to the above-designated matter by which the Food and Drug Administration (FDA) has proposed a collection of information designed to inform the selection of graphic warning labels for cigarette packs and cigarette advertisements. The undersigned strongly urge the Office of Information and Regulatory Affairs (OIRA) to make it a priority to approve this collection of information as promptly as possible. In a lawsuit brought by the undersigned, the United States District Court for the District of Massachusetts has found that FDA unlawfully withheld and unreasonably delayed promulgation of a rule requiring these graphic warnings. *American Academy of Pediatrics v. FDA*, Case No. 1:16-cv-11985, (D. MA), Order, September 5, 2018. FDA has stated that the information collection proposed herein—and analysis of the information to be collected—are necessary for it to promulgate a proposed rule. The court currently has under consideration competing proposals by the plaintiffs and by FDA to establish a court-ordered deadline for promulgation of a final rule. Under these circumstances, it is urgent for OIRA to permit FDA to proceed with the information collection as soon as possible so that FDA can soon be in a position to promulgate a proposed rule.

The Family Smoking Prevention and Tobacco Control Act of 2009 ("Tobacco Control Act") amended the Federal Cigarette Labeling and Advertising Act to direct FDA to require manufacturers of cigarettes sold in the United States to place graphic warning labels on cigarette packs and in cigarette advertising. 15 U.S.C. § 1333(d). The statute directed FDA to promulgate a rule to accomplish this goal no later than June 22, 2011 and the new warning labels were required to be made effective by September 22, 2012. Although FDA promulgated such a rule on June 22, 2011, the rule was invalidated by order of the United States Court of Appeals for the District of Columbia Circuit in 2012,[1] prior to its being made effective, because the specific graphics chosen were found not to meet constitutional standards. In March 2013 FDA announced that it would begin the process of selecting new graphic warnings to meet its obligation under the Tobacco Control Act. The process of selecting new graphic warnings has already taken nearly six years since it was commenced. Since FDA's 2013 announcement, nearly three million Americans have died of tobacco-related disease and four million under the age of 18 have smoked their first cigarette. It is clear that increasing public understanding of the negative health consequences of smoking is an exigently important public health goal. OIRA should not further delay the fulfillment of FDA's statutory obligation.

In the notice, FDA addresses and responds fully to the comments it received when it proposed this information collection in September. These responses adequately address all the concerns raised by the comments. Moreover, FDA has reasonably estimated the reporting burden. OIRA should make it a priority to approve this information collection as promptly as possible.

Respectfully submitted,

American Academy of Pediatrics

Massachusetts Chapter of the American Academy of Pediatrics

American Cancer Society, Inc.

American Cancer Society Cancer Action Network, Inc.

American Heart Association

American Lung Association

Campaign for Tobacco-Free Kids

Truth Initiative

Dr. Ted Kremer

Dr. Jonathan Winickoff

Dr. Lynda Young

[1] *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205 (D.C. Cir. 2012).