



November 19, 2018

Dockets Management Staff [HFA-305]
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. FDA-2018-N-3552

Ladies and Gentlemen:

The undersigned organizations submit this comment in the above-designated docket. FDA has represented that the information collection proposed in this docket is intended to provide data for the final study before FDA promulgates graphic warning labels for cigarette packs and cigarette advertisements as required by the Family Smoking Prevention and Tobacco Control Act of 2009. The background information in the notice accurately describes the severe consequences of cigarette smoking in the United States and states that the results of the study will inform the Agency's efforts to implement the mandatory graphic warning label statements required by law.

In September of this year, a federal judge found, in a case brought by the undersigned parties, that FDA had both "unlawfully withheld" and "unreasonably delayed" agency action in issuing a final rule mandating graphic health warnings for cigarettes.¹ Given this ruling, and the public health importance of graphic warning labels, FDA must move forward to complete the study as soon as possible to facilitate the prompt promulgation of a rule to require such warning labels. In doing so, FDA must take every available opportunity to minimize delays that may be attributable to the Paperwork Reduction Act. The value of effective warning labels on cigarette

¹ *American Academy of Pediatrics, et al. v. U.S. Food and Drug Administration*, CA No. 1:16-cv-11985-IT, Slip op. (D. Mass. September 5, 2018).

packs and cigarette advertising far outweighs the minimal burdens imposed on the volunteer survey participants.

Respectfully submitted,

American Academy of Pediatrics

Massachusetts Chapter of the American Academy of Pediatrics, Inc.

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