



August 17, 2020

K. Michael Cummings, PhD, MPH
National Tobacco Reform Initiative
Department of Psychiatry & Behavioral Sciences
Medical University of South Carolina
67 President Street, MSC 861
Charleston, SC 29425

Re: Docket FDA-2020-P-1052

Dear Dr. Cummings:

This is a tentative response to inform you that the Food and Drug Administration (FDA) does not yet have a final answer to the issues raised in your citizen petition received on March 9, 2020, submitted on behalf of the National Tobacco Reform Initiative.

Your petition requests FDA to take certain actions in its regulation of tobacco products, including that FDA modify its regulatory framework through the lens of the continuum of risk while also recommending statutory changes to the Family Smoking Prevention and Tobacco Control Act.

Your request raises significant, complex issues requiring extensive review and analysis by Agency officials. FDA is currently considering the issues raised by your citizen petition and will issue a final response when our analysis is complete. This tentative response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)).

Regards,

Beverly Chernaik
Director, Office of Regulations
Center for Tobacco Products
Food and Drug Administration