



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Center for Tobacco Products
9200 Corporate Boulevard
Rockville MD 20850-3229

October 7, 2013

D. Douglas Blanke, JD
Director, Tobacco Control Legal Consortium
William Mitchell College of Law
875 Summit Avenue
St. Paul, MN 55105

Re: Docket No. FDA-2013-P-0435

Dear Mr. Blanke:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition submitted on April 12, 2013, on behalf of the Tobacco Control Legal Consortium and the African American Tobacco Control Leadership Council; American Academy of Pediatrics; American Association for Cancer Research; American Cancer Society – Cancer Action Network; American Heart Association; American Legacy Foundation; American Lung Association; American Public Health Association; Americans for Nonsmokers' Rights; Asian Pacific Partners for Empowerment, Advocacy and Leadership; Association for the Treatment of Tobacco Use and Dependence; Campaign for Tobacco-Free Kids; Corporate Accountability International; NAATPN, Inc. (parent organization of the National African American Tobacco Prevention Network); National Association of County and City Health Officials; National Latino Alliance for Health Equity; Society for Research on Nicotine and Tobacco; Summit Health Institute for Research and Education, Inc.; and Valerie B. Yerger, N.D.

Your petition requests that the Agency prohibit menthol as a characterizing flavoring in cigarettes. Specifically, your petition requests that FDA (1) add menthol to the list of additives and constituents in the prohibition on characterizing flavors in cigarettes and cigarette smoke directed by section 907(a)(1)(A) of the Federal Food, Drug, and Cosmetic Act and (2) work with appropriate entities to provide support to smokers of menthol cigarettes who will quit as a result of the requested prohibition on menthol in cigarettes.

FDA has been unable to reach a decision on your petition because it raises significant, complex issues requiring extensive review and analysis by Agency officials. As you may know, FDA issued an advance notice of proposed rulemaking on July 24, 2013, seeking comments, including comments on FDA's preliminary scientific evaluation of public health issues related to the use of menthol in cigarettes, and data, research, or other information that may inform regulatory actions FDA might take with respect to menthol in cigarettes (78 FR 44484).

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This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely,

A handwritten signature in black ink that reads "Mitchell Zeller". The signature is written in a cursive, flowing style.

Mitchell Zeller
Director, Center for Tobacco Products