DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

March 5, 2014

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

Re: Docket FDA-2013-P-1127/CP1

Dear Mr. Blanke:

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 September 9, 2013, on behalf of the Tobacco Control Legal Consortium; American Public Health Association; Association of State and Territorial Health Officials; National Association of County and City Health Officials; National Association of Local Boards of Health; New York State Department of Health; Healthy Communities Office, Providence, Rhode Island; Public Health - Seattle & King County, Washington; and the West Virginia Bureau for Public Health, Division of Tobacco Prevention.

Your petition requests that FDA "assert jurisdiction over and regulate the manufacturing, marketing, sale, and distribution of certain non-cigarette tobacco products, also known as 'other tobacco products' (OTPs)." In addition to asserting jurisdiction over all tobacco products, your petition requests FDA "extend many of the existing restrictions and requirements for cigarettes and smokeless tobacco to all tobacco products." FDA is currently considering the issues you raised in your citizen petition.

As you may know, FDA's proposed rule, "Tobacco Products Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act," was received by the Office of Management and Budget (OMB) on October 1, 2013. For more information, see the Unified Agenda entry at http://www.reginfo.gov/public/jsp/EO/eoDashboard.jsp?agency_cd=0000&agency_nm=All&stage_cd=2&from_page=index.jsp&sub_index=0).

In addition, 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)).

Sincerely,

Mitchell Zeller
Director, Center for Tobacco Products