DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Center for Tobacco Products
10903 New Hampshire Avenue
Silver Spring, MD 20993

May 5, 2016

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

Maggie Mahoney, J.D.
Director, Tobacco Control Legal Consortium
William Mitchell College of Law
875 Summit Avenue
Saint Paul, Minnesota 55105

Dear Ms. Mahoney:

This is a final response regarding your citizen petition received on May 10, 2011, filed 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, Office of Mayor Angel Taveras, City of Providence RI; Public Health - Seattle & King County WA; and the Division of Tobacco Prevention, West Virginia Bureau for Public Health, Office of Community Health Systems and Health Promotion, requesting 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 that the Food and Drug Administration (FDA or agency) "extend many of the existing restrictions and requirements for cigarettes and smokeless tobacco to all tobacco products."

We interpret your citizen petition to request that FDA initiate a rulemaking deeming certain tobacco products subject to Chapter IX of the Federal Food, Drug, and Cosmetic Act, as amended by the Family Smoking Prevention and Tobacco Control Act; consider regulating the manufacturing, marketing, sale, and distribution of certain non-cigarette tobacco products; and extend many of the existing restrictions and requirements for cigarettes and smokeless tobacco to all tobacco products. FDA's rulemaking procedures are governed by the Administrative Procedure Act, 5 U.S.C. 551 et seq., and the agency's regulations at 21 CFR 10.40. These requirements also apply when a citizen petition requests the agency to initiate rulemaking. See 21 CFR 10.30(f). These provisions set forth, among other things, the procedures for issuing a notice of proposed rulemaking, obtaining public comment, and promulgating a final rule.

We grant your request to initiate a rulemaking. As you know, FDA issued a proposed rule on April 25, 2014, "Tobacco Products Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act" (79 FR 23142). FDA's rulemaking was broad in scope, including what products should be deemed and what additional regulatory requirements should be imposed at the same time as deeming (if any), and requested public comment on a wide range of issues. FDA received more than 135,000 comments on the proposed rule, and these were similarly broad in scope regarding what products should be

deemed and what additional regulatory requirements should be imposed at the same time as deeming. FDA's final rule is on public display today in the Office of the Federal Register at https://www.federalregister.gov/public-inspection.

This final response is provided in accordance with FDA's regulation on citizen petitions (21 CFR 10.30).

Sincerely,

Beverly Chernaik

Beverly Chernaik, J.D.
Director, Office of Regulations
Center for Tobacco Products