



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

SEP - 5 2013

Thomas Farley, MD, MPH
Commissioner
New York City Department of Health & Mental Hygiene
42-09 28th Street
Long Island City, NY 11101

Re: Docket No. FDA-2013-P-0285/CP1

Dear Dr. Farley:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on March 11, 2013, on behalf of New York City Department of Health & Mental Hygiene, American Cancer Society Cancer Action Network, American Heart Association, American Lung Association, Campaign for Tobacco-Free Kids, Legacy, Public Citizen, and Tobacco Control Legal Consortium.

Specifically, your petition requests that, "on or before July 1, 2013, the FDA propose regulations mandating that each tobacco product produced or sold in the United States bear a unique counterfeit-resistant identifying code that allows its origin to be identified, and links to a computer database of required records that permits the product to be tracked and traced." You request that these regulations take effect on or before December 31, 2013.

Your petition raises significant, complex issues requiring extensive review and analysis by Agency officials. We will respond to your petition after we have reached a decision on your request. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)).

Sincerely,

A handwritten signature in black ink, reading "Mitchell Zeller". The signature is written in a cursive style with a large, stylized "M" and "Z".

Mitchell Zeller
Director, Center for Tobacco Products