February 26, 2016

Mr. Mitchell Zeller
Director, Center for Tobacco Products
U.S. Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

Dear Mr. Zeller:

The undersigned organizations are increasingly concerned that major tobacco companies are introducing new tobacco products into the marketplace without the regulatory review required by the Family Smoking Prevention and Tobacco Control Act of 2009 ("Tobacco Control Act").

The premarket review provisions of the Tobacco Control Act are intended to prevent the tobacco industry from continuing to introduce new tobacco products that are more harmful, more addictive and more appealing, particularly to young people. Section 910(a)(2) of the statute prohibits the commercial marketing of a new tobacco product unless FDA has issued an order finding the product "appropriate for the protection of the public health" in response to an application filed under Section 910, or the requirements have been met for the introduction of a product "substantially equivalent" to a predicate product under Section 910(a)(2) and Section 905(j). A "new tobacco product" under Section 910(a) is "any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007," or any modification of a tobacco product commercially marketed after that date.

It appears that major tobacco companies continue to market new products without an order from FDA that they have met the public health standard for new products or that they have been found substantially equivalent to a predicate product. From publicly available information, these are some of the non-compliant new products that have been introduced into the market over the last several years:

- Marlboro Midnight, which Philip Morris announced in October of last year will be marketed as a new cigarette,[1] and which the Marlboro website now says is "available coast to coast."[2] This product is a menthol cigarette which, according to a widely quoted industry analyst, is targeted to "a younger demographic."[3]

[1] Presentation of Marty Barrington, CEO of Altria Group, Briefing of Investor Analysts on Third Quarter Earnings, Oct. 29, 2015 http://www.thestreet.com/story/13344984/3/altria-group-mo-earnings-report-q3-2015-conference-call-transcript.html.
[2] http://marlboro.com.
[3] Melissa Kress, "The Resurgence of Combustible Cigarettes Continues," *Convenience Store News*, October 26, 2015, http://www.csnews.com/product-categories/tobacco/resurgence-combustible-cigarettes-continues?nopaging=1.

- Reynolds American Inc.'s subsidiary, American Snuff, "debuted" new Grizzly Wintergreen in March 2015, according to press reports.[4]

- Lorillard's Newport Smooth Select, a menthol brand which, according to the Lorillard website, was "launched" in 2013.[5]

- Philip Morris USA, Inc. launched Marlboro Edge in October 2013, according to trade press reports.[6]

- Three new brands of snus – Thunder Xtreme, Offroad and Oden's Extreme, by Kretek International, Inc., were introduced in 2013. [7]

- Marlboro Black NXT, featuring a crushable menthol capsule which, according to press reports, Philip Morris USA Inc. introduced in September 2012.[8]

- Marlboro Southern Cut, appeared on the Marlboro website as a "new" product ("Introducing New Marlboro Southern Cut") in December 2012, although an initial version of "small batch" Marlboro Craft Blends were promoted in July 2011.[9]

- Pall Mall Black and Pall Mall White, two new menthol products, introduced by RJ Reynolds in September 2012.[10]

- Copenhagen Southern Blend Snuff, marketed by Philip Morris and described by the company in its 2012 Corporate Responsibility Progress Report as "selected as the best new smokeless tobacco product in the OTP (other tobacco product) category in CSP Magazine's 2012 Retailer Choice Awards."[11]

Certain of the undersigned organizations have written FDA repeatedly to alert the agency of the apparent introduction of multiple new products without premarket review.[12] Because FDA

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[4] http://www.journalnow.com/business/business_news/local/reynolds-expands-distribution-for-its-top-selling-cigarette-and-new/article_803c5a48-d7d8-11e4-8a02-c7067fd3b64c.html.
[5] http://www.lorillard.com/brands/.
[6] http://www.cspnet.com/print/csp-magazine/article/cigarette-crystal-ball.
[7] http://www.csnews.com/product-categories/tobacco/kretek-enters-north-american-snus-market?nopaging=1
[8] http://www.cspnet.com/category-news/tobacco/articles/philip-morris-enters-capsule-market.
[9] https://trinketsandtrash.org/detail.php?artifactid=7530&page=1 and https://trinketsandtrash.org/detail.php?artifactid=6760&page=1.
[10] http://www.cspnet.com/news/tobacco/articles/pall-mall-black-white.
[11] http://public.thecorporatelibrary.net/sustain/sr_2012_13995.pdf.
[12] See Letter to CTP Director Zeller from Campaign for Tobacco-Free Kids, November 5, 2015; Letter to Acting Commissioner Ostroff from Legacy (now Truth Initiative) and Campaign for Tobacco-Free Kids, April 29, 2015; Letter to CTP Director Zeller from Campaign for Tobacco-Free Kids, May 3, 2013; Letter to CTP Director Zeller from Campaign for Tobacco-Free Kids, April 11, 2013; Letter to CTP Director Deyton from Campaign for Tobacco-Free Kids, September 18, 2012.

has provided so little information in response, it is difficult to determine the reasons why such products remain on the market. However, given the circumstances in which these products were introduced, it is implausible that all of them were the subject of substantial equivalence applications filed by March 22, 2011 and that they were marketed before that date. If such products were not on the market on that date, and the subject of substantial equivalence applications filed by that date, there is no apparent basis for them to remain on the market and FDA should take immediate action to remove them.[13]

That FDA has not taken the actions necessary to remove these products from the market represents a serious failure to protect the public health. Given that the avoidance of premarket review seriously undercuts the public health protections of the Tobacco Control Act, please explain why no enforcement actions have been taken by FDA against these products and indicate what the agency plans to do to prevent additional products from entering the market without the required regulatory review.

Thank you for your prompt attention to this important matter.

Sincerely yours,

Action on Smoking and Health
American Academy of Family Physicians
American Academy of Oral and Maxillofacial Pathology
American Academy of Oral Medicine
American Academy of Pediatrics
American Association for Respiratory Care
American Cancer Society Cancer Action Network
American College of Cardiology
American Dental Association
American Heart Association
American Lung Association
American Medical Student Association
American Psychological Association
American Public Health Association
American School Health Association
American Thoracic Society
Association of Maternal & Child Health Programs
Association of Schools and Programs of Public Health

[13] Even if substantial equivalence applications had been filed for these products by March 22, 2011, if the marketing claims made for these products by their manufacturers were true, it is doubtful that they would meet the criteria for substantial equivalence. If substantial equivalence reports for these products have been filed, FDA should promptly review them and, if they are not meritorious, remove these products from the market.

Association of State and Territorial Health Officials
Campaign for Tobacco-Free Kids
Cancer Prevention and Treatment Fund
Community Anti-Drug Coalitions of America
International Association for the Study of Lung Cancer
March of Dimes
National African American Tobacco Prevention Network
National Association of County & City Health Officials
National Latino Alliance for Health Equity
National Network of Public Health Institutes
Oncology Nursing Society
Prevent Cancer Foundation
Prevention Institute
Society for Cardiovascular Angiography and Interventions
Society for Research on Nicotine and Tobacco
Tobacco Control Legal Consortium
Trust for America's Health
Truth Initiative