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August 9, 2021

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

Sent by E-mail

RE: Continued introduction of new menthol cigarettes and flavored cigars without FDA marketing authorization

Dear Director Zeller:

The tobacco industry has a long history of introducing new products to attract new smokers and ensure that established smokers maintain their interest in smoking. For this reason, the Family Smoking Prevention and Tobacco Control Act (TCA) does not permit the introduction of “new tobacco products” (those introduced or modified after February 15, 2007), without rigorous premarket review by FDA and the issuance of premarket orders authorizing their sale. Nevertheless, a seemingly never-ending stream of products advertised as “new” continue to enter the U.S. marketplace without marketing orders.

We write to bring to your attention the continued introduction of flavored “new tobacco products” in defiance of the premarket review requirements of the TCA. More specifically, we write regarding Reynolds American, Inc.’s **Newport Boost menthol cigarettes** and Swedish Match’s **White Owl flavored cigars**. Particularly in light of the commitment FDA announced on April 29, 2021 to advance two tobacco product standards prohibiting menthol as a characterizing flavor in cigarettes and all characterizing flavors, including menthol, in cigars,¹ **FDA should: (1) prioritize enforcement against both sets of flavored “new tobacco products” that appear to be adulterated and misbranded without the required FDA marketing authorization and (2) expedite the issuance of proposed and final rules to**

¹ News Release, FDA, FDA Commits to Evidence-Based Actions Aimed at Saving Lives and Preventing Future Generations of Smokers (Apr. 29, 2021), <https://www.fda.gov/news-events/press-announcements/fda-commits-evidence-based-actions-aimed-saving-lives-and-preventing-future-generations-smokers> (FDA News Release).

establish menthol cigarette and flavored cigar product standards to eliminate these products from the marketplace.

The public health impact of the existing menthol cigarette and flavored cigar market is devastating enough, but the willingness of major tobacco manufacturers to continue to illegally introduce flavored, combustible “new tobacco products” underscores the need for further bold FDA actions. Menthol cigarettes and flavored cigars exact a disproportionate toll on the health and wellbeing of both young people and historically marginalized populations, including Black Americans. Each day FDA allows menthol cigarettes and flavored cigars to remain on the market represents countless additional kids lured into tobacco use and prolonged worsening of unacceptable health disparities. Without further delay, the agency must exercise its power under the TCA to put an end to this devastation.

I. Newport Boost Menthol Cigarettes

Marketing materials “introducing” Newport Boost cigarettes, such as the mailer below, made their way to consumers this summer. Newport Boost cigarettes are “two new styles that let [users] experience a boost of menthol.” One style boosts “menthol to more menthol,” and the other boosts “non-menthol to menthol.” These products seem to be a new addition to Reynolds’ line of menthol capsule cigarettes, including Lucky Strike Activate (Blue, Green), Pall Mall Activate (Blue, Green), and Camel Crush (Menthol, Menthol Silver, Rich, Smooth, Smooth Silver).



Newport Boost cigarettes appear to be “new tobacco products” because they were obviously introduced long after February 15, 2007. A capsule has been inserted into the filter of each cigarette to add menthol flavoring when users squeeze it. By the mailer’s own language,² this is a new physical attribute, not simply a change in the product’s label or packaging. Thus, it represents “a change in design, . . . [a] constituent, . . . or in the content[or] delivery [of an] additive or ingredient,” menthol, and thus qualifies as a “new tobacco product.”³ Because they are “new tobacco products,” they cannot legally be introduced to the market without premarket authorization from FDA as required under section 910 of the TCA, but no such orders have been issued. Without FDA marketing authorization, Newport Boost cigarettes are adulterated and misbranded under the Federal Food, Drug, and Cosmetic Act (FDCA), as amended by the TCA.⁴

In its April 29 announcement, FDA emphasized the urgency of action to end the adverse impact of menthol cigarettes on public health, and particularly on communities of color.⁵ Given that urgency, it is incongruous that the agency would allow the illegal introduction to the market of new menthol cigarette products designed to enhance the appeal of these products. Consistent with its April 29 announcement, FDA should immediately prioritize enforcement against these new menthol combustible cigarettes.

II. White Owl Flavored Cigars

The Deeming Rule, effective August 8, 2016, required cigars and other newly deemed tobacco products that meet the TCA’s definition of “new tobacco product” to also seek FDA premarket authorization.⁶ While newly deemed tobacco products *already on the market as of August 8, 2016* were subject to FDA’s Compliance Policy deferring enforcement of required premarket review, the Deeming Rule prohibited “new tobacco products” from being introduced *after August 8, 2016* unless they first

² In determining that these are “new tobacco products” FDA is justified in relying upon the manufacturer’s own claims, either express or implied, that the product was recently introduced to the market. Of course, if those claims are false, then the advertising of Newport Boost cigarettes is false and misleading because it leads consumers to falsely believe that a new tobacco product with a new physical attribute — “a boost of menthol” — has just become available for sale in the United States. In this case, the products would be misbranded under the Federal Food, Drug & Cosmetic Act, as amended by the TCA. 21 U.S.C. 387c(a)(7)(A).

³ “New tobacco products” means “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 (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007.” 21 U.S.C. 387j(a)(1). *See also Philip Morris USA Inc. v. FDA*, 202 F.Supp.3d 31, 51 (D.D.C. 2016) (finding a “new tobacco product” encompasses only the “physical attributes of the product itself, as distinct from its label or the package in which it is contained”).

⁴ 21 U.S.C. 387b(6)(A); 21 U.S.C. 387b(a)(6).

⁵ FDA News Release, *supra* note 1.

⁶ Final Rule, Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, 81 Fed. Reg. 28,974 (May 10, 2016) (relevant sections codified at 21 C.F.R. pt. 1100).

underwent premarket review and received a marketing authorization.⁷ Despite the Deeming Rule, new flavors of White Owl cigars have regularly been introduced to the market *after August 8, 2016* without the required FDA marketing orders.⁸ Swedish Match also openly advertises its plans to continue doing so.⁹

Researchers recently described one White Owl January 2021 promotion that is particularly egregious because of its likely appeal to young people: a “Limited Edition Chocolate & Vanilla Swirl.”¹⁰ The researchers also highlighted how the promotion of White Owl “Swirl” is nearly identical to other tobacco industry actions promoting e-cigarettes resembling candy and dessert-like products, which the FDA, sometimes with the Federal Trade Commission, enforced against in 2018.¹¹ Further, consumers were enticed to “Give Swirl a Whirl” as if it would be their first chance to try out the new flavor.¹²

The White Owl website, reproduced below, also advertised in December 2020 that “Swirl” was “Coming Soon,” clearly implying that the “limited edition” combination of chocolate and vanilla flavors, which are physical attributes of the product, wasn’t previously available.

⁷ *Id.* at 29,011. See also Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization (Revised); Guidance for Industry; Availability, 85 Fed. Reg. 23973 (Apr. 30, 2020) (first issued in January 2020 and re-issued in April 2020 “to reflect the court’s order in *Am. Acad. of Pediatrics v. Food & Drug Admin.*, No. 8:18-cv-883 PWG, Dkt. No. 182 (D. Md. Apr. 22, 2020) granting a motion for a 120-day extension (until September 9, 2020) in light of the global outbreak of respiratory illness caused by a new coronavirus).

⁸ Ollie Ganz et al., *Innovative promotional strategies and diversification of flavoured mass merchandise cigar products: a case study of Swedish match*, TOBACCO CONTROL 1, 4 (2021), <https://pubmed.ncbi.nlm.nih.gov/33526442/> (explaining that based on Nielsen National C-Track data, “it is unlikely that all current [cigar] flavours on the market correspond with a predicate cigar” and acknowledging the burden on FDA to discern what is and isn’t a “new tobacco product”); see also Charlie Minato, *Guantanamera Sues Swedish Match, Others Over “Duo” Trademark*, HALFWHEEL.COM (May 5, 2021), <https://halfwheel.com/guantanamera-sues-swedish-match-others-over-duo-trademark/393672/> (describing ongoing litigation where plaintiff alleges, among other things, that White Owl DUOS flavored cigars are illegal because they have not received FDA marketing orders).

⁹ Zeinab Safi et al., *White Owl launches sweepstakes to promote new dessert-flavored cigar*, TOBACCO CONTROL (2021), <https://tobaccocontrol.bmj.com/content/early/2021/05/23/tobaccocontrol-2021-056590> (citing Ganz et al., *supra* note 9).

¹⁰ *Id.*

¹¹ News Release, FDA, FDA warns company for selling e-liquids that resemble kid-friendly foods as part of the agency’s ongoing Youth Tobacco Prevention Plan (Nov. 29, 2018), <https://web.archive.org/web/20190108213140/https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm627123.htm>.

¹² Safi et al., *supra* note 10.



Two more recent examples of new White Owl flavored cigars making their post-Deeming Rule debut include “Jamaican Me Happy,” a tropical drink flavor given the product’s labeling, which made its first appearance on the White Owl website as “Available Now” in June 2021 along with “Coconut Rum” flavor, which is “Coming [in] September”:

AVAILABLE NOW

JAMAICAN ME HAPPY

Now, you can take a puff of paradise - but only for a limited time! Jamaican Me Happy is the latest exclusive smoking experience from White Owl and one that's sure to stir you up. Vibrant and tropical, this slow burn cigarillo delivers a fresh, fruity flavor that lasts. [Learn More.](#)

COMING SEPTEMBER

COCONUT RUM

LIMITED EDITION

Enjoy the essence of the islands when you crack open the latest flavored cigar creation from White Owl—Coconut Rum. [Learn more.](#)

Both are described as the “latest” and “limited time” or “limited edition” flavors of White Owl, which in combination with the phrases “available now” and “coming September,” indicate to consumers that they are new flavored cigars.

The continued post-Deeming Rule introduction and marketing of “limited edition” White Owl flavored cigars provides ample evidence that they are “new tobacco products” that require premarket authorization from FDA. However, like Newport Boost cigarettes, no such orders have been issued.¹³ Additionally, no marketing applications appear to have been submitted for any White Owl flavored cigars by the court-ordered September 9, 2020 deadline for newly deemed products that were *already on the market as of August 8, 2016*.¹⁴ Without FDA marketing authorization, White Owl flavored cigars are adulterated and misbranded under the FDCA.¹⁵ Given FDA’s April 29 announcement that it intends to issue a product standard to prohibit all flavors in cigars because of their disproportionate popularity among youth, particularly Black youth,¹⁶ FDA should immediately prioritize enforcement against these new flavored cigars.

III. Menthol Cigarette and Flavored Cigar Product Standards

In addition to prioritizing enforcement action against illegally marketed menthol cigarettes and flavored cigars like Newport Boost cigarettes and White Owl cigars, the FDA should move swiftly to finalize and implement the menthol cigarette and flavored cigar product standards. The agency’s April 29, 2021 stated commitment to advancing the two flavored product standards was an important step toward ending the tobacco-related disease and death that so disproportionately affect communities of color.¹⁷ However, it was long overdue because “[f]or too long, tobacco companies have been enabled to promote menthol cigarettes to the Black community, preying particularly on Black youth.”¹⁸

The industry’s marketing targeting the African American community has led to 85% of Black smokers now smoking menthol cigarettes, compared to less than 10% in the 1950s.¹⁹ Additionally, cigars have become the most popular tobacco product among Black high school students and the second most

¹³ A search for PMTA, SE, and EX REQ marketing orders for White Owl flavored cigars on FDA’s website revealed none as of the submission of this letter.

¹⁴ A search for White Owl flavored cigars on the voluntary lists of deemed new tobacco products with timely applications on FDA’s website, which would allow the continued marketing of the products until a negative FDA action on the application or the expiration of a one-year FDA review period, revealed none as of the submission of this letter.

¹⁵ 21 U.S.C. 387b(6)(A); 21 U.S.C. 387b(a)(6).

¹⁶ FDA News Release, *supra* note 1.

¹⁷ Press Release, Am. Med. Ass’n, FDA agrees to ban menthol to protect African Americans (Apr. 29, 2021), <https://www.ama-assn.org/press-center/press-releases/fda-agrees-ban-menthol-protect-african-americans>.

¹⁸ *Id.*

¹⁹ Phillip S. Gardiner, *The African Americanization of menthol cigarette use in the United States*, 6 (Supp. 1) NICOTINE & TOBACCO RES. S55, S59 (2004); Cristine D. Delnevo et al., *Banning Menthol Cigarettes: A Social Justice Issue Long Overdue*, 22 NICOTINE & TOBACCO RES. 1673, 1674 (2020).

used tobacco product, after e-cigarettes, among all high school students.²⁰ And, the predatory marketing continues to this day, as demonstrated by this May 2021 Newport Boost ad in *US Weekly* featuring what appears to be an African-American woman.²¹

While the FDA recognized the myriad of evidence-based public health benefits that the menthol cigarette and flavored cigar product standards would have—significantly reducing youth initiation, increasing the chances of smoking cessation, and both reducing health disparities and promoting health equity— it inexplicably indicated its intent to take as much as a year to issue the proposed rules.²² Given that FDA has been studying the impact of menthol cigarettes and flavored cigars for over a decade and has accumulated overwhelming scientific evidence on their adverse effects on public health during those years,²³ there is no justification for the agency to take as long as a year to issue proposed rules. The issuance of proposed and final rules must be expedited on a timeline that reflects the urgency of protecting the public from these products.



The longer FDA takes to act, the greater the opportunity for the tobacco companies to introduce even more new menthol cigarettes and flavored cigars to increase the appeal of these deadly and addictive products.

²⁰ Andrea S. Gentzke et al., *Tobacco Product Use Among Middle and High School Students—United States, 2020*, 69 MORBIDITY & MORTALITY WKLY. REP. 1881, 1884 (Dec. 17, 2020), <https://www.cdc.gov/mmwr/volumes/69/wr/pdfs/mm6950a1-H.pdf>.

²¹ Rutgers School of Public Health, *Trinkets and Trash: Artifacts of the Tobacco Epidemic*, <http://trinketsandtrash.org/detail.php?artifactid=15540&page=1> (capturing Newport Boost ad in May 10, 2021 issue of *Us Weekly*).

²² FDA News Release, *supra* note 1.

²³ FDA Response to Citizen Petition, Dkt. No. FDA-2013-P-0435, at 3-7 (Apr. 29, 2021), <https://www.regulations.gov/document/FDA-2013-P-0435-0106>.

Sincerely,

Action on Smoking & Health

African American Tobacco Control Leadership Council

American Academy of Pediatrics

American Cancer Society Cancer Action Network

American Heart Association

American Lung Association

American Medical Association

Association of Black Cardiologists

Black Women's Health Imperative

Campaign for Tobacco-Free Kids

NAACP

National Medical Association

Public Health Law Center

The Center for Black Health & Equity

Truth Initiative

CC: Dr. Janet Woodcock, Acting Commissioner, FDA