

March 10, 2023

Dr. Brian King Director, Center for Tobacco Products U.S. Food and Drug Administration 10903 New Hampshire Ave. Silver Spring, MD 20993-002

Re: New Cigarette Products Introduced to Evade California Flavors Law

Submitted by e-mail.

Dear Dr. King:

On December 21, 2022, California's law prohibiting the retail sale of menthol cigarettes and other flavored tobacco products—Senate Bill 793 ("S.B. 793")—went into effect, after 63% of voters approved the new law in an industry-supported referendum in November. Cigarette companies wasted no time and immediately began introducing new products to the California market designed to appeal to the state's menthol smokers and to circumvent the new law. In addition to potential state law violations, these cigarettes appear to violate the Family Smoking Prevention and Tobacco Control Act ("Tobacco Control Act" or "TCA"), including the TCA's prohibition on the introduction of new tobacco products without marketing orders and the prohibition on non-menthol, non-tobacco flavored cigarettes.

Because the new products appear to violate federal law, and, if allowed to remain on the market, will substantially harm public health, the undersigned medical, public health, civil rights and community organizations urge you to immediately commence an investigation of these new products and to ensure that appropriate enforcement proceedings are initiated to prevent their continued sale. We also urge the FDA to ensure that these and other similar emerging cigarettes are covered by, and do not evade, a final FDA rule prohibiting menthol cigarettes.

#### Tobacco Control Act

The Tobacco Control Act prohibits the introduction of all "new tobacco products" that have not undergone rigorous premarket review by FDA and received a premarket order authorizing their sale. 21 U.S.C. § 387j. The statute defines a new tobacco product as:

- (A) any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007; or
- (B) 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.

#### Id. § 387j(a)(1).

The Tobacco Control Act also prohibits the introduction of any cigarette with a characterizing flavor other than tobacco or menthol. *Id.* § 387g(a)(1)(A). As you know, in May 2022, FDA proposed a tobacco product standard that would prohibit menthol as a characterizing flavor in cigarettes ("menthol cigarette rule"). *See* Tobacco Product Standard for Menthol Cigarettes, 87 Fed. Reg. 26,454 (proposed May 4, 2022). Once the menthol cigarette rule is finalized and implemented, no flavored cigarette (other than tobacco-flavored ones) will be legal to sell in the United States.

#### R.J. Reynolds Camel and Newport Cigarettes

Even before S.B. 793 went into effect, R.J. Reynolds primed Californians for two new Camel products designed to provide a new taste sensation to substitute for the menthol-flavored products that would soon exit the market. Reynolds' promotional material gave a "Camel Heads Up" notifying people who smoke that it had "crafted two new non-menthol styles with a taste and smoking experience you'll love." Exhibit 1. It announced that two new brands of products, Camel Crisp Non-Menthol and Camel Crush Oasis Non-Menthol Capsule, were "coming soon." Camel Crisp, according to the Heads Up, "offers smooth tobacco flavor and a crisp smoking experience." Camel Crush Oasis, meanwhile, "puts a new twist on your favorite capsule experience – transforming Camel's original non-menthol blend into a tropical oasis." *Id*.

Once California's law took effect, Reynolds sent a mailer to people who smoke, again announcing that it was "introducing" these new products. Exhibit 2. "Your favorite menthol styles are gone," the mailer read, "but we've crafted two new non-menthol blends with you in mind." *Id.* A separate ad for Camel Crisp Non-Menthol promises "a crisp new experience" which "offers smooth tobacco flavor and a crisp smoking experience from the very first draw" resulting in "a taste that satisfies the senses." Exhibit 3. Ads for Crush Oasis Non-Menthol instructed consumers to "crush like never before" (Exhibit 4) and touted that it is "the only crush of its kind." Exhibit 5. The latter ad lists three variations of the product – Crush Oasis Green, Crush Oasis Blue, and Crush Oasis Silver – with the packaging for each of the products featuring blue and/or green hues and the words "Tropical Oasis." *Id.* Finally, the Camel website advertises that it is "introducing new blends" and features the Camel Crisp Non-Menthol and three Camel Crush Oasis Non-Menthol products. Exhibit 6. Under the TCA, these cigarettes are "new tobacco products" because they were introduced long after February 15, 2007. Reynolds' marketing materials<sup>1</sup> repeatedly point out that these products are "new blends" and "new styles." Exhibits 1, 2, & 6. Moreover, with respect to the Camel Crush Oasis Non-Menthol products, the marketing material suggests that the capsules in these products represent "a change in design, . . . [a] constituent, . . . or in the content, delivery or form of . . . any . . . additive or ingredient." 21 U.S.C. § 387j(a)(1)(B); *see* Exhibits 1 ("puts a new twist on your favorite capsule experience"), 4 ("crush like never before"), & 5 ("the only crush of its kind"). These are changes to a physical attribute of a product, not simply a change to the product's labeling or packaging.<sup>2</sup> Accordingly, such products, are "new tobacco products" under the statute and are required to undergo premarket review prior to introduction. We have been unable to locate marketing orders for these products,<sup>3</sup> suggesting that they are being illegally marketed in violation of the TCA.

Moreover, Reynolds' claims that Camel Crisp offers "a crisp new experience" and "a taste that satisfies the senses" (Exhibit 3) and that the Camel Crush Oasis products "transform[] Camel's original non-menthol blend into a tropical oasis" (Exhibit 4) suggest that these new cigarettes may "contain, as a constituent (including a smoke constituent) or additive, an artificial or natural flavor . . . other than tobacco or menthol . . ." in violation of the TCA's Special Rule for Cigarettes. 21 USC § 387g(a)(1)(A). Presumptively, that these products are being marketed specifically to Californians who smoke menthol cigarettes as a substitute for menthol flavor indicates that they have a characterizing flavor.<sup>4</sup>

Another Reynolds product, "New Non-Menthol Newport" cigarettes, introduced in the wake of California's law taking effect, is also likely a "new tobacco product" under the TCA. Reynolds' marketing supports this conclusion, with the words "New fresh taste, same satisfaction" plastered next to images of the products. Exhibit 7. In July 2020, FDA issued a substantial equivalence order for a product named "Newport Non-Menthol Box."<sup>5</sup> The order

<sup>&</sup>lt;sup>1</sup> 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 is false and misleading because it leads consumers to falsely believe that a new tobacco product with a new physical attribute 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).

<sup>&</sup>lt;sup>2</sup> See 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").

<sup>&</sup>lt;sup>3</sup> See FDA, Marketing Orders for SE, <u>https://www.fda.gov/tobacco-products/substantial-equivalence/marketing-orders-se</u> (last visited Mar. 8, 2023); FDA, Marketing Orders for Exemption from SE, <u>https://www.fda.gov/tobacco-products/exemption-substantial-equivalence/marketing-orders-exemption-se</u> (last visited Mar. 8, 2023).

<sup>&</sup>lt;sup>4</sup> Of course, the claim in Reynolds' advertising that its Camel Crisp Non-Menthol product "offers smooth tobacco flavor" (Exhibit 3) cannot be controlling on whether the new product has a characterizing flavor, given that the company is marketing this product as having a taste that will substitute for the menthol flavored products now prohibited from being sold in California. It is implausible that Reynolds intends the phrases "crisp new experience" and a "new non-menthol style[] with a taste and smoking experience you'll love" (Exhibit 1) to suggest that it is offering only an unflavored product to give people who smoke menthol cigarettes what the California statute has taken away – a taste sensation close to the flavor of menthol.

<sup>&</sup>lt;sup>5</sup> <u>https://www.fda.gov/media/146098/download</u>.

lists the characterizing flavor for the new product as "none," although the predicate product is a menthol cigarette ("Newport Menthol Box").<sup>6</sup> If the new product does provide a "new fresh taste," as Reynolds' advertising states, then it would not appear to be the same product that was the subject of the July, 2020 SE order, which was listed as having no characterizing flavor.<sup>7</sup>

If, on the other hand, Reynolds claims that the newly introduced product is the subject of the July, 2020 SE order, then we also urge FDA to investigate whether the order is accurate that the SE product contains no characterizing flavor, particularly given Reynolds' marketing of this product as a substitute for the menthol cigarettes that may no longer be sold under California law. As a Reynolds mailer put it: "The menthol ban is here but we've got you covered, California." Exhibit 8. Another mailer for Newport non-menthol cigarettes is headed, "Never compromise, California." Exhibit 9. These ads convey the message that the new products are designed to give people who smoke menthol cigarettes exactly what was taken away from them by S.B. 793 and to do it "without compromise." The ads also repeatedly use the word "fresh," which years of industry advertising has strongly associated with menthol in cigarettes: "Introducing what's next in fresh," (Exhibit 9); "new fresh taste, same satisfaction." Exhibit 7. Moreover, the packaging mimics the green packaging which also has become strongly associated with menthol flavoring.

Similar concerns exist for Newport EXP, another brand of "non-menthol" Newports. In December 2022 – the same month California's flavors law took effect – Reynolds sent out a mailer announcing the arrival of the new products and describing their flavors: "Newport EXP has arrived, California. And it's unlike any smoking experience that's come before." Exhibit 10. There are (at least) two EXP products – MAX and MIX. As the advertising states, both products allow people who smoke to "[i]mmerse yourself in a fresh intensity that is designed to satisfy the senses. Dial things up a notch with EXP MAX for bold, lasting flavor. For a more balanced experience that's sensational & smooth, there's EXP MIX." *Id.* Another ad for these products are not the subject of any marketing orders.<sup>8</sup> FDA must investigate whether these products violate the TCA as new tobacco products introduced without a marketing order and as cigarettes containing a characterizing flavor other than tobacco or menthol.

#### ITG Brands' Kool Cigarettes

ITG Brands also responded to California's flavored tobacco law by introducing new cigarettes. The company's new "non-menthol Kool" cigarettes are available "only in California," (Exhibit 12) are packaged in green and blue to look exactly like the comparable

<sup>&</sup>lt;sup>6</sup> *Id.* at 3.

<sup>&</sup>lt;sup>7</sup> FDA also issued orders finding products named Newport Non-Menthol Box and Newport Non-Menthol Box 100s to be exempt from substantial equivalence review. *See* Exempt Orders, <u>EX0000251</u>, <u>EX0000252</u>, <u>EX0000253</u>, <u>EX0000254</u> (Sep. 24, 2018); Exempt Orders, <u>EX0000229</u>, <u>EX0000230</u>, <u>EX0000231</u> (July 13, 2018). Because these products also were listed as having no characterizing flavor, they likely do not correspond to any of the Reynolds non-menthol products that were recently introduced into California.

<sup>&</sup>lt;sup>8</sup> See FDA, Marketing Orders for SE, <u>https://www.fda.gov/tobacco-products/substantial-equivalence/marketing-orders-se</u> (last visited Mar. 8, 2023); FDA, Marketing Orders for Exemption from SE, <u>https://www.fda.gov/tobacco-products/exemption-substantial-equivalence/marketing-orders-exemption-se</u> (last visited Mar. 8, 2023).

Kool menthol cigarettes sold elsewhere (Exhibit 13) and are offered in the same varieties of "bold and assertive taste" and "smooth, mellow taste." Exhibit 12. It is also significant that, even at this early promotional stage for these new products, Black models are featured in the ads (Exhibit 14), indicating that ITG is using the same marketing strategy of targeting the Black community that has been so successful in promoting the menthol cigarettes that may no longer be sold in California. The clear message here is that Kool cigarettes marketed in California have flavors designed to be as close as possible to the traditional menthol flavor. FDA must investigate if these products contain a characterizing flavor and whether they are subject to any marketing orders. We have again been unable to locate any such marketing orders.<sup>9</sup>

#### FDA's Proposed Menthol Cigarette Rule

The introduction and marketing of these products as substitutes for menthol cigarettes suggests that the industry believes it has found a loophole in California's law on menthol cigarettes and other flavored tobacco products. It is imperative that FDA consider these and other emerging products in crafting its own rule prohibiting menthol as a characterizing flavor in cigarettes. 87 Fed. Reg. 26,454. While we believe these products would be considered flavored cigarettes under the factors that FDA has laid out in the proposed rule,<sup>10</sup> we strongly urge FDA to continually evaluate these and other emerging products to ensure they are covered by the proposed rule.

#### **Conclusion**

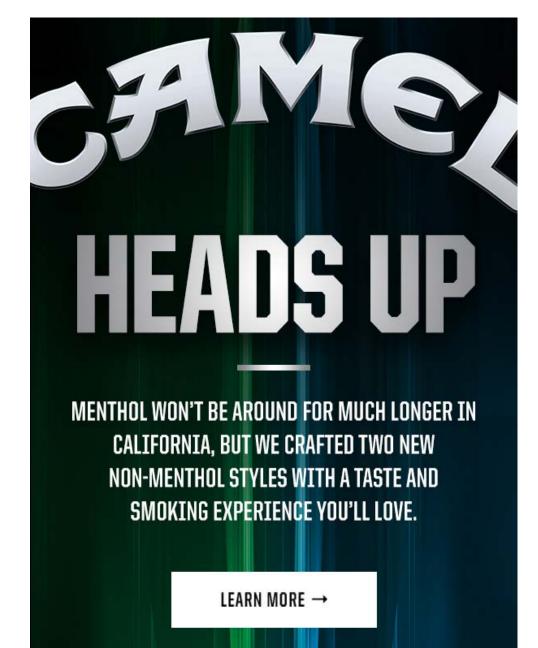
For the reasons above, we urge FDA to commence an immediate investigation into – and take appropriate enforcement against – the new cigarettes that are being introduced into California as a way to circumvent that state's recently enacted flavored tobacco law, and into other products that seek to evade California's new law. These cigarettes, which are "new tobacco products" under federal law, appear to violate the Tobacco Control Act's premarket review requirements and, potentially, the statute's prohibition on flavored cigarettes (other than tobacco or menthol). In light of the industry's response to California's law, as well as the industry's long history of searching for and exploiting any perceived loophole, FDA should ensure that these and other emerging products are covered by, and do not evade, its own menthol cigarette rule.

Respectfully submitted,

<sup>&</sup>lt;sup>9</sup> See FDA, Marketing Orders for SE, <u>https://www.fda.gov/tobacco-products/substantial-equivalence/marketing-orders-se</u> (last visited Mar. 8, 2023); FDA, Marketing Orders for Exemption from SE, <u>https://www.fda.gov/tobacco-products/exemption-substantial-equivalence/marketing-orders-exemption-se</u> (last visited Mar. 8, 2023).

<sup>&</sup>lt;sup>10</sup> "Among the factors that FDA believes are relevant in determining whether a cigarette has a characterizing flavor are: [1] The presence and amount of artificial or natural flavor additives, compounds, constituents, or ingredients, or any other flavoring ingredient in a tobacco product, including its components or parts; [2] The multisensory experience (i.e., taste, aroma, and cooling or burning sensations in the mouth and throat) of a flavor during use of a tobacco product, including its components or parts; [3] Flavor representations (including descriptors), either explicit or implicit, in or on the labeling (including packaging) or advertising of tobacco products; and [4] Any other means that impart flavor or represent that the tobacco products has a characterizing flavor." 87 Fed. Reg. at 26,455.

Action on Smoking & Health African American Tobacco Control Leadership Council (AATCLC) American Academy of Pediatrics American Cancer Society Cancer Action Network American Cancer Society Cancer Action Network American Heart Association American Lung Association American Medical Association Americans for Nonsmokers Rights Campaign for Tobacco-Free Kids Parents Against Vaping e-cigaretttes (PAVe) Truth Initiative CC: Dr. Robert Califf, Commissioner, U.S. Food and Drug Administration



# CRISP NON-MENTHOL

CAMEL CRISP OFFERS SMOOTH Tobacco flavor and a Crisp Smoking experience.

# COMING SOON

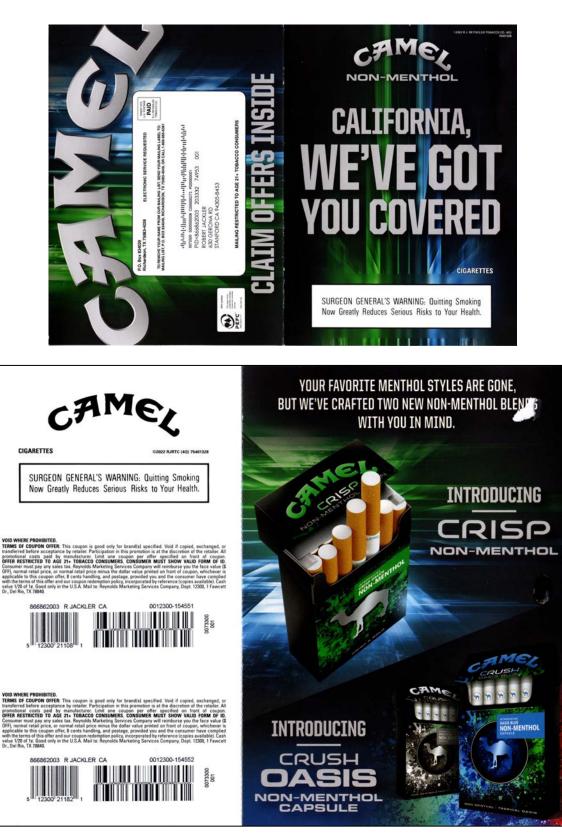
#### CRUSH OASIS THE ONLY CAPBULE

NO

RISP CREAN NON-MENTHOL

CRUSH OASIS PUTS A NEW TWIST ON YOUR FAVORITE CAPSULE EXPERIENCE – TRANSFORMING CAMEL'S ORIGINAL NON-MENTHOL BLEND INTO A TROPICAL OASIS.

> NON-MENTHOL CAPSULE



value 1/2 Dr. Del R









# Exhibit 7











# discover more



# Satisfaction Reimagined.

Newport EXP has arrived, California. And it's unlike any smoking experience that's come before. Immerse yourself in a fresh intensity that is designed to satisfy the senses. Dial things up a notch with EXP MAX for bold, lasting flavor. For a more balanced experience that's sensational & smooth, there's EXP MIX. Both styles are made with & smooth, there's EXP MIX. Both styles are made with premium tobacco blends that provide a new, fresh twist premium tobacco blends that provide a new. fresh twist that you'll just have to experience for yourself. Find out more newport-pleasure.com/california







Menthol KOOL Brands

