March 27, 2019

Dockets Management Staff
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. FDA-2018-D-3244

Ladies and Gentlemen:

The undersigned organizations submit these comments in the above-designated docket concerning FDA's draft guidance titled "Enforcement Policy for Certain Marketed Tobacco Products" (the "Draft Guidance"). If finalized, the Draft Guidance would supersede the existing guidance issued in September 2015, "Enforcement Policy for Certain (Provisional) Tobacco Products that FDA Finds Not Substantially Equivalent" (the "2015 Guidance"). In the Draft Guidance, FDA proposes to give manufacturers, distributors, importers, and retailers an unjustified grace period to "sell off" existing stock of products—which have already been on the market for at least eight years—after FDA has found them to be "not substantially equivalent" ("NSE") and thus adulterated and misbranded under the Food, Drug, & Cosmetic Act ("FDCA"). The proposed policy would protect the financial interests of everyone in the supply chain at the expense of the health of the consumer. The Draft Guidance is inconsistent with FDA's statutory obligation to protect the public health and should be withdrawn.

A. Background

The Tobacco Control Act defines a "new tobacco product" as a tobacco product that was not commercially marketed as of February 15, 2007. FDCA § 910(a)(1)(A). It prohibits the marketing of any new tobacco product in the absence of an FDA marketing order. The Act created an exception, however, for new tobacco products that the manufacturer alleged were substantially equivalent" ("SE") to a product commercially marketed as of February 15, 2007, provided that (1) the new product was commercially marketed by March 22, 2011 and (2) the

manufacturer had filed an SE application with FDA by March 22, 2011. New tobacco products that met these requirements were permitted to stay on the market unless and until FDA denied the SE application. Such products are generally referred to as "provisional" tobacco products.

Under the Tobacco Control Act, in order to find a product "substantially equivalent" to a predicate product, FDA must find that a product either has "the same characteristics" as the predicate product or that it does not have the same characteristics and does not "raise a different question of public health." FDCA § 910(a)(3)(A). When FDA finds that a product is Not Substantially Equivalent ("NSE"), it has therefore found that the product does not have the same characteristics as the predicate product *and* that it "raises a different question of public health." For example, in 2015, FDA found that R.J. Reynolds' Camel Crush products were NSE because the manufacturer had failed to demonstrate that the product's "increased yields of harmful or potentially harmful constituents, higher level of menthol, and/or the addition of new ingredients … when compared to the predicate products do not raise different questions of public health." In addition, FDA specified that the applicant had "fail[ed] to demonstrate that the addition of a menthol capsule in the filter did not affect consumer perception and use." Once found NSE, the product was adulterated and misbranded under FDCA §§ 902(6)(A) and 903(a)(6) and was required to be removed from the market. Under the guidance then in effect, FDA stated that it would not take enforcement action for 30 days from the date of issuance of the NSE order, but that policy applied only to product that was already in the inventory of retailers.

FDA received more than 3,500 SE applications prior to March 22, 2011. However, because FDA prioritized its review of SE applications filed for products introduced *after* March 22, 2011, it delayed review of the SE applications for the provisional tobacco products for years. All the while, these products have stayed on the market.

B. <u>The Draft Guidance Prioritizes the Tobacco Industry's Economic Interests Over the Public Health.</u>

The Draft Guidance applies only to provisional tobacco products. Such products are cigarettes, smokeless tobacco, or roll-your-own tobacco, as these were the only categories of tobacco products that were subject to FDA jurisdiction as of March 22, 2011. FDA has allowed all of these products to remain on the market until the agency acts on their provisional SE applications. As a result, these products have already been on the market without any meaningful regulatory oversight for at least eight years.

The proposed draft guidance amends the enforcement policy FDA will follow when the agency finds that a provisional tobacco product is NSE. Unfortunately, the new policy greatly expands the permissible marketing of products *after* FDA has found that they "have different characteristics" and "raise different questions of public health" than the predicate product. First, the Draft Guidance expands the parties protected from enforcement in the wake of an NSE order to cover the entire supply chain. While the 2015 Guidance limited protection to product already

in the inventory of retailers, the Draft Guidance explicitly includes manufacturers, importers, and distributors within the zone of protection. Indeed, *it arguably applies even to product manufactured subsequent to an NSE order.* Second, under the Draft Guidance the adulterated product can continue to be sold during the pendency of any administrative appeal. And even if the appeal is denied, manufacturers, importers, distributors, and retailers could continue to market the NSE product for yet another 30 days without FDA enforcement. Given that all SE applications potentially eligible for this policy have already been pending at least eight years, we are concerned that the Draft Guidance creates another opening for extended, even indefinite marketing of tobacco products even after they have been found to raise public health questions.

FDA gives no reason for the change in its approach from the 2015 Guidance. Rather, FDA explains that the purpose of the new, broad 30-day enforcement stay is to "provide time for a sell-off" of these adulterated and misbranded products. Given that FDA has found that these products actually do "raise different questions of public health," this policy is fundamentally at odds with the public health and with the Tobacco Control Act. It encourages companies to push as much of the NSE tobacco product into distribution as possible immediately after an NSE order and gives companies throughout the distribution chain a free pass so they can squeeze every last drop of revenue from products that FDA has found may raise new public health concerns. Like Camel Crush, these products may have higher levels of hazardous or potentially hazardous components than predicate products and that may have elements that affect consumer perception and use.

In short, establishment of a policy based on such misplaced priorities, with no justification for expanding protection from enforcement for makers and sellers of NSE products, is contrary to FDA's fundamental statutory obligation to protect the public health. Eight years of marketing adulterated and misbranded tobacco products is long enough. FDA should rescind the Draft Guidance and continue to follow the enforcement policy in the 2015 Guidance.

Respectfully submitted,

American Academy of Pediatrics

American Cancer Society Cancer Action Network

American Heart Association

American Lung Association

Campaign for Tobacco-Free Kids

Public Health Law Center

Truth Initiative