February 2, 2023

Tony Abboud
Executive Director
Vapor Technology Association
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Washington, D.C. 20004
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Dear Mr. Abboud:

Thank you for your letter of November 3, 2022,[1] concerning the Food and Drug Administration's (FDA or Agency) regulation of non-tobacco nicotine (NTN) products.

FDA is fully committed to implementing the new federal law clarifying its authority to regulate tobacco products containing NTN, including synthetic nicotine. Manufacturers of these products are now held to the same public health standards, including premarket review, as tobacco-derived nicotine (TDN) products. Irrespective of whether the product contains TDN or NTN, it is illegal to sell or distribute tobacco products that the FDA has not authorized. On August 8, 2016, all deemed tobacco products, including e-cigarettes, became subject to FDA's tobacco authorities. As a matter of enforcement discretion at the time, the Agency stated that it intended to defer enforcement for a period of time of the premarket authorization requirement for certain deemed new products on the market as of August 8, 2016. However, in light of later data on youth use and other information, FDA revised this policy in its 2020 enforcement priorities guidance. That guidance described how the Agency intended to prioritize its limited enforcement resources regarding certain ENDS products. It also noted that all deemed new tobacco products on the market without authorization are illegally marketed and that the Agency "retains discretion to pursue enforcement action at any time" against such products. Accordingly, your letter's assertion that FDA is "us[ing] its enforcement discretion to allow . . . products to remain on the market" while they undergo review is not correct. On the contrary, as the guidance reiterates, all illegally marketed TDN e-cigarette products are subject to FDA enforcement.

The same principle applies to NTN products; specifically, all illegally marketed NTN products are subject to enforcement.[2] The NTN timelines, set by the Consolidated Appropriations Act of 2022, did not include a period for continued marketing of unauthorized new products beyond the

[1] In your letter, dated November 3, 2022, you stated you were following up on correspondence from June 10, 2022. FDA does not have a record of correspondence from Vapor Technology Association on this date.
[2] Under the Consolidated Appropriations Act of 2022 (the Appropriations Act) (Public Law 117-103), enacted on March 15, 2022, tobacco products that contain NTN, including synthetic nicotine, are subject to the provisions in chapter IX of the Federal Food, Drug, and Cosmetic Act (FD&C Act), including the requirement in section 910 for premarket review of new tobacco products.

law's specific deadlines, the last of which passed in July. Therefore, all NTN products on the market without premarket authorization, whether they have a pending application or not, are illegal and are subject to FDA enforcement.

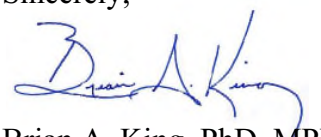
FDA cannot affirmatively allow or permit the unlawful marketing of tobacco products, including TDN and NTN e-cigarette products; as the above statements reflect, all illegally marketed products are subject to FDA enforcement, such a seizure, civil money penalty, or injunction. Moreover, FDA has not adopted a broad policy of enforcement discretion with respect to TDN or NTN e-cigarette products that lack the required premarket authorization. Of course, it is true that we are unable to take enforcement action against every illegally marketed tobacco product. Recognizing that reality, and that we need to make the best use of Agency resources, we continue to make enforcement decisions on a case-by-case basis. However, this case-by-case approach does not amount to a policy of deferred enforcement.

As you state in your letter, in 2021, FDA published a list of products for which a PMTA had been submitted by the court-ordered September 9, 2020, deadline.[3] As noted above, this year's NTN timelines, set by Congress, did not include a period for continued marketing of unauthorized new products after July 13, 2022, and no NTN product has been authorized to date. Therefore, a public list of products for which NTN PMTAs have been filed is unnecessary. All Marketing Granted Orders are listed on FDA's website; those are the only new products that may be legally marketed at this time.

We appreciate your support of our compliance and enforcement actions, including the recent injunctions. If you have specific information or suggestions for the Agency related to enforcement, CTP would welcome such input. We will continue to use our resources to find and take action against those companies that manufacture or sell illegal products.

Thank you for your interest in this issue.

Sincerely,



Brian A. King, PhD, MPH
Director, Center for Tobacco Products

[3] *See Am. Acad. of Pediatrics v. Food & Drug Admin.*, 399 F. Supp. 3d 479, 487 (D. Md. 2019) (setting ten month deadline); *Am. Acad. of Pediatrics v. Food & Drug Admin.*, No. 8:18-cv-883, ECF No. 182 (Apr. 22, 2020) (extending deadline to September 9, 2020).