November 3, 2022

VIA ELECTRONIC MAIL

Brian King, PhD, Director
Center for Tobacco Products
Document Control Center (DCC)
9200 Corporate Blvd., Room 020J
Rockville, MD 20850

Re: Non-Tobacco Nicotine PMTA List and Enforcement Discretion Clarification

Dear Director King,

I am writing to follow up on our June 10, 2022, and July 11, 2022 correspondence.

First, we wish to reiterate our June 10, 2022 request that CTP publish a list of products for which non-tobacco nicotine (NTN) PMTAs have been filed. A similar request was made by other groups. With all the illegal disposable products that continue to flood the U.S. market for which no PMTA has been filed, a published list of products with *applications currently under review by CTP* is even more important than before. After the initial PMTA deadline for tobacco-derived nicotine (TDN) products, CTP published a list of millions of products for which an application had been filed. Now that CTP has conducted its initial review of NTN PMTAs, and has winnowed the list of products for which it has accepted applications (1,600), we encourage CTP to quickly publish this reduced list so that all retailers, distributors and consumers know precisely which products are currently being reviewed by CTP. This will retailers stocking product, industry self-enforcement announcements, FDA's inspectors who are in the field, and consumers need to know which products are undergoing CTP review.

Second, we also wish to reiterate our July 11, 2022, correspondence about CTP's continued use of enforcement discretion regarding products covered by a pending PMTA. As you know, FDA generally, and CTP specifically, has a long history of using enforcement discretion to allow products in various categories to remain on the market as they go through the review process. CTP's recent statements on enforcement discretion are summarized in the attachment and, we believe, all make clear FDA's continued use of enforcement discretion as to all tobacco products.

Enforcement discretion, of course, has always been a necessity since under Section 910 of the Tobacco Control Act FDA is required to review all submitted PMTAs within 180 days but, as I am sure you know, that has never happened. Even after the court order imposing a transition period of "lawful marketing" for TDN products until September 9, 2021, CTP noted that it still "*retains enforcement discretion*" to allow products to remain on the market while it reviews TDN PMTAs. Similarly, the amendment to the Tobacco Control Act (TCA) covering NTN products required FDA to review all submitted PMTAs within 60 days which obviously could never happen in a diligent review process. Thus, as we have noted, CTP must continue to use its enforcement discretion to review NTN product applications after July 13, 2022.

As noted in our July 11, 2022 letter, Congress, though it could have done so, did *not* require the removal of NTN products pending CTP's review of a pending PMTA and did not limit CTP enforcement discretion after July 13. To briefly summarize, here are the four relevant statutory sections:

1. Under Section (d)(2)(A), Congress expressly stated that "as a condition to market" all manufacturers wishing to continue selling their products must file a PMTA no later than May 14, 2022.
2. Under Section (d)(2)(B), Congress expressly stated that companies which filed PMTAs "may continue to market" their products during what the Act calls a "transition period."
3. Under Section (d)(2)(C), Congress expressly required that if a company did not file a PMTA for its synthetic products by May 14, 2022, that company is "not eligible for continued marketing."
4. Under Sec. (d)(3), Congress expressly stated that products which are not approved by July 13, 2022, including those subject to "pending applications," are "in violation of…section 910 if such tobacco product does not have an order in effect." of the FDCA, 21 USC 387j.

As we explained, the first step any court looking would take is to review the plain language of the statute. In this case, the plain language of the law neither requires the removal of products with pending NTN PMTAs from the market after July 13, nor amends CTP's current processes for protecting public health, nor divests the Agency of its enforcement discretion. To be sure, while Congress expressly forbid continued marketing under certain provisions of the law, in the operative Section (d)(3) which addressed what happens after July 13, 2022, Congress' plain language does not prohibit continued marketing. Instead, Congress only stated that products with pending PMTAs would be "in violation of…section 910" of the FDCA which places those NTN products with pending PMTAs in precisely the same position *as every other product* with a pending PMTA for which CTP has used and continues to use its enforcement discretion to allow those products to remain on the market.

Moreover, anyone claiming that Congress' *intent* was to remove all such products with pending PMTAs cannot cite any evidence of their desired interpretation. To be sure, Congress could have banned synthetic nicotine products, if that is what it intended, but it did not do so. Instead, Congress expressly authorized manufacturers to bring new products to market after the Act's passage. As importantly, as CTP's attorneys will likely confirm, given that the NTN amendment to the FDCA was passed without *any* public hearing, committee statement, report language or floor debate, there is no Congressional intent that can be relied upon to resolve any ambiguity in the plain language, and post-Act proclamations by Members of Congress are simply not part of the legislative history.

We are writing not only to reiterate the importance of CTP continuing to use enforcement discretion to work with companies moving through the PMTA process but to also seek clarity from you for the marketplace. As we predicted in our letter, CTP has been called upon by outside groups to remove all NTN products from the market even though they have applications pending. Also, we have seen some businesses taking the position that only products covered by pending TDN PMTAs can continue to be sold subject to FDA's enforcement discretion, while products covered by pending NTN PMTAs cannot be sold and are not subject to FDA's enforcement discretion. As we are sure you appreciate, no one should be allowed to create market advantages by improperly interpreting CTP's position.

So, the question that we would appreciate being addressed is has CTP changed its long-standing approach of permitting pre-existing products, covered by a PMTA under CTP review, to remain on the market subject to FDA's enforcement discretion until a decision is made and, if so, how has it changed?

Finally, in our view, there is no more pressing issue than going after the bad actors flaunting FDA authority and which are competing, with enormous advantage, against those good acting companies which are invested in and committed to the PMTA process. As I mentioned at FDLI, we thank you for the recent DOJ enforcement announcements but there is much more that can be done. To that end, I want to reiterate our prior offers to share specific ideas and data tools that would dramatically aid and accelerate CTP's enforcement efforts. Understanding that you have many demands on your time, we remain eager to get a date on the calendar for the meeting we have been working on scheduling.

In the interim, we would greatly appreciate your response to the important enforcement discretion question posed above. As always, we thank you for your time and consideration.

Warmest regards,

Tony Abboud
Executive Director

cc: VTA Board of Directors
Eshael Johnson

Enclosure

ATTACHMENT: RECENT CTP ENFORCEMENT DISCRETION STATEMENTS

On September 9, 2021, Director Zeller explained, "All new tobacco products on the market without the statutorily required premarket authorization are marketed unlawfully and are subject to enforcement action at FDA's discretion, as recognized in the court's order regarding the Sept. 9, 2020 premarket application deadline," and "per the court order, products for which applications were submitted by the deadline could generally remain on the market for up to a year from the date of the application—or until Sept. 9, 2021, at the latest—pending FDA review, although *FDA retains enforcement discretion*."[1]

As of April 11, 2022, FDA's "Market and Distribute a Tobacco Product" page makes clear that all "New tobacco products on the market without the required premarket authorization are marketed unlawfully and subject to enforcement action at the FDA's discretion."[2]

On June 15, 2022, Acting-Director Mital said, "all new tobacco products on the market without the statutorily required pre-market authorization are marketed unlawfully and are subject to enforcement action at FDA's discretion." With respect to NTN products she also explained, "And products, according to the law, must receive a marketing granted order from FDA by July 13th of this year, in order to remain on the market. Products on the market after July 13th, without an FDA marketing granted order are in violation of section 910 of the Food Drug and Cosmetic Act and may be subject to FDA enforcement."[3]

On July 8, 2022, responding to a question about whether FDA will remove synthetic nicotine products with pending PMTAs from the market after July 13, 2022, an FDA spokesperson said such products will be "subject to enforcement action at FDA's discretion."

On July 13, 2022, CTP explained: "'FDA is working diligently to process the substantial number of applications submitted and, as always, will make marketing decisions based on the best available science and will pursue compliance and enforcement actions when warranted,' said Dr. King. 'We remain fully committed to taking whatever steps are necessary to protect the public health and to provide timely updates on our ongoing progress regulating non-tobacco nicotine products.'"[4]

On September 9, 2022, CTP stated, "NTN products can only be legally marketed in the United States if it received premarket authorization from FDA. Without marketing authorization from FDA, a product is in violation of the FD&C Act and is subject to FDA enforcement."[5]

On October 14, 2022, CTP announced that, "FDA has also accepted over 1,600 applications, with the vast majority being for e-cigarette or e-liquid products. While the application review is ongoing, FDA remains vigilant in overseeing the market and will continue to use our compliance and enforcement resources to curb the unlawful marketing of NTN products."[6]

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[1] https://www.fda.gov/tobacco-products/ctp-newsroom/perspective-fdas-progress-tobacco-product-application-review-and-related-enforcement
[2] https://www.fda.gov/tobacco-products/products-guidance-regulations/market-and-distribute-tobacco-product
[3] https://fdlievents.org/wp-content/uploads/2022/06/MITAL.pdf (a transcript of her comments is available).
[4] https://www.fda.gov/tobacco-products/ctp-newsroom/fda-continues-implement-law-regulate-non-tobacco-nicotine-products-warns-retailers-and-manufacturers?utm_campaign=ctp-ntn&utm_content=CTPStatement&utm_medium=email&utm_source=govdelivery&utm_term=stratcomms
[5] https://www.statnews.com/2022/07/08/fda-appears-to-hold-off-on-crackdown-on-synthetic-nicotine-products-despite-calls-from-congress/?utm_source=STAT+Newsletters&utm_campaign=59efec4a3c-Daily_Recap&utm_medium=email&utm_term=0_8cab1d7961-59efec4a3c-154070498
[6] https://www.fda.gov/tobacco-products/ctp-newsroom/fda-completes-initial-review-95-non-tobacco-nicotine-product-applications-agency-has-issued-over-60