Overview of FDA PMTA Process for Vapor Products

March 1, 2023

PRESENTED BY

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Background: Tobacco Control Act

In June 2009, Congress passed The Family Smoking and Tobacco Control Act.

At that time "tobacco product" was defined as "**any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product**…"

Enumerated list: cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco.

And any other tobacco products that FDA "deems" subject to the Act.

Background: FDA's Deeming Rule

On August 8, 2016, FDA's Deeming Rule became effective.

FDA's Deeming Rule "deemed" all products that were "made or derived from tobacco" subject to FDA's authority, including e-cigarettes (closed and open) and disposables.

For products to remain on the market, the product must have been on the market as of August 8, 2016, **and** a PMTA must have been submitted by September 9, 2020.

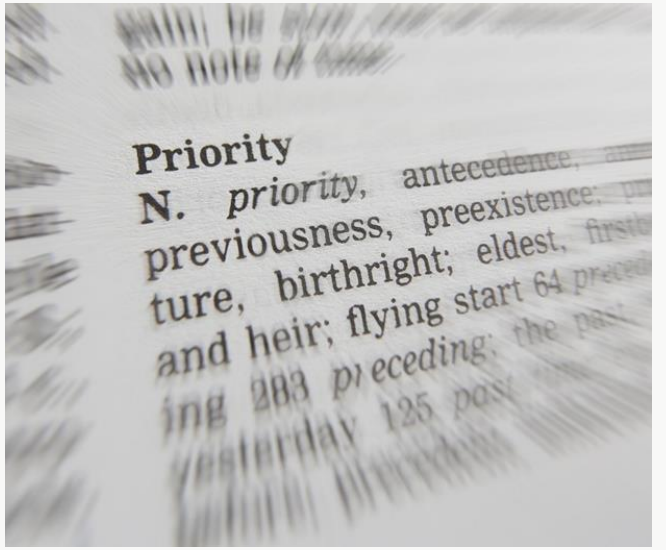
Background: FDA's Enforcement Guidance

FDA announced its intent to **prioritize enforcement against**

(i) **any flavored, cartridge-based ENDS** product (other than a tobacco- or menthol-flavored ENDS products);

(ii) any ENDS product that is offered for sale after **September 9, 2020**, and for which the manufacturer has not submitted a premarket tobacco product application (PMTA); and

(iii) any ENDS product that is likely to be used by youth, including products that imitate food packaging that is marketed to youth.



Flavored, cartridge-based ENDS products (other than tobacco- and menthol- flavors) **cannot be marketed unless and until FDA issues a Marketing Granted Order (MGO).**

Tobacco Harm Reduction

"Envisioning a world…where adults who still need or want nicotine could get it from alternative and less harmful sources, needs to be the cornerstone of our efforts."

—Then-FDA Commissioner Gottlieb (July 27, 2017)

" If you could take every adult smoker and fully switch them to [e-cigarettes], that would have a substantial public health impact."

—Then-FDA Commissioner Gottlieb (Sept. 25, 2018)

PMTA Submissions

PMTA submissions are voluminous and include the following types of information:

- Information concerning investigations which have been made to show the health risks of such tobacco product and whether such tobacco product presents less risk than other tobacco products;
- Design data;
- Information about components, ingredients, additives, and constituents;
- Information about manufacturing processes;
- Marketing plan information; and
- Rigorous scientific analyses.

PMTA Review Process

https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/premarket-tobacco-product-applications#4

FDA's Review

Congress directed FDA to weigh certain factors, including **public-health effects**:

- Risks and benefits to the population as a whole, including people who would use the proposed new tobacco product, as well as non-users;
- Whether people who currently use any tobacco product would be more or less likely to stop using such products if the proposed new tobacco product were available;
- Whether people who currently do not use any tobacco products would be more or less likely to begin using tobacco products if the new product were available; and
- The methods, facilities, and controls used to manufacture, process, and pack the new tobacco product.

FDA's Review

In weighing these factors and ultimately issuing a marketing order, FDA must find that a PMTA **provides sufficient "scientific evidence" and "clinical data" that demonstrate that marketing of a product is "appropriate for the protection of the public health."**

- If FDA determines the marketing of the product is appropriate for the protection of the public health, FDA issues a Marketing Granted Order (MGO).
- If not, FDA must issue a Marketing Denial Order (MDO).

Postmarketing Requirements

Even after FDA issues a MGO for a PMTA, FDA maintains regulatory authority, including:

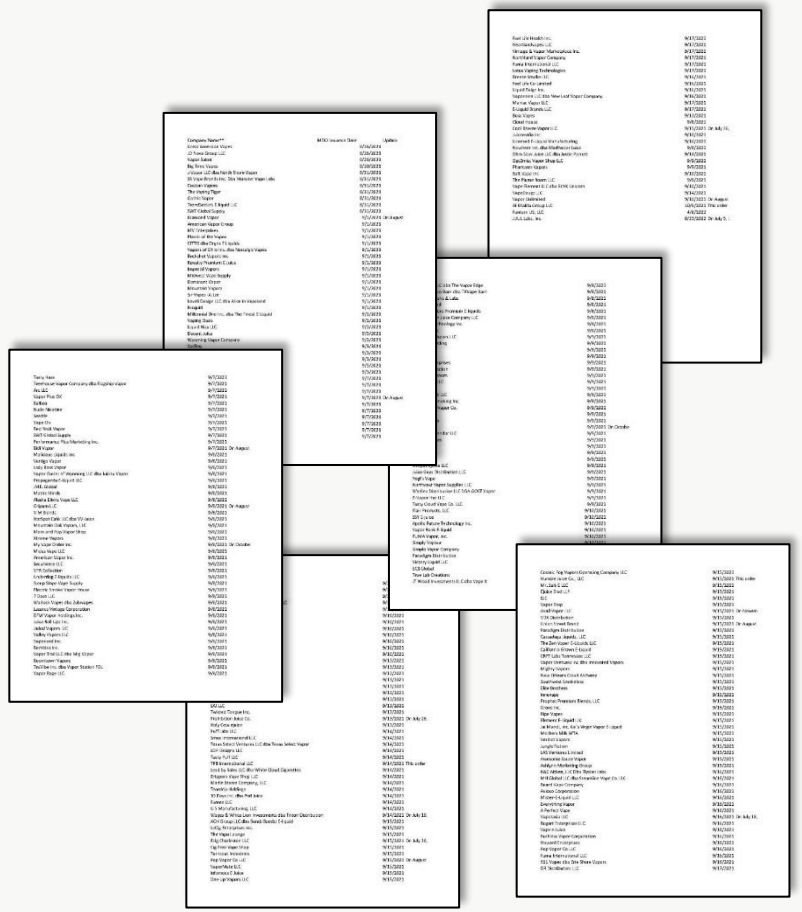
- Postmarket reporting and surveillance;
- FDA may require additional reporting under the terms of the MGO;
- Restrict marketing and promotional efforts that may appeal to youth;
- Potential enforcement actions against manufacturers for misbranded/adulterated products’
- Potential enforcement actions against retailers that sell non-cleared products and/or sell to minors.

FDA Actions

FDA has taken action on over 99% of the 6.7 million PMTAS timely submitted.

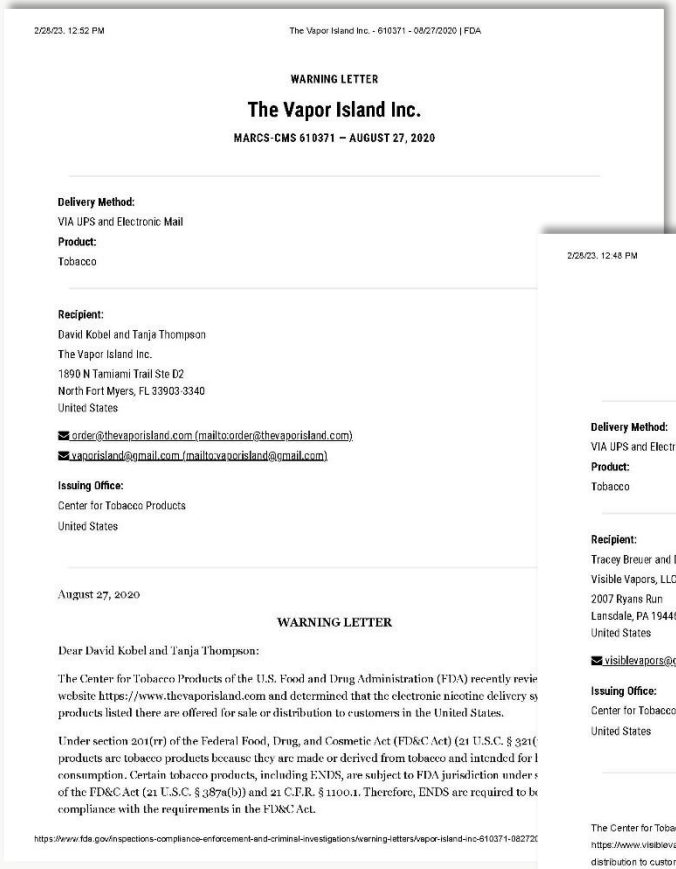
As of September 2021 (the most recent FDA press release on the subject), FDA has issued **MDOs for 946,000 flavored ENDS products.**

FDA has issued **23 MGOs for ENDS products – all tobacco flavored**.



FDA Enforcement Actions

FDA has issued **over 170 warning letters** to firms that have over **17 million e-cigarette products listed with FDA for which a PMTA has not been submitted**.



2/28/23, 12:52 PM The Vapor Island Inc. - 610371 - 08/27/2020 | FDA

WARNING LETTER

The Vapor Island Inc.

MARCS-CMS 610371 – AUGUST 27, 2020

Delivery Method:
VIA UPS and Electronic Mail
Product:
Tobacco

Recipient:
David Kobel and Tanja Thompson
The Vapor Island Inc.
1890 N Tamiami Trail Ste D2
North Fort Myers, FL 33903-3340
United States

order@thevaporisland.com (mailto:order@thevaporisland.com)
vaporisland@gmail.com (mailto:vaporisland@gmail.com)

Issuing Office:
Center for Tobacco Products
United States

August 27, 2020

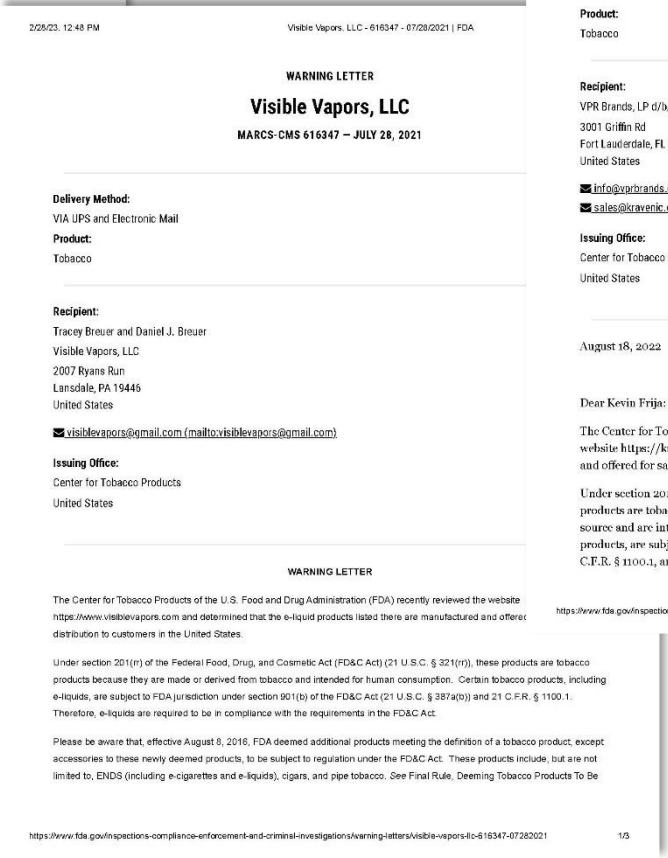
WARNING LETTER

Dear David Kobel and Tanja Thompson:

The Center for Tobacco Products of the U.S. Food and Drug Administration (FDA) recently revie
website https://www.thevaporisland.com and determined that the electronic nicotine delivery sy
products listed there are offered for sale or distribution to customers in the United States.

Under section 201(rr) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. § 321(
products are tobacco products because they are made or derived from tobacco and intended for h
consumption. Certain tobacco products, including ENDS, are subject to FDA jurisdiction under s
of the FD&C Act (21 U.S.C. § 387a(b)) and 21 C.F.R. § 1100.1. Therefore, ENDS are required to be
compliance with the requirements in the FD&C Act.

https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/vapor-island-inc-610371-082720



2/28/23, 12:48 PM Visible Vapors, LLC - 616347 - 07/28/2021 | FDA

WARNING LETTER

Visible Vapors, LLC

MARCS-CMS 616347 – JULY 28, 2021

Delivery Method:
VIA UPS and Electronic Mail
Product:
Tobacco

Recipient:
Tracey Breuer and Daniel J. Breuer
Visible Vapors, LLC
2007 Ryans Run
Lansdale, PA 19446
United States

visiblevapors@gmail.com (mailto:visiblevapors@gmail.com)

Issuing Office:
Center for Tobacco Products
United States

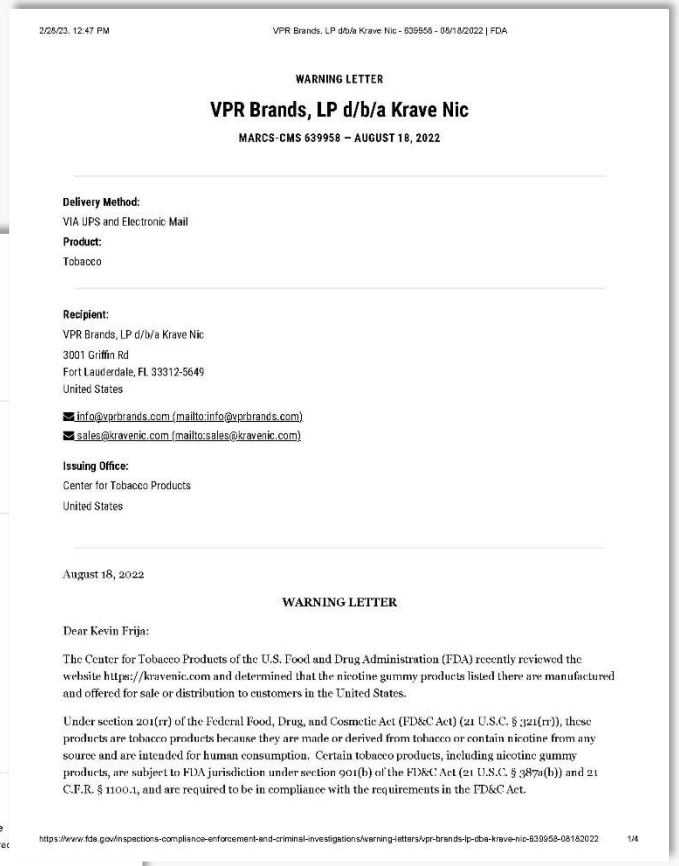
WARNING LETTER

The Center for Tobacco Products of the U.S. Food and Drug Administration (FDA) recently reviewed the website
https://www.visiblevapors.com and determined that the e-liquid products listed there are manufactured and offered
distribution to customers in the United States.

Under section 201(rr) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. § 321(rr)), these products are tobacco products because they are made or derived from tobacco and intended for human consumption. Certain tobacco products, including e-liquids, are subject to FDA jurisdiction under section 901(b) of the FD&C Act (21 U.S.C. § 387a(b)) and 21 C.F.R. § 1100.1. Therefore, e-liquids are required to be in compliance with the requirements in the FD&C Act.

Please be aware that, effective August 8, 2016, FDA deemed additional products meeting the definition of a tobacco product, except accessories to these newly deemed products, to be subject to regulation under the FD&C Act. These products include, but are not limited to, ENDS (including e-cigarettes and e-liquids), cigars, and pipe tobacco. *See* Final Rule, Deeming Tobacco Products To Be

https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/visible-vapors-llc-616347-07282021 1/3



2/28/23, 12:47 PM VPR Brands, LP d/b/a Krave Nic - 639958 - 08/18/2022 | FDA

WARNING LETTER

VPR Brands, LP d/b/a Krave Nic

MARCS-CMS 639958 – AUGUST 18, 2022

Delivery Method:
VIA UPS and Electronic Mail
Product:
Tobacco

Recipient:
VPR Brands, LP d/b/a Krave Nic
3001 Griffin Rd
Fort Lauderdale, FL 33312-5649
United States

info@vprbrands.com (mailto:info@vprbrands.com)
sales@kravenic.com (mailto:sales@kravenic.com)

Issuing Office:
Center for Tobacco Products
United States

August 18, 2022

WARNING LETTER

Dear Kevin Frija:

The Center for Tobacco Products of the U.S. Food and Drug Administration (FDA) recently reviewed the website https://kravenic.com and determined that the nicotine gummy products listed there are manufactured and offered for sale or distribution to customers in the United States.

Under section 201(rr) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. § 321(rr)), these products are tobacco products because they are made or derived from tobacco or contain nicotine from any source and are intended for human consumption. Certain tobacco products, including nicotine gummy products, are subject to FDA jurisdiction under section 901(b) of the FD&C Act (21 U.S.C. § 387a(b)) and 21 C.F.R. § 1100.1, and are required to be in compliance with the requirements in the FD&C Act.

https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/vpr-brands-lp-dba-krave-nic-639958-08182022 1/4

Any Questions