

UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

Deborah S. Hunt
Clerk

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POTTER STEWART U.S. COURTHOUSE
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Filed: September 23, 2021

Ms. Sarah M. Harris
Williams & Connolly
725 Twelfth Street, N.W.
Washington, DC 20005

Mr. Mark Raza
US Dept of HHS/OGC/FDD
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: Case No. 21-3855, *Turning Point Brands, Inc., et al v. FDA*
Originating Case No.: PM0001093

Dear Counsel,

This case has been docketed as number **21-3855** with the caption that is enclosed on a separate page. Please check the caption for accuracy and notify the Clerk's Office if any corrections should be made.

Before preparing any documents to be filed, counsel are strongly encouraged to read the Sixth Circuit Rules at www.ca6.uscourts.gov. If you have not established a PACER account and registered with this court as an ECF filer, you should do so immediately.

The following forms should be downloaded from the web site and filed with the Clerk's office by **October 7, 2021**.

	Appearance of Counsel
Petitioner:	Disclosure of Corporate Affiliations Application for Admission to 6th Circuit Bar (if applicable)
Respondent:	Appearance of Counsel

More specific instructions are printed on each form. These deadlines are important - if the initial forms are not timely filed the case will be dismissed for want of prosecution.

If you have questions after reviewing the forms and the rules, please contact the Clerk's office for assistance.

Sincerely,

s/Antoinette Macon
Case Manager
Direct Dial No. 513-564-7015

Enclosure

OFFICIAL COURT OF APPEALS CAPTION FOR 21-3855

TURNING POINT BRANDS, INC.; TPB INTERNATIONAL, LLC

Petitioners

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION

Respondent

**UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT**

Turning Point Brands, Inc. and TPB
International, LLC,

Petitioners,

v.

U.S. Food and Drug Administration,

Respondent.

Case No. 21-_____

PETITION FOR REVIEW

Pursuant to 21 U.S.C. § 387l(a) and Federal Rule of Appellate Procedure 15(a), Turning Point Brands, Inc. and TPB International, LLC (collectively, “TPB”) hereby petition the Court for review of the U.S. Food and Drug Administration’s Marketing Denial Order, dated September 14, 2021. The order denies TPB’s September 5, 2020 bundled Premarket Tobacco Product Applications (assigned Submission Tracking Number PM0001093) for certain of TPB’s electronic nicotine delivery system products. Attached as Exhibit A is a copy of the order to be reviewed. Petitioners’ Disclosure of Corporate Affiliations and Financial Interest is being filed under separate cover.

TPB seeks review of the order on the grounds that it is arbitrary and capricious, an abuse of discretion, contrary to the Federal Food, Drug, and

Cosmetic Act, as amended by the Family Smoking Prevention and Tobacco Control Act of 2009, and otherwise not in accordance with law. TPB respectfully requests that the Court, on review, vacate or modify, in whole or in part, the foregoing order for which TPB has petitioned for review. TPB also requests such other and further relief to which it may be justly entitled, including such relief as necessary to ensure that TPB may continue to market the products subject to the challenged order.

Dated: September 22, 2021

Respectfully submitted,

/s/ Sarah M. Harris

David M. Zinn

Joseph M. Terry

Sarah M. Harris

Whitney Hermandorfer

Andrew L. Hoffman

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*Attorneys for Petitioners
Turning Point Brands, Inc.
and TPB International, LLC*

CERTIFICATE OF SERVICE

Pursuant to Federal Rules of Appellate Procedure 15(c) and 25(d), I hereby certify that on September 22, 2021, a true and correct copy of the foregoing **Petition for Review** was served on the following by electronic mail and first class mail, in addition to filing the **Petition for Review** electronically with the Clerk.

Janet Woodcock, Acting Commissioner
United States Food and Drug Administration
10903 New Hampshire Avenue, HF-1
Silver Spring, MD 20993-0002
Janet.Woodcock@fda.hhs.gov

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Ann Oxenham, Assistant Deputy Chief Counsel for Litigation
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Mitch Zeller, Director
Matthew R. Holman, Director, Office of Science
Grace Kaiyuan, Regulatory Health Project Manager
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*Attorney for Petitioners
Turning Point Brands, Inc.
and TPB International, LLC*

EXHIBIT A



U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

September 14, 2021

DENIAL

TPB International, LLC
Attention: Brittani Cushman, Senior Vice President External Affairs
5201 Interchange Way
Louisville, KY 40229

FDA Submission Tracking Number (STN): PM0001093, see Appendix A

Dear Ms. Cushman:

We are denying a marketing granted order for the products identified in Appendix A.

Based on our review of your PMTAs¹, we determined that the new products, as described in your applications and specified in Appendix A, lack sufficient evidence to demonstrate that the marketing of these products is appropriate for the protection of the public health (APPH). Therefore, you cannot introduce or deliver for introduction these products into interstate commerce in the United States. Doing so is a prohibited act under section 301(a) of the FD&C Act, the violation of which could result in enforcement action by FDA.

If you choose to submit new applications for these products, you must fulfill all requirements set forth in section 910(b)(1). You may provide information to fulfill some of these requirements by including an authorization for FDA to cross-reference a Tobacco Product Master File. Error! Bookmark not defined. You may not cross-reference information submitted in the PMTAs subject to this Denial.

Based on review of your PMTAs, we identified the following key basis for our determination:

1. All of your PMTAs lack sufficient evidence demonstrating that your flavored ENDS will provide a benefit to adult users that would be adequate to outweigh the risks to youth. In light of the known risks to youth of marketing flavored ENDS, robust and reliable evidence is needed regarding the magnitude of the potential benefit to adult smokers. This evidence could have been provided using a randomized controlled trial and/or longitudinal cohort study that demonstrated the benefit of your flavored ENDS products over an appropriate comparator tobacco-flavored ENDS. Alternatively, FDA would consider other evidence but only if it reliably and robustly evaluated the impact of the new flavored vs. tobacco-flavored products on adult smokers' switching or cigarette reduction over time. Although your PMTAs contained clinical studies with abuse liability outcomes and a cross-sectional survey evaluating patterns of use, this evidence is not sufficient to show a benefit to adult smokers of using these flavored ENDS because it does not evaluate product switching or cigarette

¹ Premarket Tobacco Product Applications (PMTAs) submitted under section 910 of the Federal Food, Drug, and Cosmetic Act (FD&C Act)

reduction resulting from use of these products over time. Without this information, FDA concludes that your application is insufficient to demonstrate that these products would provide an added benefit that is adequate to outweigh the risks to youth and, therefore, cannot find that permitting the marketing of your new tobacco products would be appropriate for the protection of the public health.

We cannot find that the marketing of your new tobacco products is APPH. The review concluded that key evidence demonstrating APPH is absent. Therefore, scientific review did not proceed to assess other aspects of the applications. FDA finds that it is not practicable to identify at this time an exhaustive list of all possible deficiencies.

Your PMTAs lack sufficient information to support a finding of APPH; therefore, we are issuing a marketing denial order. Upon issuance of this order, your products are misbranded under section 903(a)(6) of the FD&C Act and adulterated under section 902(6)(A) of the FD&C Act. Failure to comply with the FD&C Act may result in FDA regulatory action without further notice. These actions may include, but are not limited to, civil money penalties, seizure, and/or injunction.

We encourage you to submit all regulatory correspondence electronically via the CTP Portal^{2,3} using eSubmitter.⁴ Alternatively, submissions may be mailed to:

Food and Drug Administration
Center for Tobacco Products
Document Control Center (DCC)
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

The CTP Portal and FDA's Electronic Submission Gateway (ESG) are generally available 24 hours a day, seven days a week; submissions are considered received by DCC on the day of successful upload. Submissions delivered to DCC by courier or physical mail will be considered timely if received during delivery hours on or before the due date⁵; if the due date falls on a weekend or holiday, the delivery must be received on or before the preceding business day. We are unable to accept regulatory submissions by e-mail.

² For more information about CTP Portal, see

<https://www.fda.gov/tobacco-products/manufacturing/submit-documents-ctp-portal>

³ FDA's Electronic Submission Gateway (ESG) is still available as an alternative to the CTP Portal.

⁴ For more information about eSubmitter, see <https://www.fda.gov/industry/fda-esubmitter>

⁵ <https://www.fda.gov/tobacco-products/about-center-tobacco-products-ctp/contact-ctp>

PM0001093, see Appendix A

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If you have any questions, please contact Grace Kaiyuan, M.B.A., MT (ASCP), Regulatory Health Project Manager, at (240) 402 - 8240 or Grace.Kaiyuan@fda.hhs.gov.

Sincerely,

Digitally signed by Matthew R. Holman -S

Date: 2021.09.14 10:55:05 -04'00'

Matthew R. Holman, Ph.D.

Director

Office of Science

Center for Tobacco Products

Enclosures **(if provided electronically, the Appendix is not included in physical mail):**

Appendix A – New Tobacco Products Subject of This Letter

Appendix A⁷
New Tobacco Products Subject of This Letter

Common Attributes of PMTAs	
Date of Submission:	September 5, 2020
Date of Receipt:	September 5, 2020
Applicant:	TPB International, LLC
Product Manufacturer:	TPB International, LLC
Product Category:	ENDS (VAPES)
Product Sub-Category:	ENDS Component

⁶ Brand/sub-brand or other commercial name used in commercial distribution.

Appendix A

New Tobacco Products Subject of This Letter

PM0001093	PD494	Vapor: Shark Kiwi Berry	ENDS(VAPES)	ENDS Component	Bottle	1 Bottle	Kiwi Berry	Nicotine: 36mg/mL, PG/VG: 44/56, E-liquid Volume: 30mL
PM0001093	PD495	Vapor: Shark Kiwi Berry	ENDS(VAPES)	ENDS Component	Bottle	1 Bottle	Kiwi Berry	Nicotine: 48mg/mL, PG/VG: 44/56, E-liquid Volume: 30mL
PM0001093	PD496	Vapor: Shark Tropic Chill	ENDS(VAPES)	ENDS Component	Bottle	1 Bottle	Tropic Chill	Nicotine: 3mg/mL, PG/VG: 27/73, E-liquid Volume: 60mL
PM0001093	PD497	Vapor: Shark Tropic Chill	ENDS(VAPES)	ENDS Component	Bottle	1 Bottle	Tropic Chill	Nicotine: 6mg/mL, PG/VG: 27/73, E-liquid Volume: 60mL
PM0001093	PD498	Vapor: Shark Tropic Chill	ENDS(VAPES)	ENDS Component	Bottle	1 Bottle	Tropic Chill	Nicotine: 18mg/mL, PG/VG: 44/56, E-liquid Volume: 30mL
PM0001093	PD499	Vapor: Shark Tropic Chill	ENDS(VAPES)	ENDS Component	Bottle	1 Bottle	Tropic Chill	Nicotine: 36mg/mL, PG/VG: 44/56, E-liquid Volume: 30mL
PM0001093	PD500	Vapor: Shark Tropic Chill	ENDS(VAPES)	ENDS Component	Bottle	1 Bottle	Tropic Chill	Nicotine: 48mg/mL, PG/VG: 44/56, E-liquid Volume: 30mL
PM0001093	PD501	Vapor: Shark Tangerine Dream	ENDS(VAPES)	ENDS Component	Bottle	1 Bottle	Tangerine Dream	Nicotine: 3mg/mL, PG/VG: 27/73, E-liquid Volume: 60mL
PM0001093	PD502	Vapor: Shark Tangerine Dream	ENDS(VAPES)	ENDS Component	Bottle	1 Bottle	Tangerine Dream	Nicotine: 6mg/mL, PG/VG: 27/73, E-liquid Volume: 60mL
PM0001093	PD503	Vapor: Shark Tangerine Dream	ENDS(VAPES)	ENDS Component	Bottle	1 Bottle	Tangerine Dream	Nicotine: 18mg/mL, PG/VG: 44/56, E-liquid Volume: 30mL
PM0001093	PD504	Vapor: Shark Tangerine Dream	ENDS(VAPES)	ENDS Component	Bottle	1 Bottle	Tangerine Dream	Nicotine: 36mg/mL, PG/VG: 44/56, E-liquid Volume: 30mL
PM0001093	PD505	Vapor: Shark Tangerine Dream	ENDS(VAPES)	ENDS Component	Bottle	1 Bottle	Tangerine Dream	Nicotine: 48mg/mL, PG/VG: 44/56, E-liquid Volume: 30mL
PM0001093	PD506	Vapor: Shark Pineapple Berry Twist	ENDS(VAPES)	ENDS Component	Bottle	1 Bottle	Pineapple Berry Twist	Nicotine: 3mg/mL, PG/VG: 27/73, E-liquid Volume: 60mL
PM0001093	PD507	Vapor: Shark Pineapple Berry Twist	ENDS(VAPES)	ENDS Component	Bottle	1 Bottle	Pineapple Berry Twist	Nicotine: 6mg/mL, PG/VG: 27/73, E-liquid Volume: 60mL
PM0001093	PD508	Vapor: Shark Pineapple Berry Twist	ENDS(VAPES)	ENDS Component	Bottle	1 Bottle	Pineapple Berry Twist	Nicotine: 18mg/mL, PG/VG: 44/56, E-liquid Volume: 30mL
PM0001093	PD509	Vapor: Shark Pineapple Berry Twist	ENDS(VAPES)	ENDS Component	Bottle	1 Bottle	Pineapple Berry Twist	Nicotine: 36mg/mL, PG/VG: 44/56, E-liquid Volume: 30mL
PM0001093	PD510	Vapor: Shark Pineapple Berry Twist	ENDS(VAPES)	ENDS Component	Bottle	1 Bottle	Pineapple Berry Twist	Nicotine: 48mg/mL, PG/VG: 44/56, E-liquid Volume: 30mL
PM0001093	PD511	Vapor: Shark Tropical Strawberry	ENDS(VAPES)	ENDS Component	Bottle	1 Bottle	Tropical Strawberry	Nicotine: 3mg/mL, PG/VG: 27/73, E-liquid Volume: 60mL
PM0001093	PD512	Vapor: Shark Tropical Strawberry	ENDS(VAPES)	ENDS Component	Bottle	1 Bottle	Tropical Strawberry	Nicotine: 6mg/mL, PG/VG: 27/73, E-liquid Volume: 60mL
PM0001093	PD513	Vapor: Shark Tropical Strawberry	ENDS(VAPES)	ENDS Component	Bottle	1 Bottle	Tropical Strawberry	Nicotine: 18mg/mL, PG/VG: 44/56, E-liquid Volume: 30mL
PM0001093	PD514	Vapor: Shark Tropical Strawberry	ENDS(VAPES)	ENDS Component	Bottle	1 Bottle	Tropical Strawberry	Nicotine: 36mg/mL, PG/VG: 44/56, E-liquid Volume: 30mL
PM0001093	PD515	Vapor: Shark Tropical Strawberry	ENDS(VAPES)	ENDS Component	Bottle	1 Bottle	Tropical Strawberry	Nicotine: 48mg/mL, PG/VG: 44/56, E-liquid Volume: 30mL
PM0001093	PD516	Vapor: Shark Vanilla Cream	ENDS(VAPES)	ENDS Component	Bottle	1 Bottle	Vanilla Cream	Nicotine: 3mg/mL, PG/VG: 27/73, E-liquid Volume: 60mL
PM0001093	PD517	Vapor: Shark Vanilla Cream	ENDS(VAPES)	ENDS Component	Bottle	1 Bottle	Vanilla Cream	Nicotine: 6mg/mL, PG/VG: 27/73, E-liquid Volume: 60mL
PM0001093	PD518	Vapor: Shark Vanilla Cream	ENDS(VAPES)	ENDS Component	Bottle	1 Bottle	Vanilla Cream	Nicotine: 18mg/mL, PG/VG: 44/56, E-liquid Volume: 30mL
PM0001093	PD519	Vapor: Shark Vanilla Cream	ENDS(VAPES)	ENDS Component	Bottle	1 Bottle	Vanilla Cream	Nicotine: 36mg/mL, PG/VG: 44/56, E-liquid Volume: 30mL
PM0001093	PD520	Vapor: Shark Vanilla Cream	ENDS(VAPES)	ENDS Component	Bottle	1 Bottle	Vanilla Cream	Nicotine: 48mg/mL, PG/VG: 44/56, E-liquid Volume: 30mL
PM0001093	PD521	Vapor: Shark Cola Float	ENDS(VAPES)	ENDS Component	Bottle	1 Bottle	Cola Float	Nicotine: 3mg/mL, PG/VG: 27/73, E-liquid Volume: 60mL
PM0001093	PD522	Vapor: Shark Cola Float	ENDS(VAPES)	ENDS Component	Bottle	1 Bottle	Cola Float	Nicotine: 6mg/mL, PG/VG: 27/73, E-liquid Volume: 60mL
PM0001093	PD523	Vapor: Shark Cola Float	ENDS(VAPES)	ENDS Component	Bottle	1 Bottle	Cola Float	Nicotine: 18mg/mL, PG/VG: 44/56, E-liquid Volume: 30mL
PM0001093	PD524	Vapor: Shark Cola Float	ENDS(VAPES)	ENDS Component	Bottle	1 Bottle	Cola Float	Nicotine: 36mg/mL, PG/VG: 44/56, E-liquid Volume: 30mL
PM0001093	PD525	Vapor: Shark Cola Float	ENDS(VAPES)	ENDS Component	Bottle	1 Bottle	Cola Float	Nicotine: 48mg/mL, PG/VG: 44/56, E-liquid Volume: 30mL