UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

ELBERT PARR TUTTLE COURT OF APPEALS BUILDING
56 Forsyth Street, N.W.
Atlanta, Georgia 30303

David J. Smith
Clerk of Court

For rules and forms visit
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September 30, 2021

Eric P. Gotting
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Appeal Number: 21-13340-D
Case Style: Bidi Vapor LLC v. U.S. Food and Drug Administration, et al
Agency Docket Number: PM0003460

This Court requires all counsel to file documents electronically using the Electronic Case Files ("ECF") system, unless exempted for good cause. Non-incarcerated pro se parties are permitted to use the ECF system by registering for an account at www.pacer.gov. Information and training materials related to electronic filing, are available at www.ca11.uscourts.gov.

Pursuant to Rule 15(c) of the Federal Rules of Appellate Procedure, you are hereby served with the following document which has been filed in this court:

11th Cir. R. 33-1(a) requires appellant to file a Civil Appeal Statement in most civil appeals. You must file a completed Civil Appeal Statement, with service on all other parties, within 14 days from the date of this letter. Civil Appeal Statement forms are available on the Internet at www.ca11.uscourts.gov, and as provided by 11th Cir. R. 33-1(a).

MEDIATION. If a Civil Appeal Statement is required to be filed, your appeal and all related matters will be considered for mediation by the Kinnard Mediation Center. The mediation services are free and the mediation process is confidential. You may confidentially request mediation by calling the Kinnard Mediation Center at 404-335-6260 (Atlanta) or 305-714-1900 (Miami). See 11th Cir. R. 33-1.

Every motion, petition, brief, answer, response and reply filed must contain a Certificate of Interested Persons and Corporate Disclosure Statement (CIP). Appellants/Petitioners must file a

CIP within 14 days after the date the case or appeal is docketed in this court; Appellees/Respondents/Intervenors/Other Parties must file a CIP within 28 days after the case or appeal is docketed in this court, regardless of whether appellants/petitioners have filed a CIP. See FRAP 26.1 and 11th Cir. R. 26.1-1.

On the same day a party or amicus curiae first files its paper or e-filed CIP, that filer must also complete the court's web-based CIP at the Web-Based CIP link on the court's website. Pro se filers (except attorneys appearing in particular cases as pro se parties) are **not required or authorized** to complete the web-based CIP.

Please use the appellate docket number noted above when making inquiries. See Fed.R.App.P. 16 and 17 as to the composition and time for filing of the record.

Attorneys who wish to participate in this appeal must be admitted to the bar of this Court, admitted for this particular proceeding pursuant to 11th Cir. R. 46-3, or admitted pro hac vice pursuant to 11th Cir. R. 46-4. In addition, all attorneys (except court-appointed counsel) who wish to participate in this appeal must file an Appearance of Counsel form within 14 days. The Application for Admission to the Bar and Appearance of Counsel Form are available at www.ca11.uscourts.gov. The clerk generally may not process filings from an attorney until that attorney files an appearance form. See 11th Cir. R. 46-6(b).

Sincerely,

DAVID J. SMITH, Clerk of Court

Reply to: Scott O'Neal, D
Phone #: (404) 335-6189

DKT-8 Agency

Case No.: _____

IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

Bidi Vapor LLC,

Petitioner,

v.

U.S. Food and Drug Administration; Janet Woodcock, M.D., Acting Commissioner; U.S. Department of Health and Human Services,

Respondents.

On Review Of FDA Marketing Denial Order (STN PM0003460)
Issued Under The Federal Tobacco Control Act

PETITIONER BIDI VAPOR LLC'S PETITION FOR REVIEW

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Telecopier: 407-841-0168

Counsel for Petitioner, Bidi Vapor LLC

CERTIFICATE OF INTERESTED PERSONS AND CORPORATE DISCLOSURE STATEMENT

Pursuant to Eleventh Circuit Rule 26.1-1, Petitioner hereby certifies that the following have an interest in the outcome of this petition for review:

1. Baker & Hostetler LLP (counsel for Petitioner)
2. Becerra, Xavier (Secretary, U.S. Department of Health and Human Services)
3. Berry, Daniel J. (Acting General Counsel, U.S. Department of Health and Human Services)
4. Chowdhury, Azim (counsel for Petitioner)
5. Durkin, Keith (counsel for Petitioner)
6. Gill, Neelam (counsel for Petitioner)
7. Gorji, Perham (Office of the Chief Counsel, U.S. Food and Drug Administration)
8. Gotting, Eric (counsel for Petitioner)
9. Gustafson, John (counsel for Petitioner)
10. Holman, Matthew, (Director, Office of Science, Center for Tobacco Products, U.S. Food and Drug Administration)
11. Johnson, Taylor (counsel for Petitioner)
12. Keller & Heckman LLP (counsel for Petitioner)

13. Lawrence, Brian (counsel for Petitioner)
14. Mednick, David (Office of the Chief Counsel, U.S. Food and Drug Administration)
15. Patel, Raj (member of Petitioner)
16. Patel, Raj, Irrevocable Trust (member of Petitioner)
17. Raza, Mark (Acting General Counsel, U.S. Food and Drug Administration)
18. Soles, Maureen (counsel for Petitioner)
19. Tarter, Javaneh (counsel for Petitioner)
20. United States Attorney's Office, Middle District of Florida
21. United States Department of Health & Human Services (Respondent)
22. United States Department of Justice
23. United States Food & Drug Administration (Respondent)
24. Vicente, Wendy (Senior Counsel, Office of the Chief Counsel, U.S. Food and Drug Administration)
25. Woodcock, Janet M.D. (Respondent)
26. Zeller, Mitch (Director, Center for Tobacco Products, U.S. Food and Drug Administration)

FRAP 26.1 Disclosure Statement: No parent corporation or publicly held corporation owns 10% or more of any stock in Bidi Vapor LLC.

11th Cir. R. 26.1-3 Certification: No publicly traded company or corporation has an interest in the outcome of this appeal.

11th Cir. R. 26.1-2 Certification: The undersigned certifies that this CIP is complete at the time of filing.

Dated: September 29, 2021.

Respectfully submitted,

/s Maureen B. Soles

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Counsel for Petitioner,
Bidi Vapor LLC

PETITION FOR REVIEW

Pursuant to the Family Smoking Prevention and Tobacco Control Act ("TCA"), 21 U.S.C. § 387*l*(a), Fed. R. App. P. 15, and 11th Cir. R. 15-2, Bidi Vapor LLC ("Bidi") hereby petitions this Court for review of a Marketing Denial Order ("MDO") issued by the U.S. Food and Drug Administration ("FDA") to Bidi on September 7, 2021. The MDO was issued pursuant to Section 910 of the TCA, 21 U.S.C. § 387*j*, and denies a marketing order sought by Bidi in Premarket Tobacco Product Applications ("PMTA") submitted to the FDA for certain electronic nicotine delivery system products manufactured and sold by Bidi (FDA Submission Tracking Number (STN) PM0003460). A copy of the MDO is attached as Exhibit A.

This Court has jurisdiction pursuant to Section 912 of the TCA, 21 U.S.C. § 387*l*(a)(1)(B), as the MDO constitutes a denial of Bidi's PMTAs. Venue is also proper in this Court because it is the regional circuit where Bidi's principal place of business, 4460 Old Dixie Hwy, Grant-Valkaria, Florida, is located.

Bidi seeks judicial review of the MDO under the TCA, 21 U.S.C. § 387*l*, the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 551, 701, *et seq.*, and the U.S. Constitution, and seeks a determination by this Court that, *inter alia*, the MDO is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law, as well as contrary to constitutional right and in excess of statutory jurisdiction, authority, or limitations, or short of statutory right. Accordingly, Bidi respectfully

requests that this Court grant its Petition for Review, and vacate and set aside the MDO, as well as provide additional relief as may be appropriate, including such relief as necessary to ensure that Bidi may continue to market the products subject to this matter to its adult consumers.

Dated: September 29, 2021

Respectfully submitted,

/s Maureen B. Soles
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Counsel for Petitioner,
Bidi Vapor LLC

CERTIFICATE OF SERVICE

I, Maureen B. Soles, hereby certify that on September 29, 2021, I filed the foregoing Petition for Review via the Court's ECF filing system. I further certify that I caused one copy to be served on the following by Certified Mail/Return Receipt Requested (per FDA's COVID-19 service rules and FRCP 4(i)) and also by electronic mail where indicated:

Hon. Merrick B. Garland
Attorney General of the United States
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950 Pennsylvania Ave., N.W.
Washington, D.C. 20530-0001

Attorney General for Administration
Justice Management Division
United States Department of Justice
950 Pennsylvania Ave., N.W.
Room 1111
Washington, D.C. 20530

Civil Process Clerk
United States Attorney's Office
Middle District of Florida
400 North Tampa Street
Suite 3200
Tampa, FL 33602

Xavier Becerra, Secretary
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Matthew R. Holman, Director, Office of Science
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/s Maureen B. Soles
Maureen B. Soles

EXHIBIT A

Marketing Denial Order for STN PM0003460, U.S. Food and Drug Administration Bidi Vapor LLC (Sept. 7, 2021)

U.S. FOOD & DRUG ADMINISTRATION

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

September 07, 2021

DENIAL

Bidi Vapor LLC
Attention: Nirajkumar Patel, CEO
4460 Old Dixie High Way
Grant Valkaria, FL 32949

FDA Submission Tracking Number (STN): PM0003460, see Appendix A

Dear Mr. Patel:

We are denying a marketing granted order for the products identified in Appendix A. Refer to Appendix B for a list of amendments received in support of your applications.

Based on our review of your PMTAs[1], 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. [2] You may not cross-reference information submitted in the PMTAs subject to this Denial.

Based on review of your PMTA, 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. We did not find such evidence in your PMTAs. Without this information, FDA concludes that your applications are insufficient to demonstrate that these products would provide an added benefit that is adequate to outweigh

[1] Premarket Tobacco Product Application (PMTA) submitted under section 910 of the Federal Food, Drug, and Cosmetic Act (FD&C Act)
[2] See guidelines at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/tobacco-product-master-files

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. As such, this is not an exhaustive list of all possible deficiencies.

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[3,4] using eSubmitter.[5] 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 date[6]; 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.

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[3] For more information about CTP Portal, see https://www.fda.gov/tobacco-products/manufacturing/submit-documents-ctp-portal
[4] FDA's Electronic Submission Gateway (ESG) is still available as an alternative to the CTP Portal.
[5] For more information about eSubmitter, see https://www.fda.gov/industry/fda-esubmitter
[6] https://www.fda.gov/tobacco-products/about-center-tobacco-products-ctp/contact-ctp

If you have any questions, please contact Antonio Thornton, Regulatory Health Project Manager, at (240) 402-3577 or Antonio.Thornton@fda.hhs.gov.

Sincerely,

Digitally signed by Matthew R. Holman -S
Date: 2021.09.07 13:12:42 -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 B – Amendments Received for These Applications

Appendix A[7]

New Tobacco Products Subject of This Letter

Common Attributes	
Submission date	September 8, 2020
Receipt date	September 8, 2020
Applicant	Bidi Vapor LLC
Product manufacturer	Bidi Vapor LLC
Product category	ENDS (VAPES)
Product subcategory	ENDS Component

[7] Brand/sub-brand or other commercial name used in commercial distribution.

Appendix B
Amendments Received for These Applications

Submission Date	Receipt Date	Applications being amended	Reviewed	Brief Description
October 13, 2020	October 13, 2020	All	Yes	Technical Update
November 23, 2020	November 23, 2020	All	Yes	Technical Update
November 23, 2020	November 23, 2020	All	Yes	Technical Update
November 24, 2020	November 24, 2020	All	Yes	Technical Update
November 24, 2020	November 24, 2020	All	Yes	Technical Update
November 24, 2020	November 24, 2020	All	Yes	Technical Update
November 24, 2020	November 24, 2020	All	Yes	Technical Update
November 24, 2020	November 24, 2020	All	Yes	Technical Update
November 24, 2020	November 24, 2020	All	Yes	Technical Update
November 24, 2020	November 24, 2020	All	Yes	Technical Update
November 25, 2020	November 25, 2020	All	Yes	Technical Update
November 25, 2020	November 25, 2020	All	Yes	Technical Update
January 6, 2021	January 6, 2021	All	Yes	Technical Update
March 23, 2021	March 23, 2021	All	Yes	Technical Update
April 20, 2021	April 20, 2021	All	Yes	Technical Update

PTH	PD Number	Product Name	Category	Subcategory	Package Type	Package Quantity	Characterizing Flavor	Additional Property
PM0003460	PD1	Bidi Stick - Arctic	ENDS(VAPES)	ENDS Component	Plastic box	1 E-Cigarette	Mint, Menthol	Length: 112.5 mm, Diameter: Not Provided, Nicotine: 60 mg/mL, PG/VG Ratio: 47.99/52.01, E-Liquid Volume: 1.4 mL, Wattage: 1.18 Wh, Battery Capacity: 280 mAh, Width: 15.5 mm, Thickness: 7 mm, Disposable
PM0003460	PD10	Bidi Stick - Winter	ENDS(VAPES)	ENDS Component	Plastic box	1 E-Cigarette	Watermelon, Melon, Menthol	Length: 112.5 mm, Diameter: Not Provided, Nicotine: 60 mg/mL, PG/VG Ratio: 48.67/51.33, E-Liquid Volume: 1.4 mL, Wattage: 1.18 Wh, Battery Capacity: 280 mAh, Width: 15.5 mm, Thickness: 7 mm, Disposable
PM0003460	PD11	Bidi Stick - Zest	ENDS(VAPES)	ENDS Component	Plastic box	1 E-Cigarette	Melon, Pineapple, Banana	Length: 112.5 mm, Diameter: Not Provided, Nicotine: 60 mg/mL, PG/VG Ratio: 48.67/51.33, E-Liquid Volume: 1.4 mL, Wattage: 1.18 Wh, Battery Capacity: 280 mAh, Width: 15.5 mm, Thickness: 7 mm, Disposable
PM0003460	PD3	Bidi Stick - Dawn	ENDS(VAPES)	ENDS Component	Plastic box	1 E-Cigarette	Mint, Ginger, Lemon	Length: 112.5 mm, Diameter: Not Provided, Nicotine: 60 mg/mL, PG/VG Ratio: 48.67/51.33, E-Liquid Volume: 1.4 mL, Wattage: 1.18 Wh, Battery Capacity: 280 mAh, Width: 15.5 mm, Thickness: 7 mm, Disposable
PM0003460	PD4	Bidi Stick - Gold	ENDS(VAPES)	ENDS Component	Plastic box	1 E-Cigarette	Fresh Mango	Length: 112.5 mm, Diameter: Not Provided, Nicotine: 60 mg/mL, PG/VG Ratio: 49.14/50.86, E-Liquid Volume: 1.4 mL, Wattage: 1.18 Wh, Battery Capacity: 280 mAh, Width: 15.5 mm, Thickness: 7 mm, Disposable
PM0003460	PD5	Bidi Stick - Marigold	ENDS(VAPES)	ENDS Component	Plastic box	1 E-Cigarette	Mango, Menthol	Length: 112.5 mm, Diameter: Not Provided, Nicotine: 60 mg/mL, PG/VG Ratio: 49.14/50.86, E-Liquid Volume: 1.4 mL, Wattage: 1.18 Wh, Battery Capacity: 280 mAh, Width: 15.5 mm, Thickness: 7 mm, Disposable
PM0003460	PD6	Bidi Stick - Regal	ENDS(VAPES)	ENDS Component	Plastic box	1 E-Cigarette	Dragonfruit, Strawberry	Length: 112.5 mm, Diameter: Not Provided, Nicotine: 60 mg/mL, PG/VG Ratio: 48.67/51.33, E-Liquid Volume: 1.4 mL, Wattage: 1.18 Wh, Battery Capacity: 280 mAh, Width: 15.5 mm, Thickness: 7 mm, Disposable
PM0003460	PD7	Bidi Stick - Solar	ENDS(VAPES)	ENDS Component	Plastic box	1 E-Cigarette	Strawberry, Blueberry	Length: 112.5 mm, Diameter: Not Provided, Nicotine: 60 mg/mL, PG/VG Ratio: 48.67/51.33, E-Liquid Volume: 1.4 mL, Wattage: 1.18 Wh, Battery Capacity: 280 mAh, Width: 15.5 mm, Thickness: 7 mm, Disposable
PM0003460	PD8	Bidi Stick - Summer	ENDS(VAPES)	ENDS Component	Plastic box	1 E-Cigarette	Blueberry, Pomegranate	Length: 112.5 mm, Diameter: Not Provided, Nicotine: 60 mg/mL, PG/VG Ratio: 48.67/51.33, E-Liquid Volume: 1.4 mL, Wattage: 1.18 Wh, Battery Capacity: 280 mAh, Width: 15.5 mm, Thickness: 7 mm, Disposable
PM0003460	PD9	Bidi Stick - Tropic	ENDS(VAPES)	ENDS Component	Plastic box	1 E-Cigarette	Mango, Apple, Orange	Length: 112.5 mm, Diameter: Not Provided, Nicotine: 60 mg/mL, PG/VG Ratio: 47.99/52.01, E-Liquid Volume: 1.4 mL, Wattage: 1.18 Wh, Battery Capacity: 280 mAh, Width: 15.5 mm, Thickness: 7 mm, Disposable