

**IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT**

7 Daze LLC,
Petitioner,

Case No. 21-_____

v.

U.S. Food and Drug Administration,
Respondent.

PETITION FOR REVIEW

Pursuant to 21 U.S.C. 387l(a) and Fed. R. App. P. 15(a), Petitioner 7 Daze LLC hereby petitions the U.S. Court of Appeals for the Ninth Circuit to review the U.S. Food and Drug Administration's Marketing Denial Order, dated September 8, 2021 (attached as Exhibit A). The order denies 7 Daze's September 9, 2020, bundled Premarket Tobacco Product Applications (assigned Submission Tracking Number PM0002394), as amended, for certain of 7 Daze's electronic nicotine delivery system products. This Court has jurisdiction to review the order under 21 U.S.C. 387l(a)(1), and venue is proper because 7 Daze's principal place of business is in this circuit (*ibid.*).

7 Daze respectfully submits that the order is defective and unlawful on multiple grounds, including 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, procedurally and substantively flawed, and otherwise not in accordance with law. See 5 U.S.C. 706(2). 7 Daze requests that the Court vacate or modify the order, in whole or in part; provide interim relief to stay the order, restore the status quo, and ensure that 7 Daze may continue to market its products subject to the order; and otherwise provide all appropriate relief to which 7 Daze may be entitled. See 21 U.S.C. 387l(b), (d).

Respectfully submitted.

/s/ Daniel L. Geysler

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Counsel for Petitioner 7 Daze LLC

October 7, 2021

CORPORATE DISCLOSURE STATEMENT

Pursuant to Fed. R. App. P. 26.1, Petitioner 7 Daze LLC states that it is a privately held company. 7 Daze has no parent corporation, and no publicly held company owns 10% or more of its stock.

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October 7, 2021

CERTIFICATE OF SERVICE

Pursuant to Fed. R. App. P. 15(c) and 25(d), I hereby certify that on October 7, 2021, an electronic copy of the foregoing Petition for Review was filed with the Clerk of the Court for the U.S. Court of Appeals for the Ninth Circuit, using the appellate CM/ECF system. I further certify that I have caused the foregoing petition to be served on the following parties by electronic mail and first-class mail:

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

Mark Raza, Acting Chief Counsel
Ann Oxenham, Assistant Deputy Chief Counsel for Litigation
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Mitch Zeller, Director
Matthew R. Holman, Director, Office of Science
Adaku Otuonye, Regulatory Health Project Manager
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October 7, 2021

EXHIBIT A



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

September 08, 2021

DENIAL

7 Daze LLC
Attention: John Lau, Managing Member
1425 South Vineyard Avenue
Ontario, CA 91761

FDA Submission Tracking Numbers (STNs): PM0002394, see Appendix A

Dear Mr. Lau:

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 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.² You may not cross-reference information submitted in the PMTA 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 survey data, this evidence is not sufficient to show a benefit to adult smokers of using these flavored ENDS because it does not

¹ Premarket Tobacco Product Applications (PMTAs) 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>

evaluate the specific products in the applications or evaluate these outcomes based on flavor type to enable comparisons between tobacco and other flavors.

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^{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 date⁶; 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.

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 Adaku Otuonye, Regulatory Health Project Manager, at (301)796-2926 or Adaku.Otuonye@fda.hhs.gov.

Sincerely,

Digitally signed by Matthew R. Holman -S
Date: 2021.09.08 14:35:26 -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 – Amendment Received for These Applications

Appendix A⁷
New Tobacco Products Subject of This Letter

Common Attributes of PMTAs	
Submission date	September 9, 2020
Receipt date	September 9, 2020
Applicant	7 Daze LLC
Product manufacturer	7 Daze LLC
Product category	ENDS(VAPES)
Product subcategory	ENDS Component

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

Appendix B
Amendment Received for These Applications

Submission Date	Receipt Date	Applications being amended	Reviewed	Brief Description
April 21, 2021	April 21, 2021	All	Yes	Additional supporting data and information

