No.

In the Supreme Court of the United States

FOOD AND DRUG ADMINISTRATION, PETITIONER

v.

SWT GLOBAL SUPPLY, INC., ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

SAMUEL R. BAGENSTOS
General Counsel
Department of Health and Human Services
Washington, D.C. 20201

MARK RAZA
Chief Counsel
WENDY S. VICENTE
Deputy Chief Counsel for Litigation
WIILLIAM H. RAWSON
Associate Chief Counsel
Food and Drug Administration
Silver Spring, MD 20993

ELIZABETH B. PRELOGAR
Solicitor General
Counsel of Record
BRIAN A. BOYNTON
Principal Deputy Assistant Attorney General
CURTIS E. GANNON
Deputy Solicitor General
VIVEK SURI
Assistant to the Solicitor General
LINDSEY POWELL
CATHERINE PADHI
Attorneys

Department of Justice
Washington, D.C. 20530-0001
SupremeCtBriefs@usdoj.gov
(202) 514-2217

QUESTION PRESENTED

The Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, Div. A, 123 Stat. 1776, requires a person to obtain authorization from the Food and Drug Administration (FDA) before introducing a new tobacco product into interstate commerce. The agency may grant such authorization only if the applicant shows, among other things, that the marketing of the product would be "appropriate for the protection of the public health." 21 U.S.C. 387j(c)(2)(A). In this case, the agency denied respondents' applications for authorization to market new e-cigarette products because they had failed to show that marketing the products would be appropriate for the protection of the public health. The question presented is:

Whether the court of appeals erred in setting aside FDA's denial orders as arbitrary and capricious.

PARTIES TO THE PROCEEDING

Petitioner (respondent below) is the Food and Drug Administration. Respondents (petitioners below) are SWT Global Supply, Inc.; Cloud House, L.L.C; Paradigm Distribution; SV Packaging, L.L.C.; and Vaporized, Inc.

RELATED PROCEEDINGS

United States Court of Appeals (5th Cir):

SWT Global Supply, Inc. v. *FDA*, No. 21-60762 (July 31, 2024)

TABLE OF CONTENTS

In the Supreme Court of the United States

No.

FOOD AND DRUG ADMINISTRATION, PETITIONER

v.

SWT GLOBAL SUPPLY, INC., ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

The Solicitor General, on behalf of the Food and Drug Administration, respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Fifth Circuit in this case.

OPINIONS BELOW

The opinion of the court of appeals (App., *infra*, 1a-6a) is available at 2024 WL 3595387. The Food and Drug Administration's marketing denial orders (App., *infra*, 7a-34a) are unreported.

JURISDICTION

The judgment of the court of appeals was entered on July 31, 2024. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. The Family Smoking Prevention and Tobacco Control Act (Act), Pub. L. No. 111-31, Div. A, 123 Stat.

1776, requires a manufacturer to obtain authorization from the Food and Drug Administration (FDA) before introducing any "new tobacco product" into interstate commerce. 21 U.S.C. 387j(a)(2)(A). The Act defines a new tobacco product as a tobacco product that was not on the market as of February 15, 2007. See 21 U.S.C. 387j(a)(1).

FDA may grant marketing authorization only if the manufacturer shows, among other things, that the product would be "appropriate for the protection of the public health." 21 U.S.C. 387j(c)(2)(A). In applying that standard, FDA must consider both the "likelihood that existing users of tobacco products will stop using such products" and the "likelihood that those who do not use tobacco products will start using such products." 21 U.S.C. 387j(c)(4). In the present context, that standard requires the agency to weigh (1) the likelihood that the new product will help existing smokers (generally adults) completely switch to less dangerous alternatives, or significantly reduce the amount they smoke, against (2) the risk that the new product will entice new users (generally youth) to begin using tobacco products.

This case concerns FDA's application of those provisions to e-cigarettes—that is, devices that aerosolize nicotine-containing "e-liquids" that users then inhale. See Ctrs. for Disease Control & Prevention, U.S. Dep't of Health & Human Servs., *E-Cigarette, or Vaping, Products Visual Dictionary* 7 (Dec. 13, 2019). In 2016, FDA promulgated a rule announcing that it would regulate e-cigarettes and e-liquids in accordance with the Act. See 81 Fed. Reg. 28,974, 29,028-29,044 (May 10, 2016). E-cigarettes and e-liquids generally qualify as "new tobacco products" because they were not on the market as of February 15, 2007. See *Avail Vapor, LLC*

v. *FDA*, 55 F.4th 409, 414 (4th Cir. 2022), cert. denied, 144 S. Ct. 277 (2023).

2. Respondents manufacture flavored e-liquids. See App., *infra*, 3a-4a. In September 2020, respondents filed applications for authorization to market e-liquids in flavors such as "sour strawberry," "goofy grape," "salted caramel cupcake," "funfetti," "grandma's cake batter," and "pixie dust." C.A. App. A2, A125, A656, A1331, A1352 (capitalization omitted).

FDA denied respondents' applications. See App., *infra*, 7a-34a; C.A. App. A145-A163, A170-A188, A836-A856, A1131-A1150, A1372-A1391. The agency relied on substantially the same reasoning in denying each of the applications. For ease of reference, we cite FDA's analysis in denying authorization for respondent SWT Global Supply's products. See C.A. App. A145-A163.

FDA explained that the literature demonstrated that flavored e-cigarettes present a "well-established" risk of "increasing the appeal of tobacco products to youth." C.A. App. A151. On the other side of the ledger, the agency determined that "the evidence regarding the role of flavors in promoting switching among adult smokers is far from conclusive" and that "the literature does not establish that flavors differentially promote switching amongst [e-cigarette] users in general." *Id.* at A155-A156. The agency accordingly reviewed respondents' applications "for any acceptably strong product-specific evidence," *id.* at A156, and found insufficient evidence to demonstrate that respondents' products "will provide a benefit to adult users that would be adequate to outweigh the risks to youth," *id.* at A158. Respondents proposed marketing plans that would purportedly address those risks by limiting youth access to their products, but FDA declined to consider the plans, not-

ing that it was "not aware of access restrictions that, to date, have been successful in sufficiently decreasing the ability of youth to obtain and use" e-cigarettes. *Id.* at A155 n.xix.

3. The Fifth Circuit granted respondents' petitions for review. See App., *infra*, 1a-6a.

The court of appeals observed that, in *Wages & White Lion Investments, L.L.C.* v. *FDA*, 90 F.4th 357 (5th Cir.) (en banc), cert. granted, 144 S. Ct. 2714 (2024), it had held that FDA had acted arbitrarily and capriciously in denying two other companies' applications for authorization to market e-liquids. See App., *infra*, 5a. The court found "no basis to distinguish this case from *Wages*" and set aside FDA's orders "for the reasons amply explained" in *Wages*. *Id.* at 6a. Specifically, the court held here, as it had in *Wages*, that FDA had unlawfully surprised the manufacturers by assertedly denying their applications "based on the absence of long-term clinical studies." *Ibid.*

REASONS FOR GRANTING THE PETITION

In the decision below, the court of appeals relied on its earlier decision in *Wages & White Lion Investments, L.L.C.* v. *FDA*, 90 F.4th 357 (5th Cir.) (en banc), cert. granted, 144 S. Ct. 2714 (2024), in holding that FDA had acted arbitrarily and capriciously in denying respondents' applications for marketing authorization. The court found "no basis to distinguish this case from *Wages*" and set aside FDA's orders "for the reasons amply explained" in *Wages*. App., *infra*, 6a.

This Court has granted certiorari to review the court of appeals' decision in *Wages*. See *FDA* v. *Wages & White Lion Investments, L.L.C.*, 144 S. Ct. 2714 (2024) (No. 23-1038). The Court should therefore hold this petition for a writ of certiorari pending its decision in

Wages and then dispose of the petition as appropriate in light of that decision.

CONCLUSION

The Court should hold this petition for a writ of certiorari pending its resolution of *FDA* v. *Wages & White Lion Investments, L.L.C.*, cert. granted, 144 S. Ct. 2714 (2024) (No. 23-1038), and then dispose of the petition as appropriate in light of that decision.

Respectfully submitted.

ELIZABETH B. PRELOGAR
Solicitor General
BRIAN M. BOYNTON
Principal Deputy Assistant Attorney General
CURTIS E. GANNON
Deputy Solicitor General
VIVEK SURI
Assistant to the Solicitor General
LINDSEY POWELL
CATHERINE PADHI
Attorneys

SAMUEL R. BAGENSTOS
General Counsel
Department of Health and Human Services
MARK RAZA
Chief Counsel
WENDY S. VICENTE
Deputy Chief Counsel for Litigation
WILLIAM H. RAWSON
Associate Chief Counsel
Food and Drug Administration

OCTOBER 2024

APPENDIX

TABLE OF CONTENTS

APPENDIX A

UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

No. 21-60762

SWT GLOBAL SUPPLY, INCORPORATED, PETITIONER

v.

FOOD & DRUG ADMINISTRATION, RESPONDENT

CONSOLIDATED WITH

No. 21-60777

CLOUD HOUSE, L.L.C., PETITIONER

v.

FOOD & DRUG ADMINISTRATION, RESPONDENT

CONSOLIDATED WITH

No. 21-60778

PARADIGM DISTRIBUTION, PETITIONER

v.

FOOD & DRUG ADMINISTRATION, RESPONDENT

CONSOLIDATED WITH

No. 21-60779

VAPORIZED, INCORPORATED, PETITIONER

v.

FOOD & DRUG ADMINISTRATION, RESPONDENT

CONSOLIDATED WITH

No. 21-60801

SV PACKAGING, L.L.C., PETITIONER

v.

FOOD & DRUG ADMINISTRATION, RESPONDENT

Filed: July 30, 2024

Petition from the Food & Drug Administration
Agency Nos. PM0003792, PM0003640,
PM0000968, PM0001094, PM0001168,
PM0001191, PM0003578

Before WIENER, ELROD, and WILSON, *Circuit Judges*.

PER CURIAM:*

Petitioners seek to set aside marketing denial orders (MDOs) issued by the Food & Drug Administration (FDA) for their e-cigarette products. In light of this court's en banc decision in *Wages & White Lion Invs., L.L.C. v. FDA*, 90 F.4th 357 (5th Cir. 2024) (en banc),

---

* This opinion is not designated for publication. *See* 5TH CIR. R. 47.5.

cert. granted, --- U.S. ----, 2024 WL 3259693 (July 2, 2024) (No. 23-1038), we grant the petitions for review, set aside the MDOs, and remand these matters to the FDA.

I.

In 2016, FDA labeled e-cigarettes and their component parts as "new tobacco products" subject to regulation under the Family Smoking Prevention and Tobacco Control Act, 21 U.S.C. §§ 387-387v. *See Wages*, 90 F.4th at 363.[1] As part of those regulations, e-cigarette manufacturers had to submit premarket tobacco applications (PMTAs) for FDA approval before selling their products. *Id.* (citing 81 Fed. Reg. 28,977 (May 10, 2016)). The deadline to submit PMTAs was September 9, 2020. *Id.* at 363 n.2.

From 2018 to 2020, FDA provided a "dizzying" array of detailed instructions explaining the requirements for PMTAs. *See id.* at 363-68. But "[n]ever in this long, winding, and byzantine regulatory process of meetings, PowerPoint decks, proposed rules, comment periods, guidance documents, and enforcement priorities did FDA *ever* say that it was contemplating an across-the-board ban on flavored products." *Id.* at 368. "Nor did FDA ever give fair notice that *flavored* product manufacturers had to submit robust scientific studies on *flavored* e-cigarette products." *Id.* at 368-69.

Petitioners are Texas and Mississippi companies that, like the petitioners in *Wages*, manufacture flavored

---

[1] *Wages* provided a full review of FDA's rule-making process at issue in this case. *See* 90 F.4th at 363–69. We provide only a short synopsis here.

nicotine-containing e-liquids used in open tank systems.[2] Petitioners submitted PMTAs for their products before the September 2020 deadline. They submitted various documents, including "Youth Access Prevention Plans," "Marketing Plans," and survey data from their customers. In accordance with FDA guidance, Petitioners explained how they would limit their marketing carefully to target adult consumers and only sell their products in age-restricted vape and tobacco-specialty shops or age-restricted online stores. Some of the petitioners joined trade associations to ensure they were complying with FDA guidelines for their PMTAs. But based on FDA's guidance, Petitioners did not conduct or otherwise proffer long-term clinical studies for their products.

"On August 26, 2021, FDA issued a press release to announce the *en masse* denial of 55,000 flavored e-cigarette applications." *Wages*, 90 F.4th at 370. "In that press release, FDA announced for the first time that, for flavored e-cigarette applications, the agency *would* require" long-term clinical studies. *Id.* Less than a month later, FDA issued an MDO to each Peti-

---

[2] Open tank e-cigarette products are different than cartridge-based products. Cartridge-based e-cigarettes are inconspicuous and easier to use, and more susceptible to abuse by youth. *See Wages*, 90 F.4th at 367-68. In contrast, open tank systems are "less innocuous in appearance" and "more complicated" to use, making them less attractive to underage vapers. *See id.* at 367. In January 2020, FDA issued an enforcement guidance document stating that it would "prioritize enforcement resources against flavored, cartridge-based [e-cigarette] products." *Id.* at 366 (internal quotations omitted). Because Petitioners bottle only product for open tank systems, "it is common ground that FDA's 2020 Enforcement Guidance did not apply to [P]etitioners or their liquids." *Id.* at 369.

tioner stating that their products had been denied. Specifically, FDA stated:

> All of your PMTAs lack sufficient evidence demonstrating that your flavored [e-cigarette products] will provide a benefit to adult users that would be adequate to outweigh the risks to youth. . . . This evidence could have been provided using a randomized controlled trial and/or longitudinal cohort study that demonstrated the benefit of your flavored [e-cigarette] products over an appropriate comparator tobacco-flavored [e-cigarette product].

In making this determination, FDA did not consider the thousands of other documents provided by Petitioners.

On October 1, 2021, Petitioners filed their petitions for review, seeking to vacate or modify the MDOs. Petitioners then filed a motion to stay their respective MDOs pending review in our court, which a motions panel granted. After the parties completed their briefing, the court placed this case in abeyance pending the decision in *Wages*. Once the mandate issued in *Wages*, the court removed this case from abeyance in April 2024.

II.

As in *Wages*, Petitioners argue that "FDA pulled a surprise switcheroo" by denying their PMTAs for lack of long-term studies after providing years of guidance that no such studies were necessary. In *Wages*, the en banc court agreed and concluded that FDA's denials of the *Wages* petitioners' PMTAs were arbitrary and capricious. 90 F.4th at 388. Specifically, the court determined that (1) FDA did not give e-cigarette manufacturers fair notice of the rule requiring long-term studies for PMTAs; (2) FDA did not acknowledge or adequately

explain its change in position; and (3) FDA ignored reasonable and serious reliance interests that manufacturers had in the pre-MDO guidance. *See id.* at 374-88.[3]

There is no basis to distinguish this case from *Wages*. As there, Petitioners in this case manufacture flavored nicotine-containing e-liquids. Petitioners spent substantial time and resources preparing their PMTAs based on FDA guidance that they would not need to submit long-term clinical studies. Nevertheless, FDA rejected their PMTAs using the same boilerplate language it used for the *Wages* petitioners' denials, as well as those of thousands of other e-cigarette manufacturers. Accordingly, for the reasons amply explained by the en banc court in *Wages*, we hold that FDA acted unlawfully here as well by denying Petitioners' PMTAs based on the absence of long-term clinical studies.

III.

For the foregoing reasons, the petitions for review are GRANTED, FDA's marketing denial orders are SET ASIDE, and these cases are REMANDED to FDA for further proceedings.

---

[3] The court also determined that FDA tried to cover up its mistakes with *post hoc* justifications at oral argument. *Wages*, 90 F.4th at 388. That reasoning does not apply in this case because no oral arguments were held.

APPENDIX B

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

DENIAL

SV Packaging LLC
Attention: Andrew Agler, CEO
373 Van Ness Avenue, Suite 100
Torrance, California 90501

FDA Submission Tracking Numbers (STNs):
PM0003578, see Appendix A

Dear Mr. Agler:

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

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.

---

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

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 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 switching or cigarette reduction over time. We did not find such evidence in your PMTAs. Without this information, FDA concludes that your application is insufficient to demonstrate that these products would provide an added benefit that is adequate

---

[2] See guidelines at https://www.fda.gov/regulatoryinformation/search-fda-guidance-documents/tobacco-product-master-files

> 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)

---

[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

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.

If you have any questions, please contact Maria Suarez, M.S.H.S., Regulatory Health Project Manager, at (301) 348 1867 or Maria.Suarez@fda.hhs.gov.

Sincerely,

Digitally signed by Matthew R. Holman -S
Date: 2021.09.10 15:28:39 -04'00'
Matthew R. Holman, Ph.D.
Director
Office of Science
Center for Tobacco Products

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

Appendix A—New Tobacco Products Subject of This Letter

---

[6] https://www.fda.gov/tobacco-products/about-center-tobacco-products-ctp/contact ctp

APPENDIX C

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

DENIAL

Vaporized Inc.
Attention: William Wikstrom, CEO/Owner
4700 Hardy Street
Hattiesburg, MS 39402-1300

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

Dear Mr. Wikstrom:

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

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

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

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 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. We did not find such evidence in your PMTAs. Without this information, FDA concludes that

---

[2] See guidelines at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/tobacco-product-master-files

> 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 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.

---

[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 Travelle Mason, Regulatory Health Project Manager, at (240) 402-7805 or Travelle.Mason@fda.hhs.gov.

Sincerely,

Digitally signed by Matthew R. Holman -S
Date: 2021.09.08 15:25:25 -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 D

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

Sept. 15, 2021

DENIAL

Paradigm Distribution
Attention: William Wikstrom
5315 Old Highway 11, Suite 2
Hattiesburg, MS 39402

FDA Submission Tracking Numbers (STNs):
PM0000968, see Appendix A

Dear Mr. Wikstrom:

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

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

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

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 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. We did not find such evidence in your PMTAs. Without this information, FDA concludes that

---

[2] See guidelines at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/tobacco-product-master-files

> 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:

---

[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

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.

If you have any questions, please contact Michael Jokoh, Regulatory Health Project Manager, at (301) 796-0502 or Michael.Jokoh@fda.hhs.gov.

Sincerely,

Digitally signed by Matthew R. Holman -S
Date: 2021.09.15 14:10:30 -04'00'
Matthew R. Holman, Ph.D.
Director
Office of Science
Center for Tobacco Products

---

[6] https://www.fda.gov/tobacco-products/about-center-tobacco-products-ctp/contact-ctp

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

Appendix A—New Products Subject of This Letter

APPENDIX E

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

Sept. 8, 2021

DENIAL

Cloud House LLC
Attention: Cameron Blake Levee, Director of Business Development
604 North Bell Boulevard
Cedar Park, TX 78613

FDA Submission Tracking Number (STN): PM0003640, see Appendix A

Dear Mr. Levee:

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 introduc-

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

tion 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 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

[2] See guidelines at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/tobacco-product-master-files

> reduction over time. Although your PMTAs contained data collected from a cross-sectional survey, this evidence is not sufficient to show a benefit to adult smokers of using these flavored ENDS because it does not evaluate the specific products in the applications, evaluate product switching or cigarette reduction resulting from use of these products over time, nor 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 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.

If you have any questions, please contact Donna Cheung, Regulatory Health Project Manager, at (240) 402-5340 or Donna.Cheung@fda.hhs.gov.

---

[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

Sincerely,

Digitally signed by Matthew R. Holman -S
Date: 2021.09.08 15:31:46 -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 F

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

Sept. 07, 2021

DENIAL

SWT Global Supply Inc.
Attention: William Thomas, COO
204 Industrial Court
Wylie, TX 75098

FDA Submission Tracking Numbers (STNs):
PM0003792, see Appendix A

Dear Mr. Thomas:

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

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

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

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 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 impact of the new flavored vs. tobacco-flavored products on adult smokers' switching or cigarette reduction over time. Without this information, FDA concludes that your application is insufficient to demonstrate that these products would

---

[2] See guidelines at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/tobacco-product-master-files

> 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

---

[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.

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.

If you have any questions, please contact Kaylene Charles, Regulatory Health Project Manager, at (301) 796-0731 or Kaylene.Charles@fda.hhs.gov.

Sincerely,

Digitally signed by Matthew R. Holman -S
Date: 2021.09.07 09:53:48 -04'00'
Matthew R. Holman, Ph.D.
Director
Office of Science
Center for Tobacco Products

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

Appendix A—New Tobacco Products Subject of This Letter

---

[6] https://www.fda.gov/tobacco-products/about-center-tobacco-products-ctp/contact-ctp

APPENDIX G

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

Aug. 31, 2021

DENIAL

SWT Global Supply Inc.
Attention: William Thomas, COO
204 Industrial Court
Wylie, TX 75098

FDA Submission Tracking Numbers (STNs):
PM0003792, see Appendix A

Dear Mr. Thomas:

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

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

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

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 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 impact of the new flavored vs. tobacco-flavored products on adult smokers' switching or cigarette reduction over time.

---

[2] See guidelines at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/tobacco-product-master-files

> 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 taking 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

If you have any questions, please contact Kaylene Charles, Regulatory Health Project Manager, at (301) 796-0731 or Kaylene.Charles@fda.hhs.gov.

---

[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

Sincerely,

Digitally signed by Matthew R. Holman -S
Date: 2021.08.31 14:51:19 -04'00'
Matthew R. Holman, Ph.D.
Director
Office of Science
Center for Tobacco Products

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

Appendix A—New Tobacco Products Subject of This Letter