

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

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WAGES AND WHITE LION INVESTMENTS,)	
LLC d/b/a TRITON DISTRIBUTION,)	
)	
Petitioner,)	
)	
v.)	Case No.
)	
UNITED STATES FOOD AND DRUG)	
ADMINISTRATION,)	
)	
Respondent.)	
<hr/>)	

PETITION FOR REVIEW

Appellant Wages and White Lion Investments, LLC d/b/a Triton Distribution (“Triton”) pursuant to Section 912 of the Federal Food, Drug and Cosmetic Act (“FDCA”), 21 U.S.C. § 387*l*, and Rule 15(a) of the Federal Rules of Appellate Procedure, respectfully submits this petition for review of two Marketing Denial Orders (“MDOs”) dated September 14, 2021, issued by Respondent United States Food and Drug Administration (“FDA”) for Triton’s non-tobacco- and non-menthol-flavored electronic nicotine delivery system (“ENDS”) products. A copy of the MDO is attached hereto as Exhibit A.

Triton appeals FDA’s MDO on the ground that FDA’s denial of Triton’s application for a marketing order is arbitrary, capricious, an abuse of discretion, or

otherwise not in accordance with law and thus must be set aside and vacated pursuant to 5 U.S.C. § 706(2)(A). Triton respectfully requests that the Court vacate or modify, in whole or in part, the Marketing Denial Order, stay its enforcement pending a determination of Triton's appeal on the merits such that Triton may be able to continue to market the subject products, and grant such other and further relief to which Triton may be entitled.

Respectfully submitted,

Dated: October 1, 2021

By: /s/ Anthony J. Hornbach
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*Counsel for Petitioner Wages and White
Lion Investments, LLC d/b/a Triton
Distribution*

CERTIFICATE OF SERVICE

Pursuant to Federal Rule of Appellate Procedure 25(d), I hereby certify that on October 1, 2021, a true and correct copy of the foregoing Petition for Review was served on the following by electronic mail and first-class mail:

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Silver Spring, MD 20993-0002
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EXHIBIT A



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

September 14, 2021

DENIAL

Wages & White Lion Investments LLC dba Triton Distribution
Attention: Jon Rose, General Manager
789 North Grove Road Suite 111
Richardson, TX 75081

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

Dear Mr. Rose:

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.

²

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 your application is insufficient to demonstrate that these products would provide an added benefit that is adequate to outweigh

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>

Multiple STNs, see Appendix A

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>

Multiple STNs, see Appendix A

If you have any questions, please contact Sammrawit Girma, Regulatory Health Project Manager, at (301) 796-5313 or Sammrawit.Girma@fda.hhs.gov.

Sincerely,

Digitally signed by Matthew R. Holman -S

Date: 2021.09.14 16:46:09 -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 Tobacco Products Subject of This Letter

Appendix B – Amendments Received for These Applications

Multiple STNs, see Appendix A

Appendix A⁷

New Tobacco Products Subject of This Letter

Common Attributes of PMTAs	
Date of Submission:	September 9, 2020
Date of Receipt:	September 9, 2020
Product Manufacturer:	Wages & White Lion Investments LLC dba Triton Distribution
Product Category:	ENDS (Electronic Nicotine Delivery System)
Product Sub-Category:	ENDS Component

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

Appendix A

PM0003790

PM0003790	Signature Series Toasted Strawberry 6mg	ENDS (VAPES)	Bottle	1 Bottle	Toasted Strawberry	Nicotine: 0mg/mL, PG/VG Ratio: 70/30, E-Liquid Volume: 60mL
PM0003790	Signature Series Toasted Strawberry 3mg	ENDS (VAPES)	Bottle	1 Bottle	Toasted Strawberry	Nicotine: 3mg/mL, PG/VG Ratio: 70/30, E-Liquid Volume: 60mL
PM0003790	Boiler Maker Hammer 3mg	ENDS (VAPES)	Bottle	1 Bottle	Hammer	Nicotine: 3mg/mL, PG/VG Ratio: 70/30, E-Liquid Volume: 60mL
PM0003790	Signature Series Toasted Strawberry 6mg	ENDS (VAPES)	Bottle	1 Bottle	Toasted Strawberry	Nicotine: 0mg/mL, PG/VG Ratio: 70/30, E-Liquid Volume: 60mL
PM0003790	Signature Series Bummy Season 3mg	ENDS (VAPES)	Bottle	1 Bottle	Bummy Season	Nicotine: 3mg/mL, PG/VG Ratio: 70/30, E-Liquid Volume: 60mL, 120mL
PM0003790	Suicide Bunny Bummy Season 6mg	ENDS (VAPES)	Bottle	1 Bottle	Bummy Season	Nicotine: 6mg/mL, PG/VG Ratio: 70/30, E-Liquid Volume: 60mL, 120mL
PM0003790	Suicide Bunny Bummy Season 3mg	ENDS (VAPES)	Bottle	1 Bottle	Bummy Season	Nicotine: 3mg/mL, PG/VG Ratio: 70/30, E-Liquid Volume: 60mL, 120mL
PM0003790	Suicide Bunny Bummy Season 6mg	ENDS (VAPES)	Bottle	1 Bottle	Bummy Season	Nicotine: 6mg/mL, PG/VG Ratio: 70/30, E-Liquid Volume: 60mL, 120mL
PM0003790	Suicide Bunny Derailed 1.5mg	ENDS (VAPES)	Bottle	1 Bottle	Derailed	Nicotine: 1.5mg/mL, PG/VG Ratio: 70/30, E-Liquid Volume: 60mL, 120mL
PM0003790	Suicide Bunny Derailed 3mg	ENDS (VAPES)	Bottle	1 Bottle	Derailed	Nicotine: 3mg/mL, PG/VG Ratio: 70/30, E-Liquid Volume: 60mL, 120mL
PM0003790	Suicide Bunny Derailed 6mg	ENDS (VAPES)	Bottle	1 Bottle	Derailed	Nicotine: 6mg/mL, PG/VG Ratio: 70/30, E-Liquid Volume: 60mL, 120mL
PM0003790	Suicide Bunny Derailed 18mg	ENDS (VAPES)	Bottle	1 Bottle	Derailed	Nicotine: 18mg/mL, PG/VG Ratio: 70/30, E-Liquid Volume: 60mL, 120mL
PM0003790	Boiler Maker Hammer 6mg	ENDS (VAPES)	Bottle	1 Bottle	Hammer	Nicotine: 6mg/mL, PG/VG Ratio: 70/30, E-Liquid Volume: 60mL, 120mL
PM0003790	Suicide Bunny Madrina 1.5mg	ENDS (VAPES)	Bottle	1 Bottle	Madrina	Nicotine: 1.5mg/mL, PG/VG Ratio: 70/30, E-Liquid Volume: 60mL, 120mL
PM0003790	Suicide Bunny Madrina 3mg	ENDS (VAPES)	Bottle	1 Bottle	Madrina	Nicotine: 3mg/mL, PG/VG Ratio: 70/30, E-Liquid Volume: 60mL, 120mL
PM0003790	Suicide Bunny Madrina 6mg	ENDS (VAPES)	Bottle	1 Bottle	Madrina	Nicotine: 6mg/mL, PG/VG Ratio: 70/30, E-Liquid Volume: 60mL, 120mL
PM0003790	Suicide Bunny Madrina 12mg	ENDS (VAPES)	Bottle	1 Bottle	Madrina	Nicotine: 12mg/mL, PG/VG Ratio: 70/30, E-Liquid Volume: 60mL, 120mL
PM0003790	Suicide Bunny Mother's Milk and Cookies 6mg	ENDS (VAPES)	Bottle	1 Bottle	Mother's Milk and Cookies	Nicotine: 6mg/mL, PG/VG Ratio: 70/30, E-Liquid Volume: 60mL, 120mL
PM0003790	Suicide Bunny Mother's Milk and Cookies 3mg	ENDS (VAPES)	Bottle	1 Bottle	Mother's Milk and Cookies	Nicotine: 3mg/mL, PG/VG Ratio: 70/30, E-Liquid Volume: 60mL, 120mL
PM0003790	Suicide Bunny Mother's Milk and Cookies 6mg	ENDS (VAPES)	Bottle	1 Bottle	Mother's Milk and Cookies	Nicotine: 6mg/mL, PG/VG Ratio: 70/30, E-Liquid Volume: 60mL, 120mL
PM0003790	Suicide Bunny Mother's Milk 6mg	ENDS (VAPES)	Bottle	1 Bottle	Mother's Milk	Nicotine: 6mg/mL, PG/VG Ratio: 70/30, E-Liquid Volume: 60mL, 120mL
PM0003790	Suicide Bunny Mother's Milk 12mg	ENDS (VAPES)	Bottle	1 Bottle	Mother's Milk	Nicotine: 12mg/mL, PG/VG Ratio: 70/30, E-Liquid Volume: 60mL, 120mL
PM0003790	Suicide Bunny Mother's Milk 18mg	ENDS (VAPES)	Bottle	1 Bottle	Mother's Milk	Nicotine: 18mg/mL, PG/VG Ratio: 70/30, E-Liquid Volume: 60mL, 120mL
PM0003790	Suicide Bunny Queen Cake 6mg	ENDS (VAPES)	Bottle	1 Bottle	Queen Cake	Nicotine: 6mg/mL, PG/VG Ratio: 70/30, E-Liquid Volume: 60mL, 120mL
PM0003790	Suicide Bunny Queen Cake 12mg	ENDS (VAPES)	Bottle	1 Bottle	Queen Cake	Nicotine: 12mg/mL, PG/VG Ratio: 70/30, E-Liquid Volume: 60mL, 120mL
PM0003790	Suicide Bunny Queen Cake 18mg	ENDS (VAPES)	Bottle	1 Bottle	Queen Cake	Nicotine: 18mg/mL, PG/VG Ratio: 70/30, E-Liquid Volume: 60mL, 120mL
PM0003790	Boiler Maker Anvil 3mg	ENDS (VAPES)	Bottle	1 Bottle	Anvil	Nicotine: 3mg/mL, PG/VG Ratio: 70/30, E-Liquid Volume: 60mL, 120mL
PM0003790	Suicide Bunny Hammer 18mg	ENDS (VAPES)	Bottle	1 Bottle	Hammer	Nicotine: 18mg/mL, PG/VG Ratio: 70/30, E-Liquid Volume: 60mL, 120mL
PM0003790	Suicide Bunny Sucker Punch 6mg	ENDS (VAPES)	Bottle	1 Bottle	Sucker Punch	Nicotine: 6mg/mL, PG/VG Ratio: 70/30, E-Liquid Volume: 60mL, 120mL
PM0003790	Suicide Bunny Sucker Punch 12mg	ENDS (VAPES)	Bottle	1 Bottle	Sucker Punch	Nicotine: 12mg/mL, PG/VG Ratio: 70/30, E-Liquid Volume: 60mL, 120mL
PM0003790	Suicide Bunny Sucker Punch 18mg	ENDS (VAPES)	Bottle	1 Bottle	Sucker Punch	Nicotine: 18mg/mL, PG/VG Ratio: 70/30, E-Liquid Volume: 60mL, 120mL
PM0003790	Suicide Bunny The O.B. 6mg	ENDS (VAPES)	Bottle	1 Bottle	The O.B.	Nicotine: 6mg/mL, PG/VG Ratio: 70/30, E-Liquid Volume: 60mL, 120mL
PM0003790	Suicide Bunny The O.B. 12mg	ENDS (VAPES)	Bottle	1 Bottle	The O.B.	Nicotine: 12mg/mL, PG/VG Ratio: 70/30, E-Liquid Volume: 60mL, 120mL
PM0003790	Suicide Bunny The O.B. 18mg	ENDS (VAPES)	Bottle	1 Bottle	The O.B.	Nicotine: 18mg/mL, PG/VG Ratio: 70/30, E-Liquid Volume: 60mL, 120mL
PM0003790	Suicide Bunny Wanderlust 6mg	ENDS (VAPES)	Bottle	1 Bottle	Wanderlust	Nicotine: 6mg/mL, PG/VG Ratio: 70/30, E-Liquid Volume: 60mL, 120mL
PM0003790	Suicide Bunny Wanderlust 12mg	ENDS (VAPES)	Bottle	1 Bottle	Wanderlust	Nicotine: 12mg/mL, PG/VG Ratio: 70/30, E-Liquid Volume: 60mL, 120mL
PM0003790	Suicide Bunny Wanderlust 18mg	ENDS (VAPES)	Bottle	1 Bottle	Wanderlust	Nicotine: 18mg/mL, PG/VG Ratio: 70/30, E-Liquid Volume: 60mL, 120mL
PM0003790	Teles Afterparty 3mg	ENDS (VAPES)	Bottle	1 Bottle	Afterparty	Nicotine: 3mg/mL, PG/VG Ratio: 70/30, E-Liquid Volume: 60mL, 120mL
PM0003790	Teles Afterparty 6mg	ENDS (VAPES)	Bottle	1 Bottle	Afterparty	Nicotine: 6mg/mL, PG/VG Ratio: 70/30, E-Liquid Volume: 60mL, 120mL
PM0003790	Teles Afterparty 12mg	ENDS (VAPES)	Bottle	1 Bottle	Afterparty	Nicotine: 12mg/mL, PG/VG Ratio: 70/30, E-Liquid Volume: 60mL, 120mL
PM0003790	Teles Bits 3mg	ENDS (VAPES)	Bottle	1 Bottle	Bits	Nicotine: 3mg/mL, PG/VG Ratio: 70/30, E-Liquid Volume: 60mL, 120mL
PM0003790	Teles Bits 6mg	ENDS (VAPES)	Bottle	1 Bottle	Bits	Nicotine: 6mg/mL, PG/VG Ratio: 70/30, E-Liquid Volume: 60mL, 120mL
PM0003790	Teles Bits 12mg	ENDS (VAPES)	Bottle	1 Bottle	Bits	Nicotine: 12mg/mL, PG/VG Ratio: 70/30, E-Liquid Volume: 60mL, 120mL
PM0003790	Boiler Maker Rivet 6mg	ENDS (VAPES)	Bottle	1 Bottle	Rivet	Nicotine: 6mg/mL, PG/VG Ratio: 70/30, E-Liquid Volume: 60mL, 120mL
PM0003790	Teles Crunch 3mg	ENDS (VAPES)	Bottle	1 Bottle	Crunch	Nicotine: 3mg/mL, PG/VG Ratio: 70/30, E-Liquid Volume: 60mL, 120mL
PM0003790	Teles Crunch 6mg	ENDS (VAPES)	Bottle	1 Bottle	Crunch	Nicotine: 6mg/mL, PG/VG Ratio: 70/30, E-Liquid Volume: 60mL, 120mL
PM0003790	Teles Crunch 12mg	ENDS (VAPES)	Bottle	1 Bottle	Crunch	Nicotine: 12mg/mL, PG/VG Ratio: 70/30, E-Liquid Volume: 60mL, 120mL
PM0003790	Teles Eight Bells 6mg	ENDS (VAPES)	Bottle	1 Bottle	Eight Bells	Nicotine: 6mg/mL, PG/VG Ratio: 70/30, E-Liquid Volume: 60mL, 120mL
PM0003790	Teles Eight Bells 12mg	ENDS (VAPES)	Bottle	1 Bottle	Eight Bells	Nicotine: 12mg/mL, PG/VG Ratio: 70/30, E-Liquid Volume: 60mL, 120mL
PM0003790	Teles Eight Bells 18mg	ENDS (VAPES)	Bottle	1 Bottle	Eight Bells	Nicotine: 18mg/mL, PG/VG Ratio: 70/30, E-Liquid Volume: 60mL, 120mL
PM0003790	Teles Experiment One 6mg	ENDS (VAPES)	Bottle	1 Bottle	Experiment One	Nicotine: 6mg/mL, PG/VG Ratio: 70/30, E-Liquid Volume: 60mL, 120mL
PM0003790	Boiler Maker Rivet 12mg	ENDS (VAPES)	Bottle	1 Bottle	Rivet	Nicotine: 12mg/mL, PG/VG Ratio: 70/30, E-Liquid Volume: 60mL, 120mL

Appendix A

PM0003790	PD57	Cloud Company Revel 3mg	ENDS(VAPES)	Bottle	1 Bottle	Revel	Nicotine: 3mg/mL, PG/VG Ratio: 80/20, E-Liquid Volume: 120mL
PM0003790	PD58	Cloud Company Revel 6mg	ENDS(VAPES)	Bottle	1 Bottle	Revel	Nicotine: 6mg/mL, PG/VG Ratio: 80/20, E-Liquid Volume: 120mL
PM0003790	PD59	Cloud Company Revel 9mg	ENDS(VAPES)	Bottle	1 Bottle	Revel	Nicotine: 9mg/mL, PG/VG Ratio: 80/20, E-Liquid Volume: 120mL
PM0003790	PD60	Boiler Maker Chisel 0mg	ENDS(VAPES)	Bottle	1 Bottle	Chisel	Nicotine: 0mg/mL, PG/VG Ratio: 70/30, E-Liquid Volumes: 30mL, 100mL
PM0003790	PD61	Cloud Company Sky 0mg	ENDS(VAPES)	Bottle	1 Bottle	Sky	Nicotine: 0mg/mL, PG/VG Ratio: 85/15, E-Liquid Volumes: 120mL
PM0003790	PD62	Cloud Company Sky 1.5mg	ENDS(VAPES)	Bottle	1 Bottle	Sky	Nicotine: 1.5mg/mL, PG/VG Ratio: 85/15, E-Liquid Volumes: 120mL
PM0003790	PD63	Cloud Company Sky 3mg	ENDS(VAPES)	Bottle	1 Bottle	Sky	Nicotine: 3mg/mL, PG/VG Ratio: 85/15, E-Liquid Volume: 120mL
PM0003790	PD64	Cloud Company Sky 5mg	ENDS(VAPES)	Bottle	1 Bottle	Sky	Nicotine: 5mg/mL, PG/VG Ratio: 85/15, E-Liquid Volume: 120mL
PM0003790	PD65	Cloud Science Alpha 0mg	ENDS(VAPES)	Bottle	1 Bottle	Alpha	Nicotine: 0mg/mL, PG/VG Ratio: 70/30, E-Liquid Volumes: 60mL, 120mL
PM0003790	PD66	Cloud Science Alpha 3mg	ENDS(VAPES)	Bottle	1 Bottle	Alpha	Nicotine: 3mg/mL, PG/VG Ratio: 70/30, E-Liquid Volumes: 60mL, 120mL
PM0003790	PD67	Cloud Science Alpha 6mg	ENDS(VAPES)	Bottle	1 Bottle	Alpha	Nicotine: 6mg/mL, PG/VG Ratio: 70/30, E-Liquid Volumes: 60mL, 120mL
PM0003790	PD68	Cloud Science Alpha 12mg	ENDS(VAPES)	Bottle	1 Bottle	Alpha	Nicotine: 12mg/mL, PG/VG Ratio: 70/30, E-Liquid Volumes: 60mL, 120mL
PM0003790	PD69	Cloud Science Delta 0mg	ENDS(VAPES)	Bottle	1 Bottle	Delta	Nicotine: 0mg/mL, PG/VG Ratio: 70/30, E-Liquid Volumes: 60mL, 120mL
PM0003790	PD70	Boiler Maker Chisel 3mg	ENDS(VAPES)	Bottle	1 Bottle	Chisel	Nicotine: 3mg/mL, PG/VG Ratio: 70/30, E-Liquid Volumes: 30mL, 100mL
PM0003790	PD71	Cloud Science Delta 3mg	ENDS(VAPES)	Bottle	1 Bottle	Delta	Nicotine: 3mg/mL, PG/VG Ratio: 70/30, E-Liquid Volumes: 60mL, 120mL
PM0003790	PD72	Cloud Science Delta 6mg	ENDS(VAPES)	Bottle	1 Bottle	Delta	Nicotine: 6mg/mL, PG/VG Ratio: 70/30, E-Liquid Volumes: 60mL, 120mL
PM0003790	PD73	Cloud Science Delta 12mg	ENDS(VAPES)	Bottle	1 Bottle	Delta	Nicotine: 12mg/mL, PG/VG Ratio: 70/30, E-Liquid Volumes: 60mL, 120mL
PM0003790	PD74	Cloud Science Epsilon 0mg	ENDS(VAPES)	Bottle	1 Bottle	Epsilon	Nicotine: 0mg/mL, PG/VG Ratio: 70/30, E-Liquid Volumes: 60mL, 120mL
PM0003790	PD75	Cloud Science Epsilon 3mg	ENDS(VAPES)	Bottle	1 Bottle	Epsilon	Nicotine: 3mg/mL, PG/VG Ratio: 70/30, E-Liquid Volumes: 60mL, 120mL
PM0003790	PD76	Cloud Science Epsilon 6mg	ENDS(VAPES)	Bottle	1 Bottle	Epsilon	Nicotine: 6mg/mL, PG/VG Ratio: 70/30, E-Liquid Volumes: 60mL, 120mL
PM0003790	PD77	Cloud Science Epsilon 12mg	ENDS(VAPES)	Bottle	1 Bottle	Epsilon	Nicotine: 12mg/mL, PG/VG Ratio: 70/30, E-Liquid Volumes: 60mL, 120mL
PM0003790	PD78	Cloud Science Epsilon-m 0mg	ENDS(VAPES)	Bottle	1 Bottle	Epsilon-m	Nicotine: 0mg/mL, PG/VG Ratio: 70/30, E-Liquid Volumes: 60mL, 120mL
PM0003790	PD79	Cloud Science Epsilon-m 3mg	ENDS(VAPES)	Bottle	1 Bottle	Epsilon-m	Nicotine: 3mg/mL, PG/VG Ratio: 70/30, E-Liquid Volumes: 60mL, 120mL
PM0003790	PD80	Cloud Science Epsilon-m 6mg	ENDS(VAPES)	Bottle	1 Bottle	Epsilon-m	Nicotine: 6mg/mL, PG/VG Ratio: 70/30, E-Liquid Volumes: 60mL, 120mL
PM0003790	PD81	Boiler Maker Chisel 6mg	ENDS(VAPES)	Bottle	1 Bottle	Chisel	Nicotine: 6mg/mL, PG/VG Ratio: 70/30, E-Liquid Volumes: 30mL, 100mL
PM0003790	PD82	Cloud Science Epsilon-m 12mg	ENDS(VAPES)	Bottle	1 Bottle	Epsilon-m	Nicotine: 12mg/mL, PG/VG Ratio: 70/30, E-Liquid Volumes: 60mL, 120mL
PM0003790	PD83	Cloud Science Gamma 0mg	ENDS(VAPES)	Bottle	1 Bottle	Gamma	Nicotine: 0mg/mL, PG/VG Ratio: 70/30, E-Liquid Volumes: 60mL, 120mL
PM0003790	PD84	Cloud Science Gamma 3mg	ENDS(VAPES)	Bottle	1 Bottle	Gamma	Nicotine: 3mg/mL, PG/VG Ratio: 70/30, E-Liquid Volumes: 60mL, 120mL
PM0003790	PD85	Cloud Science Gamma 6mg	ENDS(VAPES)	Bottle	1 Bottle	Gamma	Nicotine: 6mg/mL, PG/VG Ratio: 70/30, E-Liquid Volumes: 60mL, 120mL
PM0003790	PD86	Cloud Science Gamma 12mg	ENDS(VAPES)	Bottle	1 Bottle	Gamma	Nicotine: 12mg/mL, PG/VG Ratio: 70/30, E-Liquid Volumes: 60mL, 120mL
PM0003790	PD87	Cloud Science Gamma-m 0mg	ENDS(VAPES)	Bottle	1 Bottle	Gamma-m	Nicotine: 0mg/mL, PG/VG Ratio: 70/30, E-Liquid Volumes: 60mL, 120mL
PM0003790	PD88	Cloud Science Gamma-m 3mg	ENDS(VAPES)	Bottle	1 Bottle	Gamma-m	Nicotine: 3mg/mL, PG/VG Ratio: 70/30, E-Liquid Volumes: 60mL, 120mL
PM0003790	PD89	Cloud Science Gamma-m 6mg	ENDS(VAPES)	Bottle	1 Bottle	Gamma-m	Nicotine: 6mg/mL, PG/VG Ratio: 70/30, E-Liquid Volumes: 60mL, 120mL
PM0003790	PD90	Cloud Science Gamma-m 12mg	ENDS(VAPES)	Bottle	1 Bottle	Gamma-m	Nicotine: 12mg/mL, PG/VG Ratio: 70/30, E-Liquid Volumes: 60mL, 120mL
PM0003790	PD91	Cold Fusion Gall 1 0mg	ENDS(VAPES)	Bottle	1 Bottle	Gall 1	Nicotine: 0mg/mL, PG/VG Ratio: 70/30, E-Liquid Volumes: 60mL, 120mL
PM0003790	PD92	Boiler Maker Chisel 12mg	ENDS(VAPES)	Bottle	1 Bottle	Chisel	Nicotine: 12mg/mL, PG/VG Ratio: 70/30, E-Liquid Volumes: 30mL, 100mL
PM0003790	PD93	Cold Fusion Gall 3 6mg	ENDS(VAPES)	Bottle	1 Bottle	Gall 2	Nicotine: 3mg/mL, PG/VG Ratio: 70/30, E-Liquid Volumes: 60mL, 120mL
PM0003790	PD94	Cold Fusion Gall 4 12mg	ENDS(VAPES)	Bottle	1 Bottle	Gall 3	Nicotine: 6mg/mL, PG/VG Ratio: 70/30, E-Liquid Volumes: 60mL, 120mL
PM0003790	PD95	Cold Fusion Gall 5 18mg	ENDS(VAPES)	Bottle	1 Bottle	Gall 4	Nicotine: 12mg/mL, PG/VG Ratio: 70/30, E-Liquid Volumes: 60mL, 120mL
PM0003790	PD96	Cold Fusion Hiss Tank 1 0mg	ENDS(VAPES)	Bottle	1 Bottle	Hiss Tank 1	Nicotine: 0mg/mL, PG/VG Ratio: 70/30, E-Liquid Volumes: 60mL, 120mL
PM0003790	PD97	Cold Fusion Hiss Tank 2 3mg	ENDS(VAPES)	Bottle	1 Bottle	Hiss Tank 2	Nicotine: 3mg/mL, PG/VG Ratio: 70/30, E-Liquid Volumes: 60mL, 120mL
PM0003790	PD98	Cold Fusion Hiss Tank 3 6mg	ENDS(VAPES)	Bottle	1 Bottle	Hiss Tank 3	Nicotine: 6mg/mL, PG/VG Ratio: 70/30, E-Liquid Volumes: 60mL, 120mL
PM0003790	PD99	Cold Fusion Hiss Tank 4 12mg	ENDS(VAPES)	Bottle	1 Bottle	Hiss Tank 4	Nicotine: 12mg/mL, PG/VG Ratio: 70/30, E-Liquid Volumes: 60mL, 120mL
PM0003790	PD227	Cold Fusion Hiss Tank 5 18mg	ENDS(VAPES)	Bottle	1 Bottle	Hiss Tank 5	Nicotine: 18mg/mL, PG/VG Ratio: 70/30, E-Liquid Volume: 60mL
PM0003790	PD228	Teles Boo 0mg	ENDS(VAPES)	Bottle	1 Bottle	Shock & Awe 1	Nicotine: 0mg/mL, PG/VG Ratio: 70/30, E-Liquid Volumes: 60mL, 120mL
PM0003790	PD229	Teles Boo 3mg	ENDS(VAPES)	Bottle	1 Bottle	Shock & Awe 1	Nicotine: 3mg/mL, PG/VG Ratio: 70/30, E-Liquid Volumes: 60mL, 120mL
PM0003790	PD230	Teles Boo 6mg	ENDS(VAPES)	Bottle	1 Bottle	Shock & Awe 1	Nicotine: 6mg/mL, PG/VG Ratio: 70/30, E-Liquid Volumes: 60mL, 120mL
PM0003790	PD231	Teles Boo 12mg	ENDS(VAPES)	Bottle	1 Bottle	Shock & Awe 1	Nicotine: 12mg/mL, PG/VG Ratio: 70/30, E-Liquid Volumes: 60mL, 120mL

Multiple STNs, see Appendix A

Appendix B
Amendments Received for These Applications

Submission Date	Receipt Date	Applications being amended	Reviewed	Brief Description
September 1, 2021	September 1, 2021	PM0004979	No. Amendment not reviewed because it was received near the completion of the scientific review.	Other – outline for intended submission of further product testing
September 1, 2021	September 2, 2021	PM0004982	No. Amendment not reviewed because it was received near the completion of the scientific review.	Other – outline for intended submission of further product testing

6United States Court of Appeals

FIFTH CIRCUIT
OFFICE OF THE CLERK

LYLE W. CAYCE
CLERK

TEL. 504-310-7700
600 S. MAESTRI PLACE,
Suite 115
NEW ORLEANS, LA 70130

October 05, 2021

Ms. Wendy S. Vicente
U.S. Food and Drug Administration
Food and Drug Division, OGC
10903 New Hampshire Avenue
White Oak 31
Room 4562
Silver Spring, MD 20993-0002

No. 21-60766 Wages and White Lion v. FDA
Agency No. 21 USC 3871

Dear Ms. Vicente,

You are served with the following document(s) under **FED. R. APP. P.**
15:

Petition for Review.

Special Guidance for Filing the Administrative Record: Pursuant to 5th Cir. R. 25.2, Electronic Case Filing (ECF) is mandatory for all counsel. Agencies responsible for filing the administrative record with this court are requested to electronically file the record via CM/ECF using one or more of the following events as appropriate:

Electronic Administrative Record Filed;
Supplemental Electronic Administrative Record Filed;
Sealed Electronic Administrative Record Filed; or
Sealed Supplemental Electronic Administrative Record Filed.

Electronic records must meet the requirements listed below. Records that do not comply with these requirements will be rejected.

- Max file size 20 megabytes per upload.
- Where multiple uploads are needed, describe subsequent files as "Volume 2", "Volume 3", etc.
- Individual documents should remain intact within the same file/upload, when possible.
- Supplemental records must contain the supplemental documents only. No documents contained within the original record should be duplicated.

Electronic records are automatically paginated for the benefit of counsel and the court and provide an accurate means of citing to the record in briefs. A copy of the paginated electronic record is provided to all counsel at the time of filing via a Notice of Docket Activity (NDA). Upon receipt, counsel should save a copy of the paginated record to their local computer.

Agencies unable to provide the administrative record via docketing in CM/ECF may instead provide a copy of the record on a flash drive or CD which we will use to upload and paginate the record.

If the agency intends to file a certified list in lieu of the administrative record, it is *required* to be filed electronically. Paper filings will not be accepted. See **FED. R. APP. P.** 16 and 17 as to the composition and time for the filing of the record.

ATTENTION ATTORNEYS: Attorneys are required to be a member of the Fifth Circuit Bar and to register for Electronic Case Filing. The "Application and Oath for Admission" form can be printed or downloaded from the Fifth Circuit's website, www.ca5.uscourts.gov. Information on Electronic Case Filing is available at www.ca5.uscourts.gov/cmecf/.

We recommend that you visit the Fifth Circuit's website, www.ca5.uscourts.gov and review material that will assist you during the appeal process. We especially call to your attention the Practitioner's Guide and the 5th Circuit Appeal Flow Chart, located in the Forms, Fees, and Guides tab.

Counsel who desire to appear in this case must electronically file a "Form for Appearance of Counsel" within 14 days from this date. You must name each party you represent, see **FED. R. APP. P.** and **5TH CIR. R.** 12. The form is available from the Fifth Circuit's website, www.ca5.uscourts.gov. If you fail to electronically file the form, we will remove your name from our docket.

Special guidance regarding filing certain documents:

General Order No. 2021-1, dated January 15, 2021, requires parties to file in paper highly sensitive documents (HSD) that would ordinarily be filed under seal in CM/ECF. This includes documents likely to be of interest to the intelligence service of a foreign government and whose use or disclosure by a hostile foreign government would likely cause significant harm to the United States or its interests. Before uploading any matter as a sealed filing, ensure it has not been designated as HSD by a district court and does not qualify as HSD under General Order No. 2021-1.

A party seeking to designate a document as highly sensitive in the first instance or to change its designation as HSD must do so by motion. Parties are required to contact the Clerk's office for guidance before filing such motions.

Sealing Documents on Appeal: Our court has a strong presumption of public access to our court's records, and the court scrutinizes any request by a party to seal pleadings, record excerpts, or other documents on our court docket. Counsel moving to seal matters must explain in particularity the necessity for sealing in our

court. Counsel do not satisfy this burden by simply stating that the originating court sealed the matter, as the circumstances that justified sealing in the originating court may have changed or may not apply in an appellate proceeding. It is the obligation of counsel to justify a request to file under seal, just as it is their obligation to notify the court whenever sealing is no longer necessary. An unopposed motion to seal does not obviate a counsel's obligation to justify the motion to seal.

Sincerely,

LYLE W. CAYCE, Clerk

Mary Stewart

By: _____
Mary C. Stewart, Deputy Clerk
504-310-7694

Enclosure(s)

cc w/encl:
Mr. Anthony J. Hornbach
Mr. Mark Raza

Provided below is the court's official caption. Please review the parties listed and advise the court immediately of any discrepancies. If you are required to file an appearance form, a complete list of the parties should be listed on the form exactly as they are listed on the caption.

Case No. 21-60766

Wages and White Lion Investments, L.L.C., doing business as
Triton Distribution,

Petitioner

v.

Food & Drug Administration,

Respondent