

SHORT RECORD
NO. 22-2463
FILED 08/18/2022

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

_____)	
GRIPUM LLC,)	
)	
Petitioner)	
)	
vs.)	CASE NO. 22-_____
)	
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), Gripum LLC (Gripum) hereby petitions the Court for review of the U.S. Food and Drug Administration’s Refuse to Accept letter, dated July 19, 2022. The letter sets forth FDA’s refusal to accept Gripum’s bundled Premarket Tobacco Product Applications (assigned Submission Tracking Number PM0005352.PD1 – PM0005352.PD161) for certain of Gripum’s electronic nicotine delivery system products. Attached as *Exhibit A* is a copy of FDA’s Refuse to Accept letter to be reviewed. FDA’s Refuse to Accept letter is a final agency action and thus this

Court has jurisdiction to review the order under 21 U.S.C. §387l(a)(1)(B), and venue is proper because Gripum's principal place of business is in this circuit (*ibid.*). Gripum's Rule 26.1 Disclosure of Corporate Affiliations and Financial Interest is being filed under separate cover.

Gripum seeks review of FDA's Refuse to Accept letter on the grounds that it is arbitrary and capricious, an abuse of discretion, contrary to both the Federal Food, Drug, and Cosmetic Act, as amended by the Family Smoking Prevention and Tobacco Control Act of 2009, the Paperwork Reduction Act of 1995, and applicable regulations, and otherwise not in accordance with law. Gripum respectfully requests that the Court, on review, vacate or modify, in whole or in part, the foregoing Refuse to Accept letter for which Gripum has petitioned for review. Gripum also requests such other and further relief to which it may be justly entitled, including such relief as necessary to ensure that Gripum may continue to market the products subject to the challenged letter.

Dated: August 18, 2022

Respectfully submitted,

/s/ J. Gregory Troutman

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Attorney for Petitioner Gripum, LLC

CERTIFICATE OF SERVICE

Pursuant to FED. R. APP. P. 15(c) and 25(d), I hereby certify that on August 18, 2022, a true and correct copy of the foregoing **Petition for Review** was served on the following by electronic mail, in addition to filing the **Petition for Review** electronically with the Clerk.

Dr. Robert Califf, Commissioner
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Silver Spring, MD 20993-0002
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Todd L. Cecil, Acting Director, Office of Science
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/s/ J. Gregory Troutman
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Attorney for Petitioner Gripum, LLC

EXHIBIT A



July 19, 2022

REFUSE TO ACCEPT

GRIPUM LLC
Attention: Raul Cosmin Onu, Owner
7825 Gross Point Rd
Skokie, IL 60077

FDA Submission Tracking Number (STN): PM0005352.PD1-PM0005352.PD161, see Appendix A

Dear Raul Cosmin Onu:

We are refusing to accept your PMTAs¹ for the tobacco products identified in Appendix A. Note that attributes in Appendix A may display converted values.

Your applications do not meet the regulatory requirements to permit substantive review for the following reasons:

1. Your applications were not submitted using FDA Form 4057b – Premarket Tobacco Product Application Product Grouping Spreadsheet as required by 21 CFR 1105.10(a)(6) and 21 CFR 1114.7(c). Although your submissions may include the required content for a PMTA, you did not submit the information in the required format using the approved FDA forms. Without the required FDA forms, your applications are administratively incomplete.
2. Your applications do not include the following information required in 21 CFR 1114.7(c) and 21 CFR 1114.7(d):
 - a. All of your applications are missing the new tobacco products' unique identification information as required per 21 CFR 1105.10(a)(7) and 21 CFR 1114.7(c)(3) within FDA Form 4057b:
 - i. Product name, including brand and sub-brand
 - ii. Product category
 - iii. Product subcategory
 - iv. Package type
 - v. Package quantity
 - vi. Characterizing flavor
 - vii. E-liquid volume
 - viii. Nicotine concentration
 - ix. PG/VG ratio
 - x. Nicotine source

Although you included the above product properties in your applications as well as your version of information you cite as FDA Form 4057b you did not include an approved FDA

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

Form 4057b. Without the required information in the approved FDA forms, your applications are administratively incomplete.

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 a new PMTA for these products, you must fulfill all requirements set forth in section 910(b)(1). In order to do so, you may cross-reference a Tobacco Product Master File submission. Your new PMTAs should include all information necessary to support acceptance and filing so FDA may perform a substantive scientific review.

Refer to Appendix B for additional information to consider submitting in future submissions. The information provided in this letter may not represent a complete list of comments and potential deficiencies.

If you have any questions, please contact Deema Slim, Regulatory Health Project Manager, at (301) 796-1085 or Deema.Slim@fda.hhs.gov.

Sincerely,

Todd L. Cecil

-S

Digitally signed by Todd L. Cecil -S

Date: 2022.07.19 12:31:31 -04'00'

For Benjamin Apelberg, Ph.D.
Deputy Director
Office of Science
Center for Tobacco Products

Enclosures:

Appendix A – New Tobacco Products Subject of This Letter

Appendix B – Additional Comments That May Be Considered for Future Submissions

Appendix A^{2,3,4}
New Tobacco Products Subject of This Letter

Common Attributes of PMTA	
Submission date:	May 12,2022
Receipt date:	May 12, 2022
Applicant:	GRIPUM LLC
Product manufacturer:	GRIPUM LLC
Product category:	ENDS (VAPES)
Product subcategory:	Open E-Liquid
Attributes	New Tobacco Product
STN:	PM0005352.PD1
Product name:	Big 100 GRPL
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	100mL
Nicotine concentration:	3mg/mL
PG/VG ratio:	15/85
Additional property:	Nicotine Source: Non-Tobacco, PG: 11.95%, VG: 69.70%
STN:	PM0005352.PD2
Product name:	Big 100 GRPL
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	100 ml
Nicotine concentration:	6 Mg/ml
PG/VG ratio:	15/85
Additional property:	Nicotine Source: Non-Tobacco, PG: 11.95%, VG: 69.40%
STN:	PM0005352.PD3
Product name:	Big 100 MLN STRAPL
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	100 ml
Nicotine concentration:	3 Mg/ml
PG/VG ratio:	13/87
Additional property:	Nicotine Source: Non-Tobacco, PG: 10.75%, VG: 69.70%

² Properties to uniquely identify the new tobacco products were provided by the applicant as of the date of this letter, and not confirmed by FDA.

³ Brand/sub-brand or other commercial name used in commercial distribution.

⁴ The applicant provided PG and VG values as percentages of ingredient formula for each product (see Additional Properties), which were further converted by FDA (see PG/VG Ratio).

STN:	PM0005352.PD4
Product name:	Big 100 MLN STRAPL
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	100 ml
Nicotine concentration:	6 Mg/ml
PG/VG ratio:	13/87
Additional property:	Nicotine Source: Non-Tobacco, PG: 10.75%, VG: 69.40%
STN:	PM0005352.PD5
Product name:	Big 100 STRAPL
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	100 ml
Nicotine concentration:	3 Mg/ml
PG/VG ratio:	18/82
Additional property:	Nicotine Source: Non-Tobacco, PG: 15.35%, VG: 69.70%
STN:	PM0005352.PD6
Product name:	Big 100 STRAPL
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	100 ml
Nicotine concentration:	6 Mg/ml
PG/VG ratio:	18/82
Additional property:	Nicotine Source: Non-Tobacco, PG: 15.35%, VG: 69.40%
STN:	PM0005352.PD7
Product name:	Big 100 STRAPL ICE
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	100 ml
Nicotine concentration:	3 Mg/ml
PG/VG ratio:	18/82
Additional property:	Nicotine Source: Non-Tobacco, PG: 14.82%, VG: 69.70%

STN:	PM0005352.PD8
Product name:	Big 100 STRAPL ICE
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	100 ml
Nicotine concentration:	6 Mg/ml
PG/VG ratio:	18/82
Additional property:	Nicotine Source: Non-Tobacco, PG: 14.82%, VG: 69.40%
STN:	PM0005352.PD9
Product name:	Cassadaga CBB
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Dessert
E-liquid volume:	30 ml
Nicotine concentration:	25 Mg/ml
PG/VG ratio:	34/66
Additional property:	Nicotine Source: Non-Tobacco, PG: 25.00%, VG: 47.50%
STN:	PM0005352.PD10
Product name:	Cassadaga CBB
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Dessert
E-liquid volume:	60 ml
Nicotine concentration:	3 Mg/ml
PG/VG ratio:	7/93
Additional property:	Nicotine Source: Non-Tobacco, PG: 5.00%, VG: 69.70%
STN:	PM0005352.PD11
Product name:	Cassadaga CBB
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Dessert
E-liquid volume:	60 ml
Nicotine concentration:	6 Mg/ml
PG/VG ratio:	7/93
Additional property:	Nicotine Source: Non-Tobacco, PG: 5.00%, VG: 69.40%

STN:	PM0005352.PD12
Product name:	Cassadaga CBC
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Dessert
E-liquid volume:	30 ml
Nicotine concentration:	25 Mg/ml
PG/VG ratio:	34/66
Additional property:	Nicotine Source: Non-Tobacco, PG: 25.00%, VG: 47.50%
STN:	PM0005352.PD13
Product name:	Cassadaga CBC
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Dessert
E-liquid volume:	60 ml
Nicotine concentration:	3 Mg/ml
PG/VG ratio:	7/93
Additional property:	Nicotine Source: Non-Tobacco, PG: 5.00%, VG: 69.70%
STN:	PM0005352.PD14
Product name:	Cassadaga CBC
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Dessert
E-liquid volume:	60 ml
Nicotine concentration:	6 Mg/ml
PG/VG ratio:	7/93
Additional property:	Nicotine Source: Non-Tobacco, PG: 5.00%, VG: 69.40%
STN:	PM0005352.PD15
Product name:	Cassadaga CBG
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Dessert
E-liquid volume:	30 ml
Nicotine concentration:	25 Mg/ml
PG/VG ratio:	34/66
Additional property:	Nicotine Source: Non-Tobacco, PG: 25.00%, VG: 47.50%

STN:	PM0005352.PD16
Product name:	Cassadaga CBG
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Dessert
E-liquid volume:	60 ml
Nicotine concentration:	3 Mg/ml
PG/VG ratio:	7/93
Additional property:	Nicotine Source: Non-Tobacco, PG: 5.00%, VG: 69.70%
STN:	PM0005352.PD17
Product name:	Cassadaga CBG
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Dessert
E-liquid volume:	60 ml
Nicotine concentration:	6 Mg/ml
PG/VG ratio:	7/93
Additional property:	Nicotine Source: Non-Tobacco, PG: 5.00%, VG: 69.40%
STN:	PM0005352.PD18
Product name:	Cassadaga CBM
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Dessert
E-liquid volume:	30 ml
Nicotine concentration:	25 Mg/ml
PG/VG ratio:	34/66
Additional property:	Nicotine Source: Non-Tobacco, PG: 25.00%, VG: 47.50%
STN:	PM0005352.PD19
Product name:	Cassadaga CBM
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Dessert
E-liquid volume:	60 ml
Nicotine concentration:	3 Mg/ml
PG/VG ratio:	7/93
Additional property:	Nicotine Source: Non-Tobacco, PG: 5.00%, VG: 69.70%

STN:	PM0005352.PD20
Product name:	Cassadaga CBM
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Dessert
E-liquid volume:	60 ml
Nicotine concentration:	6 Mg/ml
PG/VG ratio:	7/93
Additional property:	Nicotine Source: Non-Tobacco, PG: 5.00%, VG: 69.40%
STN:	PM0005352.PD21
Product name:	Cassadaga CBN
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Dessert
E-liquid volume:	30 ml
Nicotine concentration:	25 Mg/ml
PG/VG ratio:	34/66
Additional property:	Nicotine Source: Non-Tobacco, PG: 25.00%, VG: 47.50%
STN:	PM0005352.PD22
Product name:	Cassadaga CBN
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Dessert
E-liquid volume:	60 ml
Nicotine concentration:	3 Mg/ml
PG/VG ratio:	7/93
Additional property:	Nicotine Source: Non-Tobacco, PG: 5.00%, VG: 69.70%
STN:	PM0005352.PD23
Product name:	Cassadaga CBN
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Dessert
E-liquid volume:	60 ml
Nicotine concentration:	6 Mg/ml
PG/VG ratio:	7/93
Additional property:	Nicotine Source: Non-Tobacco, PG: 5.00%, VG: 69.40%

STN:	PM0005352.PD24
Product name:	Cassadaga CBO
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Dessert
E-liquid volume:	30 ml
Nicotine concentration:	25 Mg/ml
PG/VG ratio:	34/66
Additional property:	Nicotine Source: Non-Tobacco, PG: 25.00%, VG: 47.50%
STN:	PM0005352.PD25
Product name:	Cassadaga CBO
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Dessert
E-liquid volume:	60 ml
Nicotine concentration:	3 Mg/ml
PG/VG ratio:	7/93
Additional property:	Nicotine Source: Non-Tobacco, PG: 5.00%, VG: 69.70%
STN:	PM0005352.PD26
Product name:	Cassadaga CBO
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Dessert
E-liquid volume:	60 ml
Nicotine concentration:	6 Mg/ml
PG/VG ratio:	7/93
Additional property:	Nicotine Source: Non-Tobacco, PG: 5.00%, VG: 69.40%
STN:	PM0005352.PD27
Product name:	Cassadaga MBC
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Tobacco
E-liquid volume:	30 ml
Nicotine concentration:	25 Mg/ml
PG/VG ratio:	34/66
Additional property:	Nicotine Source: Non-Tobacco, PG: 25.00%, VG: 47.50%

STN:	PM0005352.PD28
Product name:	Cassadaga MBC
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Tobacco
E-liquid volume:	60 ml
Nicotine concentration:	3 Mg/ml
PG/VG ratio:	7/93
Additional property:	Nicotine Source: Non-Tobacco, PG: 5.00%, VG: 69.70%
STN:	PM0005352.PD29
Product name:	Cassadaga MBC
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Tobacco
E-liquid volume:	60 ml
Nicotine concentration:	6 Mg/ml
PG/VG ratio:	7/93
Additional property:	Nicotine Source: Non-Tobacco, PG: 5.00%, VG: 69.40%
STN:	PM0005352.PD30
Product name:	Cassadaga Moma
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	30 ml
Nicotine concentration:	25 Mg/ml
PG/VG ratio:	34/66
Additional property:	Nicotine Source: Non-Tobacco, PG: 25.00%, VG: 47.50%
STN:	PM0005352.PD31
Product name:	Cassadaga Moma
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	60 ml
Nicotine concentration:	3 Mg/ml
PG/VG ratio:	7/93
Additional property:	Nicotine Source: Non-Tobacco, PG: 5.00%, VG: 69.70%

STN:	PM0005352.PD32
Product name:	Cassadaga Moma
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	60 ml
Nicotine concentration:	6 Mg/ml
PG/VG ratio:	7/93
Additional property:	Nicotine Source: Non-Tobacco, PG: 5.00%, VG: 69.40%
STN:	PM0005352.PD33
Product name:	Cassadaga Moma Chilled
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	30 ml
Nicotine concentration:	25 Mg/ml
PG/VG ratio:	34/66
Additional property:	Nicotine Source: Non-Tobacco, PG: 25.00%, VG: 47.50%
STN:	PM0005352.PD34
Product name:	Cassadaga Moma Chilled
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	60 ml
Nicotine concentration:	3 Mg/ml
PG/VG ratio:	7/93
Additional property:	Nicotine Source: Non-Tobacco, PG: 5.00%, VG: 69.70%
STN:	PM0005352.PD35
Product name:	Cassadaga Moma Chilled
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	60 ml
Nicotine concentration:	6 Mg/ml
PG/VG ratio:	7/93
Additional property:	Nicotine Source: Non-Tobacco, PG: 5.00%, VG: 69.40%

STN:	PM0005352.PD36
Product name:	Fruitx Berry
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	100 ml
Nicotine concentration:	3 Mg/ml
PG/VG ratio:	8/92
Additional property:	Nicotine Source: Non-Tobacco, PG: 6.23%, VG: 69.70%
STN:	PM0005352.PD37
Product name:	Fruitx Berry
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	100 ml
Nicotine concentration:	6 Mg/ml
PG/VG ratio:	8/92
Additional property:	Nicotine Source: Non-Tobacco, PG: 6.23%, VG: 69.40%
STN:	PM0005352.PD38
Product name:	Fruitx Melon
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	100 ml
Nicotine concentration:	3 Mg/ml
PG/VG ratio:	14/86
Additional property:	Nicotine Source: Non-Tobacco, PG: 11.00%, VG: 69.70%
STN:	PM0005352.PD39
Product name:	Fruitx Melon
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	100 ml
Nicotine concentration:	6 Mg/ml
PG/VG ratio:	14/86
Additional property:	Nicotine Source: Non-Tobacco, PG: 11.00%, VG: 69.40%

STN:	PM0005352.PD40
Product name:	Fruitx Strawberry
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	100 ml
Nicotine concentration:	3 Mg/ml
PG/VG ratio:	9/91
Additional property:	Nicotine Source: Non-Tobacco, PG: 7.00%, VG: 69.70%
STN:	PM0005352.PD41
Product name:	Fruitx Strawberry
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	100 ml
Nicotine concentration:	6 Mg/ml
PG/VG ratio:	9/91
Additional property:	Nicotine Source: Non-Tobacco, PG: 7.00%, VG: 69.40%
STN:	PM0005352.PD42
Product name:	G2 CRNY4
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Dessert
E-liquid volume:	100 ml
Nicotine concentration:	3 Mg/ml
PG/VG ratio:	11/89
Additional property:	Nicotine Source: Non-Tobacco, PG: 8.94%, VG: 69.70%
STN:	PM0005352.PD43
Product name:	G2 CRNY4
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Dessert
E-liquid volume:	100 ml
Nicotine concentration:	6 Mg/ml
PG/VG ratio:	11/89
Additional property:	Nicotine Source: Non-Tobacco, PG: 8.94%, VG: 69.40%

STN:	PM0005352.PD44
Product name:	G2 MR COOK
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Dessert
E-liquid volume:	100 ml
Nicotine concentration:	3 Mg/ml
PG/VG ratio:	7/93
Additional property:	Nicotine Source: Non-Tobacco, PG: 5.41%, VG: 69.70%
STN:	PM0005352.PD45
Product name:	G2 MR COOK
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Dessert
E-liquid volume:	100 ml
Nicotine concentration:	6 Mg/ml
PG/VG ratio:	7/93
Additional property:	Nicotine Source: Non-Tobacco, PG: 5.41%, VG: 69.40%
STN:	PM0005352.PD46
Product name:	G2 VZLA
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Dessert
E-liquid volume:	100 ml
Nicotine concentration:	3 Mg/ml
PG/VG ratio:	9/91
Additional property:	Nicotine Source: Non-Tobacco, PG: 7.24%, VG: 69.70%
STN:	PM0005352.PD47
Product name:	G2 VZLA
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Dessert
E-liquid volume:	100 ml
Nicotine concentration:	6 Mg/ml
PG/VG ratio:	9/91
Additional property:	Nicotine Source: Non-Tobacco, PG: 7.24%, VG: 69.40%

STN:	PM0005352.PD48
Product name:	OPMH BLST
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	30 ml
Nicotine concentration:	24 Mg/ml
PG/VG ratio:	39/61
Additional property:	Nicotine Source: Non-Tobacco, PG: 30.95%, VG: 47.60%
STN:	PM0005352.PD49
Product name:	OPMH BLST
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	30 ml
Nicotine concentration:	35 Mg/ml
PG/VG ratio:	40/60
Additional property:	Nicotine Source: Non-Tobacco, PG: 30.95%, VG: 46.50%
STN:	PM0005352.PD50
Product name:	OPMH BLST
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	60 ml
Nicotine concentration:	3 Mg/ml
PG/VG ratio:	7/93
Additional property:	Nicotine Source: Non-Tobacco, PG: 5.95%, VG: 74.70%
STN:	PM0005352.PD51
Product name:	OPMH BLST
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	60 ml
Nicotine concentration:	6 Mg/ml
PG/VG ratio:	7/93
Additional property:	Nicotine Source: Non-Tobacco, PG: 5.95%, VG: 74.40%

STN:	PM0005352.PD52
Product name:	OPMH CHRI
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	30 ml
Nicotine concentration:	24 Mg/ml
PG/VG ratio:	43/57
Additional property:	Nicotine Source: Non-Tobacco, PG: 36.00%, VG: 47.60%
STN:	PM0005352.PD53
Product name:	OPMH CHR
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	30 ml
Nicotine concentration:	35 Mg/ml
PG/VG ratio:	44/56
Additional property:	Nicotine Source: Non-Tobacco, PG: 36.00%, VG: 46.50%
STN:	PM0005352.PD54
Product name:	OPMH CHRI
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	60 ml
Nicotine concentration:	3 Mg/ml
PG/VG ratio:	19/81
Additional property:	Nicotine Source: Non-Tobacco, PG: 16.00%, VG: 69.70%
STN:	PM0005352.PD55
Product name:	OPMH CHRI
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	60 ml
Nicotine concentration:	6 Mg/ml
PG/VG ratio:	19/81
Additional property:	Nicotine Source: Non-Tobacco, PG: 16.00%, VG: 69.40%

STN:	PM0005352.PD56
Product name:	OPMH CODE
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	30 ml
Nicotine concentration:	24 Mg/ml
PG/VG ratio:	42/58
Additional property:	Nicotine Source: Non-Tobacco, PG: 33.95%, VG: 47.60%
STN:	PM0005352.PD57
Product name:	OPMH CODE
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	30 ml
Nicotine concentration:	35 Mg/ml
PG/VG ratio:	42/58
Additional property:	Nicotine Source: Non-Tobacco, PG: 33.95%, VG: 46.50%
STN:	PM0005352.PD58
Product name:	OPMH CODE
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	60 ml
Nicotine concentration:	3 Mg/ml
PG/VG ratio:	5/95
Additional property:	Nicotine Source: Non-Tobacco, PG: 3.95%, VG: 79.70%
STN:	PM0005352.PD59
Product name:	OPMH CODE
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	60 ml
Nicotine concentration:	6 Mg/ml
PG/VG ratio:	5/95
Additional property:	Nicotine Source: Non-Tobacco, PG: 3.95%, VG: 79.40%

STN:	PM0005352.PD60
Product name:	OPMH TVSC
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Dessert
E-liquid volume:	60 ml
Nicotine concentration:	3 Mg/ml
PG/VG ratio:	6/94
Additional property:	Nicotine Source: Non-Tobacco, PG: 4.95%, VG: 74.70%
STN:	PM0005352.PD61
Product name:	OPMH TVSC
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Dessert
E-liquid volume:	60 ml
Nicotine concentration:	6 Mg/ml
PG/VG ratio:	6/94
Additional property:	Nicotine Source: Non-Tobacco, PG: 4.95%, VG: 74.40%
STN:	PM0005352.PD62
Product name:	OPMH WTS GOLD
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Tobacco
E-liquid volume:	30 ml
Nicotine concentration:	24 Mg/ml
PG/VG ratio:	40/60
Additional property:	Nicotine Source: Non-Tobacco, PG: 32.25%, VG: 47.60%
STN:	PM0005352.PD63
Product name:	OPMH WTS GOLD
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Tobacco
E-liquid volume:	30 ml
Nicotine concentration:	35 Mg/ml
PG/VG ratio:	41/59
Additional property:	Nicotine Source: Non-Tobacco, PG: 32.25%, VG: 46.50%

STN:	PM0005352.PD64
Product name:	OPMH WTS GOLD
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Tobacco
E-liquid volume:	60 ml
Nicotine concentration:	12 Mg/ml
PG/VG ratio:	15/85
Additional property:	Nicotine Source: Non-Tobacco, PG: 12.25%, VG: 68.80%
STN:	PM0005352.PD65
Product name:	OPMH WTS GOLD
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Tobacco
E-liquid volume:	60 ml
Nicotine concentration:	3 Mg/ml
PG/VG ratio:	15/85
Additional property:	Nicotine Source: Non-Tobacco, PG: 12.25%, VG: 69.70%
STN:	PM0005352.PD66
Product name:	OPMH WTS GOLD
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Tobacco
E-liquid volume:	60 ml
Nicotine concentration:	6 Mg/ml
PG/VG ratio:	15/85
Additional property:	Nicotine Source: Non-Tobacco, PG: 12.25%, VG: 69.40%
STN:	PM0005352.PD67
Product name:	OPMH WTS OG
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Tobacco
E-liquid volume:	30 ml
Nicotine concentration:	24 Mg/ml
PG/VG ratio:	42/58
Additional property:	Nicotine Source: Non-Tobacco, PG: 34.95%, VG: 47.60%
STN:	PM0005352.PD68
Product name:	OPMH WTS OG
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Tobacco
E-liquid volume:	30 ml
Nicotine concentration:	35 Mg/ml
PG/VG ratio:	43/57
Additional property:	Nicotine Source: Non-Tobacco, PG: 34.95%, VG: 46.50%

STN:	PM0005352.PD69
Product name:	OPMH WTS OG
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Tobacco
E-liquid volume:	60 ml
Nicotine concentration:	12 Mg/ml
PG/VG ratio:	24/76
Additional property:	Nicotine Source: Non-Tobacco, PG: 19.95%, VG: 63.80%
STN:	PM0005352.PD70
Product name:	OPMH WTS OG
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Tobacco
E-liquid volume:	60 ml
Nicotine concentration:	3 Mg/ml
PG/VG ratio:	24/76
Additional property:	Nicotine Source: Non-Tobacco, PG: 19.95%, VG: 64.70%
STN:	PM0005352.PD71
Product name:	OPMH WTS OG
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Tobacco
E-liquid volume:	60 ml
Nicotine concentration:	6 Mg/ml
PG/VG ratio:	24/76
Additional property:	Nicotine Source: Non-Tobacco, PG: 19.95%, VG: 64.40%
STN:	PM0005352.PD72
Product name:	OPMH WTS PLAT
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Tobacco
E-liquid volume:	30 ml
Nicotine concentration:	24 Mg/ml
PG/VG ratio:	40/60
Additional property:	Nicotine Source: Non-Tobacco, PG: 31.25%, VG: 47.60%
STN:	PM0005352.PD73
Product name:	OPMH WTS PLAT
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Tobacco
E-liquid volume:	30 ml
Nicotine concentration:	35 Mg/ml
PG/VG ratio:	40/60
Additional property:	Nicotine Source: Non-Tobacco, PG: 31.25%, VG: 46.50%

STN:	PM0005352.PD74
Product name:	OPMH WTS PLAT
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Tobacco
E-liquid volume:	60 ml
Nicotine concentration:	12 Mg/ml
PG/VG ratio:	14/86
Additional property:	Nicotine Source: Non-Tobacco, PG: 11.25%, VG: 68.80%
STN:	PM0005352.PD75
Product name:	OPMH WTS PLAT
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Tobacco
E-liquid volume:	60 ml
Nicotine concentration:	3 Mg/ml
PG/VG ratio:	14/86
Additional property:	Nicotine Source: Non-Tobacco, PG: 11.25%, VG: 69.70%
STN:	PM0005352.PD76
Product name:	OPMH WTS PLAT
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Tobacco
E-liquid volume:	60 ml
Nicotine concentration:	6 Mg/ml
PG/VG ratio:	14/86
Additional property:	Nicotine Source: Non-Tobacco, PG: 11.25%, VG: 69.40%
STN:	PM0005352.PD77
Product name:	OPMH WTS ROSE
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Tobacco
E-liquid volume:	30 ml
Nicotine concentration:	24 Mg/ml
PG/VG ratio:	40/60
Additional property:	Nicotine Source: Non-Tobacco, PG: 31.25%, VG: 47.60%
STN:	PM0005352.PD78
Product name:	OPMH WTS ROSE
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Tobacco
E-liquid volume:	30 ml
Nicotine concentration:	35 Mg/ml
PG/VG ratio:	40/60
Additional property:	Nicotine Source: Non-Tobacco, PG: 31.25%, VG: 46.50%

STN:	PM0005352.PD79
Product name:	OPMH WTS ROSE
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Tobacco
E-liquid volume:	60 ml
Nicotine concentration:	12 Mg/ml
PG/VG ratio:	14/86
Additional property:	Nicotine Source: Non-Tobacco, PG: 11.25%, VG: 68.80%
STN:	PM0005352.PD80
Product name:	OPMH WTS ROSE
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Tobacco
E-liquid volume:	60 ml
Nicotine concentration:	3 Mg/ml
PG/VG ratio:	14/86
Additional property:	Nicotine Source: Non-Tobacco, PG: 11.25%, VG: 69.70%
STN:	PM0005352.PD81
Product name:	OPMH WTS ROSE
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Tobacco
E-liquid volume:	60 ml
Nicotine concentration:	6 Mg/ml
PG/VG ratio:	14/86
Additional property:	Nicotine Source: Non-Tobacco, PG: 11.25%, VG: 69.40%
STN:	PM0005352.PD82
Product name:	OPMH WTS WHITE
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Tobacco
E-liquid volume:	30 ml
Nicotine concentration:	24 Mg/ml
PG/VG ratio:	36/64
Additional property:	Nicotine Source: Non-Tobacco, PG: 27.00%, VG: 47.60%
STN:	PM0005352.PD83
Product name:	OPMH WTS WHITE
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Tobacco
E-liquid volume:	30 ml
Nicotine concentration:	35 Mg/ml
PG/VG ratio:	37/63
Additional property:	Nicotine Source: Non-Tobacco, PG: 27.00%, VG: 46.50%

STN:	PM0005352.PD84
Product name:	OPMH WTS WHITE
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Tobacco
E-liquid volume:	60 ml
Nicotine concentration:	12 Mg/ml
PG/VG ratio:	9/91
Additional property:	Nicotine Source: Non-Tobacco, PG: 7.00%, VG: 68.80%
STN:	PM0005352.PD85
Product name:	OPMH WTS WHITE
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Tobacco
E-liquid volume:	60 ml
Nicotine concentration:	3 Mg/ml
PG/VG ratio:	9/91
Additional property:	Nicotine Source: Non-Tobacco, PG: 7.00%, VG: 69.70%
STN:	PM0005352.PD86
Product name:	OPMH WTS WHITE
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Tobacco
E-liquid volume:	60 ml
Nicotine concentration:	6 Mg/ml
PG/VG ratio:	9/91
Additional property:	Nicotine Source: Non-Tobacco, PG: 7.00%, VG: 69.40%
STN:	PM0005352.PD87
Product name:	Primitive BBMP
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	30 ml
Nicotine concentration:	25 Mg/ml
PG/VG ratio:	36/64
Additional property:	Nicotine Source: Non-Tobacco, PG: 27.00%, VG: 47.60%

STN:	PM0005352.PD88
Product name:	Primitive BBMP
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	60 ml
Nicotine concentration:	3 Mg/ml
PG/VG ratio:	9/91
Additional property:	Nicotine Source: Non-Tobacco, PG: 7.00%, VG: 69.70%
STN:	PM0005352.PD89
Product name:	Primitive BBMP
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	60 ml
Nicotine concentration:	6 Mg/ml
PG/VG ratio:	9/91
Additional property:	Nicotine Source: Non-Tobacco, PG: 7.00%, VG: 69.40%
STN:	PM0005352.PD90
Product name:	Primitive Black
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	100 ml
Nicotine concentration:	3 Mg/ml
PG/VG ratio:	15/85
Additional property:	Nicotine Source: Non-Tobacco, PG: 12.00%, VG: 69.70%
STN:	PM0005352.PD91
Product name:	Primitive Black
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	100 ml
Nicotine concentration:	6 Mg/ml
PG/VG ratio:	15/85
Additional property:	Nicotine Source: Non-Tobacco, PG: 12.00%, VG: 69.40%

STN:	PM0005352.PD92
Product name:	Primitive Black
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	30 ml
Nicotine concentration:	25 Mg/ml
PG/VG ratio:	40/60
Additional property:	Nicotine Source: Non-Tobacco, PG: 32.00%, VG: 47.50%
STN:	PM0005352.PD93
Product name:	Primitive BRMP
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	30 ml
Nicotine concentration:	25 Mg/ml
PG/VG ratio:	39/61
Additional property:	Nicotine Source: Non-Tobacco, PG: 30.25%, VG: 47.50%
STN:	PM0005352.PD94
Product name:	Primitive BRMP
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	60 ml
Nicotine concentration:	3 Mg/ml
PG/VG ratio:	13/87
Additional property:	Nicotine Source: Non-Tobacco, PG: 10.25%, VG: 69.70%
STN:	PM0005352.PD95
Product name:	Primitive BRMP
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	60 ml
Nicotine concentration:	6 Mg/ml
PG/VG ratio:	13/87
Additional property:	Nicotine Source: Non-Tobacco, PG: 10.24%, VG: 69.40%

STN:	PM0005352.PD96
Product name:	Primitive BTMP
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	30 ml
Nicotine concentration:	25 Mg/ml
PG/VG ratio:	36/64
Additional property:	Nicotine Source: Non-Tobacco, PG: 27.00%, VG: 47.50%
STN:	PM0005352.PD97
Product name:	Primitive BTMP
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	60 ml
Nicotine concentration:	3 Mg/ml
PG/VG ratio:	9/91
Additional property:	Nicotine Source: Non-Tobacco, PG: 7.00%, VG: 69.70%
STN:	PM0005352.PD98
Product name:	Primitive BTMP
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	60 ml
Nicotine concentration:	6 Mg/ml
PG/VG ratio:	9/91
Additional property:	Nicotine Source: Non-Tobacco, PG: 7.00%, VG: 69.40%
STN:	PM0005352.PD99
Product name:	Primitive ESMP
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	30 ml
Nicotine concentration:	25 Mg/ml
PG/VG ratio:	37/63
Additional property:	Nicotine Source: Non-Tobacco, PG: 27.98%, VG: 47.50%

STN:	PM0005352.PD100
Product name:	Primitive ESMP
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	60 ml
Nicotine concentration:	3 Mg/ml
PG/VG ratio:	10/90
Additional property:	Nicotine Source: Non-Tobacco, PG: 7.98%, VG: 69.70%
STN:	PM0005352.PD101
Product name:	Primitive ESMP
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	60 ml
Nicotine concentration:	6 Mg/ml
PG/VG ratio:	10/90
Additional property:	Nicotine Source: Non-Tobacco, PG: 7.98%, VG: 69.40%
STN:	PM0005352.PD102
Product name:	Primitive FLKD
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	30 ml
Nicotine concentration:	25 Mg/ml
PG/VG ratio:	39/61
Additional property:	Nicotine Source: Non-Tobacco, PG: 30.00%, VG: 47.50%
STN:	PM0005352.PD103
Product name:	Primitive FLKD
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	60 ml
Nicotine concentration:	3 Mg/ml
PG/VG ratio:	13/87
Additional property:	Nicotine Source: Non-Tobacco, PG: 10.00%, VG: 69.70%

STN:	PM0005352.PD104
Product name:	Primitive FLKD
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	60 ml
Nicotine concentration:	6 Mg/ml
PG/VG ratio:	13/87
Additional property:	Nicotine Source: Non-Tobacco, PG: 10.00%, VG: 69.40%
STN:	PM0005352.PD105
Product name:	Primitive Grizzly
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	100 ml
Nicotine concentration:	3 Mg/ml
PG/VG ratio:	13/87
Additional property:	Nicotine Source: Non-Tobacco, PG: 10.00%, VG: 69.70%
STN:	PM0005352.PD106
Product name:	Primitive Grizzly
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	100 ml
Nicotine concentration:	6 Mg/ml
PG/VG ratio:	13/87
Additional property:	Nicotine Source: Non-Tobacco, PG: 10.00%, VG: 69.40%
STN:	PM0005352.PD107
Product name:	Primitive Grizzly
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	30 ml
Nicotine concentration:	25 Mg/ml
PG/VG ratio:	39/61
Additional property:	Nicotine Source: Non-Tobacco, PG: 30.00%, VG: 47.50%

STN:	PM0005352.PD108
Product name:	Primitive Kodiak
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	100 ml
Nicotine concentration:	3 Mg/ml
PG/VG ratio:	16/84
Additional property:	Nicotine Source: Non-Tobacco, PG: 13.00%, VG: 69.70%
STN:	PM0005352.PD109
Product name:	Primitive Kodiak
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	100 ml
Nicotine concentration:	6 Mg/ml
PG/VG ratio:	16/84
Additional property:	Nicotine Source: Non-Tobacco, PG: 13.00%, VG: 69.40%
STN:	PM0005352.PD110
Product name:	Primitive Kodiak
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	30 ml
Nicotine concentration:	25 Mg/ml
PG/VG ratio:	41/59
Additional property:	Nicotine Source: Non-Tobacco, PG: 33.00%, VG: 47.50%
STN:	PM0005352.PD111
Product name:	Primitive MPNDA
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	30 ml
Nicotine concentration:	25 Mg/ml
PG/VG ratio:	40/60
Additional property:	Nicotine Source: Non-Tobacco, PG: 32.00%, VG: 47.50%

STN:	PM0005352.PD112
Product name:	Primitive MPNDA
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	60 ml
Nicotine concentration:	3 Mg/ml
PG/VG ratio:	15/85
Additional property:	Nicotine Source: Non-Tobacco, PG: 12.00%, VG: 69.70%
STN:	PM0005352.PD113
Product name:	Primitive MPNDA
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	60 ml
Nicotine concentration:	6 Mg/ml
PG/VG ratio:	15/85
Additional property:	Nicotine Source: Non-Tobacco, PG: 12.00%, VG: 69.40%
STN:	PM0005352.PD114
Product name:	Primitive PCMP
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	30 ml
Nicotine concentration:	25 Mg/ml
PG/VG ratio:	36/64
Additional property:	Nicotine Source: Non-Tobacco, PG: 27.00%, VG: 47.50%
STN:	PM0005352.PD115
Product name:	Primitive PCMP
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	60 ml
Nicotine concentration:	3 Mg/ml
PG/VG ratio:	9/91
Additional property:	Nicotine Source: Non-Tobacco, PG: 7.00%, VG: 69.70%

STN:	PM0005352.PD116
Product name:	Primitive PCMP
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	60 ml
Nicotine concentration:	6 Mg/ml
PG/VG ratio:	9/91
Additional property:	Nicotine Source: Non-Tobacco, PG: 7.00%, VG: 69.40%
STN:	PM0005352.PD117
Product name:	Primitive PNMP
Package type:	Bottle
Package quantity:	Flavored
Characterizing flavor (CF):	1 Bottles
Flavored, as identified:	Fruit
E-liquid volume:	30 ml
Nicotine concentration:	25 Mg/ml
PG/VG ratio:	36/64
Additional property:	Nicotine Source: Non-Tobacco, PG: 27.00%, VG: 47.50%
STN:	PM0005352.PD118
Product name:	Primitive PNMP
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	60 ml
Nicotine concentration:	3 Mg/ml
PG/VG ratio:	9/91
Additional property:	Nicotine Source: Non-Tobacco, PG: 7.00%, VG: 69.70%
STN:	PM0005352.PD119
Product name:	Primitive PNMP
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	60 ml
Nicotine concentration:	6 Mg/ml
PG/VG ratio:	9/91
Additional property:	Nicotine Source: Non-Tobacco, PG: 7.00%, VG: 69.40%

STN:	PM0005352.PD120
Product name:	Primitive Polar
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	100 ml
Nicotine concentration:	3 Mg/ml
PG/VG ratio:	14/86
Additional property:	Nicotine Source: Non-Tobacco, PG: 10.95%, VG: 69.70%
STN:	PM0005352.PD121
Product name:	Primitive Polar
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Fruit
Flavored, as identified:	Flavored
E-liquid volume:	100 ml
Nicotine concentration:	6 Mg/ml
PG/VG ratio:	14/86
Additional property:	Nicotine Source: Non-Tobacco, PG: 10.95%, VG: 69.40%
STN:	PM0005352.PD122
Product name:	Primitive Polar
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	30 ml
Nicotine concentration:	25 Mg/ml
PG/VG ratio:	39/61
Additional property:	Nicotine Source: Non-Tobacco, PG: 30.95%, VG: 47.50%
STN:	PM0005352.PD123
Product name:	Primitive RZMP
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	30 ml
Nicotine concentration:	25 Mg/ml
PG/VG ratio:	39/61
Additional property:	Nicotine Source: Non-Tobacco, PG: 30.00%, VG: 47.50%

STN:	PM0005352.PD124
Product name:	Primitive RZMP
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	60 ml
Nicotine concentration:	3 Mg/ml
PG/VG ratio:	13/87
Additional property:	Nicotine Source: Non-Tobacco, PG: 10.00%, VG: 69.70%
STN:	PM0005352.PD125
Product name:	Primitive RZMP
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	60 ml
Nicotine concentration:	6 Mg/ml
PG/VG ratio:	13/87
Additional property:	Nicotine Source: Non-Tobacco, PG: 10.00%, VG: 69.40%
STN:	PM0005352.PD126
Product name:	Primitive SKMP
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	30 ml
Nicotine concentration:	25 Mg/ml
PG/VG ratio:	43/57
Additional property:	Nicotine Source: Non-Tobacco, PG: 36.00%, VG: 47.50%
STN:	PM0005352.PD127
Product name:	Primitive SKMP
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	60 ml
Nicotine concentration:	3 Mg/ml
PG/VG ratio:	8/92
Additional property:	Nicotine Source: Non-Tobacco, PG: 6.00%, VG: 69.70%

STN:	PM0005352.PD128
Product name:	Primitive SKMP
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	60 ml
Nicotine concentration:	6 Mg/ml
PG/VG ratio:	8/92
Additional property:	Nicotine Source: Non-Tobacco, PG: 6.00%, VG: 69.40%
STN:	PM0005352.PD129
Product name:	Primitive VSTG
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	30 ml
Nicotine concentration:	25 Mg/ml
PG/VG ratio:	39/61
Additional property:	Nicotine Source: Non-Tobacco, PG: 31.00%, VG: 47.50%
STN:	PM0005352.PD130
Product name:	Primitive VSTG
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	60 ml
Nicotine concentration:	3 Mg/ml
PG/VG ratio:	14/86
Additional property:	Nicotine Source: Non-Tobacco, PG: 11.00%, VG: 69.70%
STN:	PM0005352.PD131
Product name:	Primitive VSTG
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	60 ml
Nicotine concentration:	6 Mg/ml
PG/VG ratio:	14/86
Additional property:	Nicotine Source: Non-Tobacco, PG: 11.00%, VG: 69.40%

STN:	PM0005352.PD132
Product name:	SGV ICE WTR
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	100 ml
Nicotine concentration:	3 Mg/ml
PG/VG ratio:	14/86
Additional property:	Nicotine Source: Non-Tobacco, PG: 10.97%, VG: 69.70%
STN:	PM0005352.PD133
Product name:	SGV ICE WTR
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	100 ml
Nicotine concentration:	6 Mg/ml
PG/VG ratio:	14/86
Additional property:	Nicotine Source: Non-Tobacco, PG: 10.97%, VG: 69.40%
STN:	PM0005352.PD134
Product name:	Transistor BB
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	60 ml
Nicotine concentration:	3 Mg/ml
PG/VG ratio:	13/87
Additional property:	Nicotine Source: Non-Tobacco, PG: 10.00%, VG: 69.70%
STN:	PM0005352.PD135
Product name:	Transistor BB
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	60 ml
Nicotine concentration:	6 Mg/ml
PG/VG ratio:	13/87
Additional property:	Nicotine Source: Non-Tobacco, PG: 10.00%, VG: 69.40%

STN:	PM0005352.PD136
Product name:	Transistor BBCD
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	60 ml
Nicotine concentration:	3 Mg/ml
PG/VG ratio:	0/100
Additional property:	Nicotine Source: Non-Tobacco, PG: 0.00%, VG: 69.70%
STN:	PM0005352.PD137
Product name:	Transistor BBCD
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	60 ml
Nicotine concentration:	6 Mg/ml
PG/VG ratio:	0/100
Additional property:	Nicotine Source: Non-Tobacco, PG: 0.00%, VG: 69.40%
STN:	PM0005352.PD138
Product name:	Transistor BD
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Dessert
E-liquid volume:	60 ml
Nicotine concentration:	3 Mg/ml
PG/VG ratio:	18/82
Additional property:	Nicotine Source: Non-Tobacco, PG: 15.50%, VG: 69.70%
STN:	PM0005352.PD139
Product name:	Transistor BD
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Dessert
E-liquid volume:	60 ml
Nicotine concentration:	6 Mg/ml
PG/VG ratio:	18/82
Additional property:	Nicotine Source: Non-Tobacco, PG: 15.50%, VG: 69.40%

STN:	PM0005352.PD140
Product name:	Transistor CMGO
Package type:	Bottle
Package quantity:	Flavored
Characterizing flavor (CF):	1 Bottles
Flavored, as identified:	Fruit
E-liquid volume:	60 ml
Nicotine concentration:	3 Mg/ml
PG/VG ratio:	12/88
Additional property:	Nicotine Source: Non-Tobacco, PG: 10.00%, VG: 74.70%
STN:	PM0005352.PD141
Product name:	Transistor CMGO
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	60 ml
Nicotine concentration:	6 Mg/ml
PG/VG ratio:	12/88
Additional property:	Nicotine Source: Non-Tobacco, PG: 10.00%, VG: 74.40%
STN:	PM0005352.PD142
Product name:	Transistor GMLK
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	60 ml
Nicotine concentration:	3 Mg/ml
PG/VG ratio:	14/86
Additional property:	Nicotine Source: Non-Tobacco, PG: 11.82%, VG: 69.70%
STN:	PM0005352.PD143
Product name:	Transistor GMLK
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	60 ml
Nicotine concentration:	6 Mg/ml
PG/VG ratio:	15/85
Additional property:	Nicotine Source: Non-Tobacco, PG: 11.82%, VG: 69.40%

STN:	PM0005352.PD144
Product name:	Transistor LMNS
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	60 ml
Nicotine concentration:	3 Mg/ml
PG/VG ratio:	23/77
Additional property:	Nicotine Source: Non-Tobacco, PG: 21.25%, VG: 69.70%
STN:	PM0005352.PD145
Product name:	Transistor LMNS
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	60 ml
Nicotine concentration:	6 Mg/ml
PG/VG ratio:	23/77
Additional property:	Nicotine Source: Non-Tobacco, PG: 21.25%, VG: 69.40%
STN:	PM0005352.PD146
Product name:	Transistor LnB
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	60 ml
Nicotine concentration:	3 Mg/ml
PG/VG ratio:	20/80
Additional property:	Nicotine Source: Non-Tobacco, PG: 17.50%, VG: 69.70%
STN:	PM0005352.PD147
Product name:	Transistor LnB
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	60 ml
Nicotine concentration:	6 Mg/ml
PG/VG ratio:	20/80
Additional property:	Nicotine Source: Non-Tobacco, PG: 17.50%, VG: 69.40%

STN:	PM0005352.PD148
Product name:	Transistor NAZO
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	60 ml
Nicotine concentration:	3 Mg/ml
PG/VG ratio:	28/72
Additional property:	Nicotine Source: Non-Tobacco, PG: 26.50%, VG: 69.70%
STN:	PM0005352.PD149
Product name:	Transistor NAZO
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	60 ml
Nicotine concentration:	6 Mg/ml
PG/VG ratio:	28/72
Additional property:	Nicotine Source: Non-Tobacco, PG: 26.50%, VG: 69.40%
STN:	PM0005352.PD150
Product name:	Transistor NTO
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	60 ml
Nicotine concentration:	3 Mg/ml
PG/VG ratio:	0/100
Additional property:	Nicotine Source: Non-Tobacco, PG: 0.00%, VG: 69.70%
STN:	PM0005352.PD151
Product name:	Transistor NTO
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	60 ml
Nicotine concentration:	6 Mg/ml
PG/VG ratio:	0/100
Additional property:	Nicotine Source: Non-Tobacco, PG: 0.00%, VG: 69.40%

STN:	PM0005352.PD152
Product name:	Transistor NTO CHL
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	60 ml
Nicotine concentration:	3 Mg/ml
PG/VG ratio:	0/100
Additional property:	Nicotine Source: Non-Tobacco, PG: 0.00%, VG: 64.70%
STN:	PM0005352.PD153
Product name:	Transistor NTO CHL
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	60 ml
Nicotine concentration:	6 Mg/ml
PG/VG ratio:	0/100
Additional property:	Nicotine Source: Non-Tobacco, PG: 0.00%, VG: 64.40%
STN:	PM0005352.PD154
Product name:	Transistor PANG
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	60 ml
Nicotine concentration:	3 Mg/ml
PG/VG ratio:	8/92
Additional property:	Nicotine Source: Non-Tobacco, PG: 6.50%, VG: 74.70%
STN:	PM0005352.PD155
Product name:	Transistor PANG
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	60 ml
Nicotine concentration:	6 Mg/ml
PG/VG ratio:	8/92
Additional property:	Nicotine Source: Non-Tobacco, PG: 6.50%, VG: 74.40%

STN:	PM0005352.PD156
Product name:	Transistor PHX
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	60 ml
Nicotine concentration:	3 Mg/ml
PG/VG ratio:	18/82
Additional property:	Nicotine Source: Non-Tobacco, PG: 16.50%, VG: 74.70%
STN:	PM0005352.PD157
Product name:	Transistor PHX
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	60 ml
Nicotine concentration:	6 Mg/ml
PG/VG ratio:	18/82
Additional property:	Nicotine Source: Non-Tobacco, PG: 16.50%, VG: 74.40%
STN:	PM0005352.PD158
Product name:	Transistor TGO CHL
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	60 ml
Nicotine concentration:	3 Mg/ml
PG/VG ratio:	21/79
Additional property:	Nicotine Source: Non-Tobacco, PG: 18.05%, VG: 69.70%
STN:	PM0005352.PD159
Product name:	Transistor TGO CHL
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	60 ml
Nicotine concentration:	6 Mg/ml
PG/VG ratio:	21/79
Additional property:	Nicotine Source: Non-Tobacco, PG: 18.05%, VG: 69.40%

STN:	PM0005352.PD160
Product name:	Transistor TGO MLN
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	60 ml
Nicotine concentration:	3 Mg/ml
PG/VG ratio:	21/79
Additional property:	Nicotine Source: Non-Tobacco, PG: 18.25%, VG: 69.70%
STN:	PM0005352.PD161
Product name:	Transistor TGO MLN
Package type:	Bottle
Package quantity:	1 Bottles
Characterizing flavor (CF):	Flavored
Flavored, as identified:	Fruit
E-liquid volume:	60 ml
Nicotine concentration:	6 Mg/ml
PG/VG ratio:	21/79
Additional property:	Nicotine Source: Non-Tobacco, PG: 18.25%, VG: 69.40%

Appendix B

Additional Comments That May Be Considered for Future Submissions

The following additional comments are intended to clarify information that you are encouraged to consider in future submissions:

1. In a PMTA submission that includes multiple new tobacco products, it is important to clearly identify which content pertains to each distinct product and show that the PMTA content requirements of Section 910(b)(1) of the FD&C Act are satisfied for each tobacco product. For example, for ENDS, FDA considers each differing flavor variant and/or nicotine strength to be a unique new tobacco product.
2. To facilitate review, applications must comply with the PMTA format requirements and be submitted using FDA forms. Be sure to provide future PMTAs using the following required forms, as appropriate: FDA 4057- Premarket Tobacco Product Application Submission, FDA 4057a- Premarket Tobacco Product Amendment and General Correspondence Submission, and FDA 4057b- Premarket Tobacco Product Application Product Grouping Spreadsheet.
 - a. FDA 4057b- Premarket Tobacco Product Application Product Grouping Spreadsheet should not be modified in any way. All fields should be populated accordingly on the "Product" tab after entering the applicant's name, product category, product subcategory, and application type on the "Introduction" tab. Refer to the PMTA Final Rule⁵ for more information about what product-specific attributes to include for your tobacco products.
3. If submitting a non-electronic PMTA, indicate that a waiver has been granted and provide a copy of the FDA granted waiver from the requirement for electronic format and content.
4. Ensure that the submitted PMTA contains the signature of a responsible official, providing an electronic signature from Adobe Acrobat or eSubmitter form, or scanning a wet signature.
5. Ensure that all certification statements are identical to the language in 21 CFR § 1114 and includes a signature by a responsible official, per section VII- Certification Statements of form FDA 4057- Premarket Tobacco Product Application Submission.
6. When providing a generic label, clearly indicate that the label is intended to be a representative label across a given product line and identify specific tobacco products the label is intended to represent and articulate which elements of the label will change based on each new product (e.g., name and PG/VG).
7. With respect to the PMTA subject of review, provide a list of any prior meetings with FDA and the scope of such meetings.
8. When submitting a PMTA that cross-references a **Tobacco Product Master File (TPMF)**, you must include written authorization from the TPMF owner that grants you authorization to

⁵ <https://www.federalregister.gov/documents/2021/10/05/2021-21011/premarket-tobacco-product-applications-and-recordkeeping-requirements>

reference the TPMF, specify the TPMF submission tracking number, and clearly identify the content that you are referencing in the TPMF. Please read the Guidance for Industry on Tobacco Product Master Files for additional information on TPMFs and how to request authorization to reference one in your PMTA.⁶

9. An environmental assessment (EA) must be submitted as part of a PMTA **for each new tobacco product**. According to 21 CFR 25.40(a), an EA should include all of the following:
 - a. Discussion of the need for the proposed action (i.e., FDA issuance of marketing granted order for your tobacco product)
 - b. Discussion of alternatives as required by section 102(2)(E) of the National Environmental Protection Act (NEPA)
 - c. Environmental impacts of the proposed action and alternatives
 - d. Listing of the agencies and persons consulted
 - e. Relevant environmental issues relating to product use and disposal from use.

Additionally, CTP requests discussion of relevant environmental issues relating to product manufacturing.

Per 21 CFR 25.40(a), an EA shall focus on relevant environmental issues for each tobacco product and is to be a concise, objective, and well-balanced document that allows the public to understand the agency's decision.

You may refer to the following resources on the CTP website for more information with respect to EAs for tobacco products:

- a. *Environmental Assessment & Claims of Categorical Exclusion*,⁷ presented during the 2018 Tobacco Product Application Review – A Public Meeting⁸
- b. *Lessons Learned from PMTA Reviews*,⁹ presented during the 2019 Deemed Tobacco Product Applications – A Public Meeting (information on EAs begins on slide 33)¹⁰
- c. FDA's Premarket Tobacco Product Marketing Orders website¹¹ for examples of EAs that comply with 21 CFR Part 25
- d. Guidance for Industry: National Environmental Policy Act; Environmental Assessments for Tobacco Products; Categorical Exclusions – Small Entity Compliance Guide.¹²

⁶ Guidance for Industry: Tobacco Product Master Files. May 2016. <https://www.fda.gov/media/97632/download>.

⁷ <https://www.fda.gov/media/117503/download>

⁸ <https://www.fda.gov/tobacco-products/ctp-newsroom/tobacco-product-application-review-public-meeting>

⁹ <https://www.fda.gov/media/133444/download>

¹⁰ <https://www.fda.gov/tobacco-products/ctp-newsroom/deemed-tobacco-product-applications-public-meeting-10282019-10292019>

¹¹ <https://www.fda.gov/tobacco-products/premarket-tobacco-product-applications/premarket-tobacco-product-marketing-orders>

¹² <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/national-environmental-policy-act-environmental-assessments-tobacco-products-categorical-exclusions>

UNITED STATES COURT OF APPEALS FOR THE SEVENTH CIRCUIT

Everett McKinley Dirksen
United States Courthouse
Room 2722 - 219 S. Dearborn Street
Chicago, Illinois 60604



Office of the Clerk
Phone: (312) 435-5850
www.ca7.uscourts.gov

AGENCY PETITION FOR REVIEW
CASE OPENING COVER LETTER

August 18, 2022

No. 22-2463	GRIPUM LLC, Petitioner v. FOOD AND DRUG ADMINISTRATION, Respondent
Originating Case Information:	
Agency Case Nos: PM0005352.PD1-PM0005352.PD161 Food & Drug Administration	

A petition for review of an order of the **Food & Drug Administration** has been filed this day in this court in the above entitled cause, and a copy of said petition is herewith served upon you.

UNITED STATES COURT OF APPEALS FOR THE SEVENTH CIRCUIT

Everett McKinley Dirksen
 United States Courthouse
 Room 2722 - 219 S. Dearborn Street
 Chicago, Illinois 60604



Office of the Clerk
 Phone: (312) 435-5850
www.ca7.uscourts.gov

NOTICE OF CASE OPENING

August 18, 2022

No. 22-2463	GRIPUM LLC, Petitioner v. FOOD AND DRUG ADMINISTRATION, Respondent
Originating Case Information:	
Agency Case Nos. PM0005352.PD1- PM0005352.PD161 Food & Drug Administration Case filed: 08/18/2022 Case type: ag/rvw Fee status: Due	

The above-captioned appeal has been docketed in the United States Court of Appeals for the Seventh Circuit.

Deadlines:

<u>Appeal No.</u>	<u>Filer</u>	<u>Document</u>	<u>Due Date</u>
22-2463	GRIPUM LLC	Fee Due	09/01/2022
22-2463	Food and Drug Administration	Agency record due	09/27/2022

THIS NOTICE SHALL NOT ACT AS A SUBSTITUTE FOR MOTIONS FOR NON-INVOLVEMENT / SUBSTITUTION OF COUNSEL. COUNSEL ARE STILL REQUIRED TO FILE THE APPROPRIATE MOTIONS.

Important Scheduling Notice!

Hearing notices are mailed shortly before the date of oral argument. Please note that counsel's unavailability for oral argument must be submitted by letter, filed electronically with the Clerk's Office, no later than the filing of the appellant's brief in a criminal case and the filing of an appellee's brief in a civil case. See Cir. R. 34(b)(3). The court's calendar is located at <http://www.ca7.uscourts.gov/cal/argcalendar.pdf>. Once scheduled, oral argument is rescheduled only in extraordinary circumstances. See Cir. R. 34(b)(4), (e).

UNITED STATES COURT OF APPEALS FOR THE SEVENTH CIRCUIT

Everett McKinley Dirksen
United States Courthouse
Room 2722 - 219 S. Dearborn Street
Chicago, Illinois 60604



Office of the Clerk
Phone: (312) 435-5850
www.ca7.uscourts.gov

AGENCY CIRCUIT RULE 3(b) FEE NOTICE

August 18, 2022

No. 22-2463	GRIPUM LLC, Petitioner v. FOOD AND DRUG ADMINISTRATION, Respondent
Originating Case Information:	
Agency Case Nos: PM0005352.PD1- PM0005352.PD161 Food & Drug Administration	

Circuit Rule 3(b) empowers the clerk to dismiss a petition for review if the docket fee is not paid within fourteen (14) days of the docketing of a petition for review. This petition for review was docketed and the fee has not been paid as of **August 18, 2022**. Depending on your situation, you should:

1. Pay the required \$500.00 docketing fee to the Clerk of the Court of Appeals. File a motion to proceed on appeal in forma pauperis with the Court of Appeals. An original and three (3) copies of that motion is required. This motion must be supported by an affidavit in the form of a sworn statement listing the assets and income of the petitioner(s). See **Form 4** of the *Appendix of Forms to the Federal Rules of Appellate Procedure*.
- 2.

If one of the above stated actions is not taken, the petition for review will be dismissed.

NOTE:

On March 2, 2015, the Seventh Circuit began accepting electronic fee payments for originating case filing fees (petitions for review and original petitions) via the CM/ECF Filing menu & final processing by PACER. Details are available at www.ca7.uscourts.gov.