PUBLIC

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: **Lina M. Khan, Chair**
Noah Joshua Phillips
Rebecca Kelly Slaughter
Christine S. Wilson
Alvaro Bedoya

In the Matter of **Altria Group, Inc.** **a corporation;** **and** **JUUL Labs, Inc.** **a corporation.**	**DOCKET NO. 9393**

RESPONDENTS' MOTION FOR OFFICIAL NOTICE OF MYBLU MARKETING DENIAL LETTER

Respondents Altria Group, Inc. ("Altria") and Juul Labs, Inc. ("JLI") respectfully request that the Commission take official notice of FDA's letter to Fontem US, LLC explaining the reasons FDA denied the Pre-Market Tobacco Application ("PMTA") for certain myBlu products ("myBlu Marketing Denial Letter"). The letter is dated April 8, 2022, but was not disclosed until May 21, 2022, in response to a Freedom of Information Act (FOIA) request by Respondent JLI. Copeland Decl. ¶ 3. By virtue of this FOIA disclosure, the myBlu Marketing Denial Letter is publicly available, and neither its accuracy nor existence can be reasonably disputed. Order at 2, No. 9393 (May 13, 2022) (holding that "[t]he fact of FDA Decision, as reported in FDA documents, is not subject to reasonable dispute"). Respondents previously requested that the Commission take official notice of FDA's press release announcing that it was denying the myBlu PMTAs. Respondents' Motion for Official Notice of Recent FDA Decisions ("Respondents' Motion") at 1, 2, 4, 6-7. But this public announcement was not accompanied by

the letter explaining the reasons for the denial. This motion thus seeks to complete the record in regard to the myBlu denials.[1]

The letter is material to the issue of the "PMTA approval prospects for Altria's products," to the extent the Commission intends to consider FDA's post-transaction and post-trial marketing orders for these purposes. *See* Order at 2, No. 9393 (May 13, 2022). In this regard, Respondents note the following:

The myBlu Marketing Denial confirms FDA's concern that e-vapor products with temperature control issues could result in unacceptable levels of harmful chemicals such as formaldehyde. The first "basis" FDA provides for its decision to deny PMTA authorization to myBlu is that "[e]vidence indicates that high coil temperature may cause emission of large quantities of aerosol HPHCs including carbonyls (e.g., acrolein, formaldehyde, acetaldehyde) and toxic metals." Ex. B at 2. Altria faced the exact same issue with its e-vapor products as the battery in its existing products did not have adequate temperature control features, resulting in high coil temperatures that generated elevated levels of the HPHCs referenced by FDA. IDF380, 394-412. While Complaint Counsel ("CC") has dismissed Altria's concern that these issues threatened its PMTA prospects as an "exaggerat[ion],"[2] the myBlu Marketing Denial Letter demonstrates that Altria's concerns were both appropriate and prescient.[3]

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[1] The parties have otherwise sought official notice of PMTA authorizations by FDA, which have consisted of both a press release and a marketing authorization letter that FDA immediately makes public. *See, e.g.*, Complaint Counsel ("CC")'s Motion for Official Notice of FDA Decision (attaching as exhibits FDA press release and marketing authorization letter); Respondents' Motion (same in connection with NJOY Ace); CC's Second Motion for Official Notice of FDA Decisions (same). Official notice of the myBlu Marketing Denial Letter will thus appropriately supplement the record regarding FDA's consideration of myBlu.

[2] CC's Response to Respondents' Motion for Official Notice of Recent FDA Decisions at 6 n.4.

[3] The myBlu denial further demonstrates that there is no basis to question the judgment of Altria's scientists at that time and that CC, having chosen to offer no expert testimony on the subject of FDA approval prospects, is improperly using the notice process to make scientific arguments and judgments that Congress expressly found the FTC not equipped to make. Respondents' Response to CC's Second Motion for Official Notice of FDA Decision at 5.

The myBlu Marketing Denial Letter also confirms FDA's focus on conversion. The letter cites as a reason for the denial the failure to demonstrate "that the new products have a potential to benefit adult smokers, who switch completely or significantly reduce their cigarette use, that would outweigh the risk to youth" that initiate nicotine use. Ex. B at 4. The letter categorizes myBlu's "Tobacco Chill" and "Intense Tobacco Chill" as flavored products and cites a lack of evidence that they do a sufficiently better job at conversion than other e-vapor products that are purely tobacco flavored and which do not pose the same alleged risk of youth initiation. Ex. B at 5, 8.

The myBlu Marketing Denial Letter is properly subject to notice under Commission Rules 3.43(f) (16 C.F.R. §3.43(f)) and 3.54(d) (16 C.F.R. §3.54(d)). Respondents respectfully request that the Commission grant their motion for official notice of the myBlu Marketing Denial Letter.

Dated: June 7, 2022

Respectfully submitted,

By: *s/* David I. Gelfand

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BEFORE THE FEDERAL TRADE COMMISSION

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In the Matter of **Altria Group, Inc.** **a corporation;** **and** **JUUL Labs, Inc.** **a corporation.**	**DOCKET NO. 9393**

[PROPOSED] ORDER GRANTING RESPONDENTS' MOTION FOR OFFICIAL NOTICE OF MYBLU MARKETING DENIAL LETTER

Upon consideration of Respondents' Motion Requesting Official Notice of myBlu Marketing Denial Letter, it is hereby ORDERED that the motion is GRANTED.

ORDERED By the Commission:

_____
April J. Tabor
Secretary

Dated:

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STATEMENT OF CONFERENCE
PURSUANT TO PARAGRAPH 4 OF SCHEDULING ORDER

In a conversation over the course of June 6-7, 2022, Respondents' counsel Jonathan Moses and Complaint Counsel Stephen Rodger and James Abell conferred in an effort in good faith to resolve by agreement the issues raised by the attached motion and were unable to reach an agreement.

Dated: June 7, 2022

By: *s/* Jonathan M. Moses
Jonathan M. Moses

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DECLARATION OF ELIZABETH COPELAND

I, Elizabeth Copeland, declare the following to be a true and correct statement of facts:

1. I am a Senior Director, Regulatory Submissions and Compliance at Juul Labs, Inc. ("JLI"). I submit this Declaration in support of Respondents' Motion for Official Notice of myBlu Marketing Denial Letter, pursuant to 16 C.F.R. §§ 3.43(f), 3.54(d). I have personal knowledge of the facts set forth in this Declaration.

2. On April 8, 2022, FDA issued a press release announcing its decision to deny the PMTA application for certain myBlu products manufactured by Fontem, US LLC. The press release stated that "FDA issued marketing denial orders to Fontem, US LLC," but FDA did not otherwise release the referenced marketing denial orders. FDA Issues Marketing Denial Orders to Fontem US for myBlu Products, FDA (April 8, 2022), https://www.fda.gov/tobacco-products/ctp-newsroom/fda-issues-marketing-denial-orders-fontem-us-myblu-products.

3. To complete the public record of FDA's decision regarding the myBlu products, JLI engaged FOI Services, Inc. to submit a FOIA request to FDA. FOI Services Inc. submitted a request on April 11, 2022, which is attached hereto as Exhibit A. The request sought the disclosure of a "Copy of the disclosable portions of the FDA reviews for the following products that were issued MDOs on 04/08/2022: myBlu Device Kit; myBlu Intense Tobacco Chill 2.5%; myBlu Intense Tobacco Chill 4.0%; myBlu Intense Tobacco 2.4%; myBlu Intense Tobacco 3.6%; myBlu Gold Leaf 1.2%; myBlu Gold Leaf 2.4%." *Id.* at 1. FDA provided an initial response to JLI's request on May 21, 2022, providing the marketing denial letter it issued to Fontem, along with technical back-up information. The marketing denial letter is attached as Exhibit B.

4. I declare under penalty of perjury that the foregoing is true and correct.

Elizabeth Copeland
June 7, 2022

EXHIBIT A

FOI Services, Inc.
23219 Stringtown Road Suite 240
Clarksburg, MD 20871-9363
Phone: 301-975-9400
Fax: 301-975-0702

04/11/2022

Food & Drug Administration
Division of Freedom of Information
Office of the Executive Secretariat, OC
5630 Fishers Lane
Room 1030
Rockville, MD 20852

Pursuant to the provisions of the Freedom of Information Act, please provide us with a copy (electronic preferred) of the following documents:

Copy of the disclosable portions of the FDA reviews for the following products that were issued MDOs on 04/08/2022: myBlu Device Kit; myBlu Intense Tobacco Chill 2.5%; myBlu Intense Tobacco Chill 4.0%; myBlu Intense Tobacco 2.4%; myBlu Intense Tobacco 3.6%; myBlu Gold Leaf 1.2%; myBlu Gold Leaf 2.4%.

If the cost of providing these documents will exceed $250.00, please send a cost estimate letter to accounting@foiservices.com. If the Agency denies any part of this request, please cite each specific reason that justifies the refusal to release the requested information.

Please refer to our control number **6242001** in your reply.

EXHIBIT B

U.S. FOOD & DRUG ADMINISTRATION

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

PUBLIC

April 08, 2022

DENIAL

Fontem US, LLC
Attention: Carole Folmar
Sr. Director, Product Integrity and Compliance, Associate General Counsel
420 North English Street
Greensboro, NC 27405

FDA Submission Tracking Numbers (STNs): PM0000720, PM0000721, (b) (4) PM0000726, (b) (4) -PM0000744

Dear Carole Folmar:

We completed substantive scientific review of your PMTAs[1] and are denying issuance of marketing granted orders for the tobacco products identified in Appendix A. Refer to Appendix B for a list of amendments received in support of your applications.

Based on our review of your PMTAs, we determined that the applications for the new tobacco products, as described in your applications and specified in Appendix A, lack sufficient evidence to demonstrate that permitting the marketing of the products subject to these applications are appropriate for the protection of the public health. 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). To do so, you may cross-reference information submitted in:

- The new tobacco product applications, PM0000720-PM0000721, (b) (4) -PM0000726, (b) (4) -PM0000744, subject to this Denial (see 21 C.F.R. 1114.17)
- Tobacco Product Master File submissions (see 21 C.F.R. 1114.17(b)(2) or 1114.17(c)(2); and guidelines at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/tobacco-product-master-files)

Your new PMTAs should clearly identify the PMTA submission type as a resubmission and include all information necessary to respond to all deficiencies identified in this letter (see 21 C.F.R. 1114.17(d)). If you decide to resubmit and cross-reference this PMTA, in addition to evaluating your response to the listed deficiencies, FDA will assess your submission to determine whether it meets the requirements of the PMTA rule and whether the application as a whole supports a finding that the marketing of your product(s) is appropriate for the protection of the public health.

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

We provide the following basis for our determination:

1. All of your PMTAs provide design features of the new products but indicate that the (b) (4) (b) (4). Evidence indicates that high coil temperature may cause emission of large quantities of aerosol HPHCs including carbonyls (e.g., acrolein, formaldehyde, acetaldehyde) and toxic metals. To demonstrate the effects of uncontrolled coil temperature on the aerosol emission of the new products, at least the quantities of the following HPHCs determined at the maximum allowable coil temperature would be needed:

    - Total nicotine
    - Acetaldehyde
    - Formaldehyde
    - Acrolein
    - Nickel
    - Lead
    - Chromium
    - Cadmium

    Furthermore, all the following information about aerosol constituent testing would be needed to accurately evaluate the aerosol data of the new products:

    - Reference product datasets (e.g., 1R6F, 1S4, 1S5, 3S1, or 3S3)
    - Complete description of quantitative test protocols and method used, and full validation reports for each analytical method
    - The names of the testing laboratories and their accreditation certificates
    - Complete datasets including reference product data, the length of time between dates of manufacture and dates of testing, the means, standard deviations and replicate number of the aerosol constituents
    - A summary of the results for all testing performed
    - Storage conditions prior to initiating testing
    - Any deviations from standards if your test methods conform to national or international standards

    Bridging and/or extrapolation approaches may be feasible in data submissions for future PMTAs when adequately justified. If you consider the product chemistry of the tobacco product used to bridge is applicable to that of the new products, the following information would be needed in future PMTAs:

    - All information that is considered necessary to fully characterize the new products and support the corresponding applicability
    - Justification for the design of the bridging and extrapolation approaches, including an explanation of how the characterized products were selected and how and why the tested products represent the untested products
    - Scientific evidence and rationale that demonstrate that the bridging and extrapolation of data from the tested products to the untested products are appropriate and adequate

- Scientific evidence and rationale demonstrating the statistical validity of the correlation established or the difference observed between the tested products and the untested products
- Scientific evidence and rationale demonstrating and the appropriateness in predicting the product characteristics of the untested products using bridging and/or extrapolation approaches

If you choose to extrapolate data across devices, scientific rationale and justification would be needed because aerosolizing device characteristics influence aerosol production, toxicant yields, use behavior, and a variety of other endpoints.

2. All of your PMTAs provide thermal test data (Device Casing and Aerosol Temperature Test Report – Rev A) for non-intense, intense, and consecutive puffing regimens. However, you do not provide scientific justifications for the sample durations of 15 puffs for the non-intense and intense puffing regimen data and 4 puffs for the consecutive puffing regimen data. Puff count is directly correlated to e-liquid consumption. Higher puff counts may allow the heater coil to continue to operate while not wetted with e-liquid, which may increase the heater coil temperature, resulting in higher toxicant yields.

   You report average measured aerosol temperatures but do not provide complete datasets, including the maximum measured aerosol temperatures. Additionally, you do not provide calibration records for the thermocouples. Aerosol temperature may affect the risk of thermal injury and toxicant yields. In order to fully characterize the new products and evaluate the risk of user injury, the following information for Device Casing and Aerosol Temperature Test Report – Rev A would be needed in future PMTAs:

   - Scientific justifications for the sample durations of 15 puffs, for the non-intense and intense puffing regimens, and 4 puffs, for the consecutive puffing regimen
   - Complete data sets, including maximum values, for aerosol temperature measurements
   - All thermocouple calibration records

3. All of your PMTAs and the information submitted during the remote regulatory assessment conducted in February and March 2021 lack details needed to evaluate e-liquid QC testing and (b) (4) liquidpod filling process. The following information would be needed in future PMTAs:

   - The name(s) of the laboratory(ies) used to determine (b) (4) levels in e-liquid QC testing
   - The laboratory accreditation of the laboratory used for QC testing, including but not limited to (b) (4) department and laboratory
   - The certification of (b) (4) cleanroom for liquidpod filling
   - The temperature and humidity of cleanroom, raw materials and released inventory room, finished goods room and warehouse at (b) (4)
   - The storage time of the finished liquidpods in (b) (4) warehouse

4. All of your PMTAs lack post-manufacturing microbiological stability information and testing validation for the finished new products (e-liquid in pods, container closure system (CCS) version 1.2). Microbial stability test data would be needed to evaluate how the CCS and product composition of the new products affect product stability over the defined shelf life. Your stability protocol (blu_PMTA_001) indicates that you plan to test each new product (CCS version 1.2) for the following parameters: pH, moisture, a_w, tobacco-specific nitrosamines (NNN and NNK), TAMC, TYMC, β-D glucan, endotoxin, and mycotoxin over shelf life. However, you did not provide any microbial stability data from this protocol in your PMTAs. Instead, you provided data for CCS versions 1.0 and 1.1 (protocol blu_PMTA _002, blu_PMTA_004, and blu_PMTA_018). The provided stability data could not be adequately bridged to the CCS version 1.2 due to differences between these versions that could affect microbial stability. For example, (b) (4) f the CCS. This change, purportedly to allow for increased airflow, can increase risk of microbial contamination and affect moisture content and overall stability of the e-liquid over the proposed shelf life.

   The lack of post-manufacturing microbial stability data for the new products means that the products could contain microbial components or organisms (e.g., bacteria, yeast and mold, bacterial and fungal spores, and toxins), which may change over storage time. The presence of microbial components or organisms may result in increased risk to public health because they may be either carcinogenic in nature or associated with the development of respiratory and/or systemic health issues.

   In addition, you modified USP <61> and <62>, which are used to measure total microbial counts (TAMC/TYMC) by diluting the liquid and collecting microorganism on a special filter. The addition of dilution and filtration steps alters the published USP methods. However, you did not provide a validation data for the modified USP methods to ensure that these methods are suitable for the new products.

   To resolve this deficiency, stability data for your final, to-be-marketed CCS version 1.2 and measurement of the above-mentioned microbiological parameters under long-term (non-accelerated) storage conditions would be needed to support the microbial stability of the new products over the proposed (b) (4) shelf life. In addition, full test validation data for the modified USP methods (including accuracy, sensitivity, specificity, and reproducibility of the test methods) would be needed in order to demonstrate that these methods are suitable for their intended use.

5. PM0000721[2], (b) (4) , (b) (4) , and PM0000744 lack sufficient evidence demonstrating that the new products have a potential to benefit adult smokers, who switch completely or significantly reduce their cigarette use, that would outweigh the risk to youth.

   There is substantial evidence that the use of flavors in tobacco products, like the Intense Tobacco Chill, (b) (4) (b) (4) flavors in the subject products, have significant appeal to youth and are associated with youth initiation of

[2] PM0000721 and PM0000744 were not included in deficiency 19, issued in a Deficiency Letter on November 27, 2020. However, FDA has subsequently determined that the main flavor constituent in these products is (b) (4) and, therefore, they are included in this deficiency.

such products. 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.[3] This evidence could be provided using a randomized controlled trial and/or longitudinal cohort study or other evidence demonstrating the benefit of your new products to adult smokers. Such evidence should include an appropriate comparator tobacco-flavored ENDS. Reliable and robust data are needed to evaluate the impact of the new products as compared to tobacco-flavored products on adult smokers' switching or cigarette reduction over time because tobacco-flavored products have not been shown to present the same risks to youth as tobacco products with other characterizing flavors. Whether other products give adult smokers comparable options for switching or cigarette reduction bears on the extent of the public health benefit that the new products arguably provide to that population. Finally, although this evidence is necessary to demonstrate that the subject ENDS provide benefits for adult smokers, it may not be sufficient to demonstrate that the marketing of the subject ENDS is appropriate for the protection of the public health: having established the benefit to adults, applications containing this evidence would still be evaluated to determine that the totality of the evidence supports a marketing authorization.

Based on the information that you provided, there is a lack of evidence to demonstrate that the subject ENDS, relative to tobacco-flavored ENDS, would provide an added benefit for adult smokers that is adequate to outweigh the substantial risks to youth. Your longitudinal switching study (Study BR-EVP/US8), which followed current cigarette smokers at baseline until they became former smokers by the three-month follow-up period, examined the differences in flavors used most often and differences in flavors respondents stated were helpful in switching. Your analysis showed no significant correlation in flavor used ("other" vs. tobacco) being helpful in quitting. Results from study BR-EVP/US16 were consistent with results from your longitudinal study (BR-EVP/US8) when the data were limited to current users of the new products. Additionally, relatively small sample size (n<25) for Study BR-EVP/US8 (which you acknowledge is ongoing in your response) render the data ineffectual for the purpose of assessing switching behavior among respondents. Therefore, the PMTAs do not contain sufficient evidence regarding the impact of the new products on switching or cigarette reduction that could potentially demonstrate the benefit of the new products over tobacco-flavored ENDS. In addition, your PMTAs include some information from the literature suggesting a positive association between use of flavored ENDS and smoking cessation. However, the published literature on the role of flavored ENDS and smoking cessation remains unclear and you do not provide product specific information to evaluate the likelihood that current tobacco users, and in particular, adult combusted cigarette smokers, will switch to the new products to a greater extent than tobacco-flavored ENDS.

6. All of your PMTAs reference Tobacco Product Master Files (TPMFs) (b) (4) , (b) (4) . However, upon review, FDA identified issues in the TPMFs for which additional information are needed by FDA to perform a complete review. The issues include lack of sufficient e-liquid and aerosol leachable study results to evaluate the potential health risks of the subcomponents of the new products, insufficient information about the laboratory accreditation of QC testing laboratory and/or QC methods, lack of complete stability

[3] Experience shows that advertising and promotion restrictions and sales access restrictions cannot mitigate the substantial risk to youth from flavored ENDS sufficiently to reduce the magnitude of adult benefit required to demonstrate APPH. Rather, for flavored ENDS, only the most stringent mitigation measures – specifically device access restrictions – have such mitigation potential. These PMTAs do not propose device access restrictions.

data, insufficient information regarding the impact of the wicking material on HPHCs, and lack of information regarding analytical methods. These issues are being conveyed separately to the TPMF owners. If you have questions related to the TPMFs, we encourage you to contact the TPMF owners. The TPMF owners' complete responses or lack thereof do not change FDA's closure of these PMTAs resulting from our determination that the new products in these PMTAs are not appropriate for the protection of public health; however, if you choose to resubmit PMTAs for your new products referencing these TPMFs, any update to the TPMFs and/or additional response by the TPMF owners would be part of FDA's review of your future PMTAs where appropriate cross-references are made.

We encourage you to submit all regulatory correspondence electronically via the CTP Portal[4,5] using eSubmitter.[6] Alternatively, submissions may be mailed to:

Food and Drug Administration
Center for Tobacco Products
Document Control Center (DCC)
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

The CTP Portal and FDA's Electronic Submission Gateway (ESG) are generally available 24 hours a day, seven days a week; submissions are considered received by DCC on the day of successful upload. Submissions delivered to DCC by courier or physical mail will be considered timely if received during delivery hours on or before the due date[7]; if the due date falls on a weekend or holiday, the delivery must be received on or before the preceding business day. We are unable to accept regulatory submissions by e-mail.

If you have any questions, please contact Barbara Banchero, Regulatory Health Project Manager, at (301) 796-1937 or Barbara.Banchero@fda.hhs.gov.

Sincerely,

Digitally signed by Matthew R. Holman -S
Date: 2022.04.08 08:43:24 -04'00'

Matthew R. Holman, Ph.D.
Director
Office of Science
Center for Tobacco Products

Enclosures:
Appendix A – New Tobacco Products Subject of This Letter
Appendix B – Amendments Received for These Applications

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

Appendix A[8,9]
New Tobacco Products Subject of This Letter

Common Attributes of PMTAs	
Date of Submission:	April 24, 2020
Date of Receipt:	April 24, 2020
Product Manufacturer:	Fontem US, LLC
Product Category:	ENDS (VAPES)
PM0000720: myblu Device Kit	
Product Sub-Category:	Closed E-Cigarette
Package Type:	Box
Package Quantity:	1 Device per Box
Length:	87.7 mm
Diameter:	18.0 mm[10]
Wattage:	1.30 Wh
Battery Capacity:	350 miliAmpere hour (mAh)
E-Liquid Volume:	Not Provided
Nicotine Concentration:	Not Provided
PG/VG ratio:	Not Provided
Characterizing Flavor:	None
Additional properties:	Voltage: 3.7 V myblu Universal Serial Bus (USB) Charging Cable
PM0000721: myblu Intense Tobacco Chill 4.0%	
Product Sub-Category:	Closed E-Liquid
Package Type:	Box
Package Quantity:	2 Cartridges
Characterizing Flavor:	Tobacco Chill
Nictotine concentration:	40 mg/mL
PG/VG ratio:	33/58[11]
E-liquid volume	1.5 mL
Additional properties:	Length: 41.6 ± 0.2 mm Depth: 7.9 ± 0.2 mm Width: 16.4 ± 0.2 mm Nicotine Content: 3.44% w/w

[8] Brand/sub-brand or other commercial name used in commercial distribution.
[9] Characterizing flavor as indicated by the applicant
[10] Applicant provided two measurements for diameter; smallest dimension [redacted] mm, largest diameter [redacted] mm.
[11] The values are percentages of the total solution, with the remaining amounts being nicotine and other flavors.

(b) (4)	
Product Sub-Category:	(b) (4)
Package Type:	
Package Quantity:	
Characterizing Flavor:	
Nicotine Concentration:	
PG/VG Ratio:	
E-Liquid Volume:	
Additional Properties:	

PM0000725: myblu Gold Leaf 1.2%	
Product Sub-Category:	Closed E-Liquid
Package Type:	Box
Package Quantity:	2 Cartridges
Characterizing Flavor:	Gold Leaf
Nicotine Concentration:	13.75 mg/mL
PG/VG Ratio:	47/49 [10]
E-Liquid Volume:	1.5 mL
Additional Properties:	Length: 41.6 ± 0.2 mm Depth: 7.9 ± 0.2 mm Width: 16.4 ± 0.2 mm Nicotine Content: 1.2% w/w

PM0000726: myblu Gold Leaf 2.4%	
Product Sub-Category:	Closed E-Liquid
Package Type:	Box
Package Quantity:	2 Cartridges
Characterizing Flavor:	Gold Leaf
Nicotine Concentration:	27.43 mg/mL
PG/VG Ratio:	47/48[10]
E-Liquid Volume:	1.5 mL
Additional Properties:	Length: 41.6 ± 0.2 mm Depth: 7.9 ± 0.2 mm Width: 16.4 ± 0.2 mm Nicotine Content: 2.4% w/w

(b) (4)	
Product Sub-Category:	(b) (4)
Package Type:	
Package Quantity:	
Characterizing Flavor:	
Nicotine Concentration:	
PG/VG Ratio:	
E-Liquid Volume:	
Additional Properties:	

(b) (4) [redacted]	
Product Sub-Category:	(b) (4) [redacted]
Package Type:	
Package Quantity:	
Characterizing Flavor:	
Nicotine Concentration:	
PG/VG Ratio:	
E-Liquid Volume:	
Additional Properties:	

(b) (4) [redacted]	
Product Sub-Category:	(b) (4) [redacted]
Package Type:	
Package Quantity:	
Characterizing Flavor:	
Nicotine Concentration:	
PG/VG Ratio:	
E-Liquid Volume:	
Additional Properties:	

(b) (4) [redacted]	
Product Sub-Category:	(b) (4) [redacted]
Package Type:	
Package Quantity:	
Characterizing Flavor:	
Nicotine Concentration:	
PG/VG Ratio:	
E-Liquid Volume:	
Additional Properties:	

(b) (4) [redacted]	
Product Sub-Category:	(b) (4) [redacted]
Package Type:	
Package Quantity:	
Characterizing Flavor:	
Nicotine Concentration:	
PG/VG Ratio:	
E-Liquid Volume:	
Additional Properties:	

[redacted] (b) (4)

Product Sub-Category:
Package Type:
Package Quantity:
Characterizing Flavor:
Nicotine Concentration:
PG/VG Ratio:
E-Liquid Volume:
Additional Properties:

[redacted] (b) (4)

[redacted] (b) (4)

Product Sub-Category:
Package Type:
Package Quantity:
Characterizing Flavor:
Nicotine Concentration:
PG/VG Ratio:
E-Liquid Volume:
Additional Properties:

[redacted] (b) (4)

[redacted] (b) (4)

Product Sub-Category:
Package Type:
Package Quantity:
Characterizing Flavor:
Nicotine Concentration:
PG/VG Ratio:
E-Liquid Volume:
Additional Properties:

[redacted] (b) (4)

[redacted] (b) (4)

Product Sub-Category:
Package Type:
Package Quantity:
Characterizing Flavor:
Nicotine Concentration:
PG/VG Ratio:
E-Liquid Volume:
Additional Properties:

[redacted] (b) (4)

(b) (4) [redacted]

Product Sub-Category:
Package Type:
Package Quantity:
Characterizing Flavor:
Nicotine Concentration:
PG/VG Ratio:
E-Liquid Volume:
Additional Properties:

(b) (4) [redacted]

(b) (4) [redacted]

Product Sub-Category:
Package Type:
Package Quantity:
Characterizing Flavor:
Nicotine Concentration:
PG/VG Ratio:
E-Liquid Volume:
Additional Properties:

(b) (4) [redacted]

(b) (4) [redacted]

Product Sub-Category:
Package Type:
Package Quantity:
Characterizing Flavor:
Nicotine Concentration:
PG/VG Ratio:
E-Liquid Volume:
Additional Properties:

(b) (4) [redacted]

(b) (4) [redacted]

Product Sub-Category:
Package Type:
Package Quantity:
Characterizing Flavor:
Nicotine Concentration:
PG/VG Ratio:
E-Liquid Volume:
Additional Properties:

(b) (4) [redacted]

(b) (4)	
Product Sub-Category:	(b) (4)
Package Type:	
Package Quantity:	
Characterizing Flavor:	
Nicotine Concentration:	
PG/VG Ratio:	
E-Liquid Volume:	
Additional Properties:	

PM0000742: myblu Intense Tobacco 2.4%	
Product Sub-Category:	Closed E-Liquid
Package Type:	Box
Package Quantity:	2 Cartridges
Characterizing Flavor:	Tobacco
Nicotine Concentration:	24 mg/mL
PG/VG Ratio:	40/54[10]
E-Liquid Volume:	1.5 mL
Additional Properties:	Length: 41.6 ± 0.2 mm Depth: 7.9 ± 0.2 mm Width: 16.4 ± 0.2 mm Nicotine Content: 2.07% w/w

PM0000743: myblu Intense Tobacco 3.6%	
Product Sub-Category:	Closed E-Liquid
Package Type:	Box
Package Quantity:	2 Cartridges
Characterizing Flavor:	Tobacco
Nicotine Concentration:	36 mg/mL
PG/VG Ratio:	38/54[10]
E-Liquid Volume:	1.5 mL
Additional Properties:	Length: 41.6 ± 0.2 mm Depth: 7.9 ± 0.2 mm Width: 16.4 ± 0.2 mm Nicotine Content: 3.10% w/w

PM0000744: myblu Intense Tobacco Chill 2.5%	
Product Sub-Category:	Closed E-Liquid
Package Type:	Box
Package Quantity:	2 Cartridges
Characterizing Flavor:	Tobacco Chill
Nicotine Concentration:	25 mg/mL
PG/VG Ratio:	33/60[10]
E-Liquid Volume:	1.5 mL
Additional Properties:	Length: 41.6 ± 0.2 mm Depth: 7.9 ± 0.2 mm Width: 16.4 ± 0.2 mm Nicotine Content: 2.14% w/w

Appendix B

Amendments Received for These Applications

Submission Date	Receipt Date	Applications being amended	Reviewed	Brief Description
November 23, 2020	November 23, 2020	All STNs	No, Administrative update	Response to OCEs November 10, 2020 Inspection Request
February 24, 2021	February 24, 2021	All STNs	Yes	Response to FDAs November 27, 2020 Deficiency Letter

CERTIFICATE OF SERVICE

I hereby certify that on June 7, 2022, I caused a true and correct copy of the foregoing to be filed electronically using the FTC's E-Filing System, which will send notification of such filing to:

April Tabor
Secretary
Federal Trade Commission
600 Pennsylvania Ave., NW, Rm. H-113
Washington, DC 20580
ElectronicFilings@ftc.gov

The Honorable D. Michael Chappell
Administrative Law Judge
Federal Trade Commission
600 Pennsylvania Ave., NW, Rm. H-110
Washington, DC 20580

I also certify that I caused the foregoing document to be served via email to:

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s/ Beth Wilkinson

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