

Technical Project Lead (TPL) Review of SE Reports

New Products Subject of this Review ¹	
STNs	SE0021835.PD2, SE0022268.PD2, SE0022270.PD2, SE0022271.PD2, SE0022273.PD2, SE0022274.PD2, SE0022276.PD2, SE0022293.PD2, SE0022295.PD2, SE0022296.PD2, SE0022297.PD2, SE0022298.PD2, SE0022299.PD2, SE0022312.PD2, SE0022313.PD2, SE0022317.PD2, SE0022319.PD2, SE0022327.PD2, SE0022329.PD2 and SE0022330.PD2
Common Attributes	
Submission date	August 30, 2020 ² , August 31, 2020 ³ , September 1, 2020 ⁴
Receipt date	September 8, 2020
Applicant	Blunt Wrap USA Inc.
Product manufacturer	Emimar S.A.
Application type	Same Characteristics
Application subtype	Regular Product Quantity
Product category	Cigars
Product subcategory	Cigar Component
Cross-Referenced Submissions	
All STNs	None
Supporting FDA Memoranda Relied Upon in this Review	
All STNs	Addendum to Memorandum: Product quantity changes in Substantial Equivalence Reports (SE Reports) for statutorily regulated tobacco products (December 31, 2019).
Recommendation	
Issue Substantially Equivalent (SE) orders for the new tobacco products subject of this review.	
Technical Project Lead (TPL):	Avena Russell Digitally signed by Avena Russell Date: 2023.12.22 12:30:47 -05'00'

Avena Russell, MS
CDR, United States Public Health Service
Division of Regulatory Project Management
Office of Science

Signatory Decision:

Concur with TPL recommendation and basis of recommendation

Todd L. Cecil -S

Digitally signed by Todd L. Cecil -S
Date: 2023.12.22 12:32:53 -05'00'

Todd L. Cecil, Ph.D.
Deputy Director
Office of Science

¹Product details, amendments, and dates provided in the Appendix. STN means submission tracking number including product static identification number (PD) if applicable. SE means substantial equivalence (report).

²Submission Date of August 30, 2022 for SE0021835.PD2, SE0022270.PD2 – SE0022271.PD2, SE0022273.PD2, SE0022297.PD2, SE0022312.PD2 – SE0022313.PD2, SE0022317.PD2, and SE0022319.PD2.

³Submission Date of August 31, 2020 for SE0022276.PD2, SE0022296.PD2, and SE0022298.PD2.

⁴Submission Date of September 01, 2020 for SE0022268.PD2, SE0022293.PD2, SE0022295.PD2, SE0022327.PD2, and SE0022329.PD2 – SE0022330.PD2.

SE0021835.PD2, SE0022268.PD2, SE0022270.PD2, SE0022271.PD2, SE0022273.PD2, SE0022274.PD2, SE0022276.PD2, SE0022293.PD2, SE0022295.PD2, SE0022296.PD2, SE0022297.PD2, SE0022298.PD2, SE0022299.PD2, SE0022312.PD2, SE0022313.PD2, SE0022317.PD2, SE0022319.PD2, SE0022327.PD2, SE0022329.PD2 and SE0022330.PD2

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1. BACKGROUND

1.1. NEW AND PREDICATE PRODUCTS

The applicant submitted information for the new and predicate products listed in detail in the Appendix.

1.2. REGULATORY ACTIVITY

On September 1, 2020 FDA received SE Reports from Blunt Wrap USA Inc. On November 24, 2020, FDA completed an Acceptance review and issued an Acceptance letter to the applicant. See Appendix A for the list of products and Appendix B for amendments received.

1.3. SCOPE OF REVIEW

This review captures all compliance, regulatory, and scientific reviews completed for the new products subject of this review.

Table 1. Disciplines reviewed

Discipline	Cycle 1	
	Reviewers	Review Date
Regulatory	Carlos Suarez	12/21/2023
Environmental Science	Allison M. Young	2/23/2023

2. COMPLIANCE REVIEW

The Office of Compliance and Enforcement (OCE) completed reviews to determine whether the applicant established that the predicate products are pre-existing tobacco products⁵ (i.e., were commercially marketed in the United States as of February 15, 2007). The OCE reviews dated January 31, 2023 and February 2, 2023 concludes that the evidence submitted by the applicant is adequate to demonstrate that the predicate products are pre-existing products and, therefore, are eligible predicate products.

OCE also completed reviews to determine whether the new products are in compliance with the Federal Food, Drug, and Cosmetic Act (FD&C Act) (see section 910(a)(2)(A)(i)(II) of the FD&C Act). The OCE reviews dated August 17, 2023 for the past quarter, and November 6, 2023 for the current quarter (user fee only), conclude that the new products are in compliance with the FD&C Act.

3. SCIENTIFIC REVIEW

Full scientific review was not initiated by the Office of Science (OS) because the product characteristics of the new and corresponding predicate tobacco products are identical except for the following changes in product quantity:

⁵ FDA updated the term “grandfathered tobacco product” (GF) to “pre-existing tobacco product” (PTP). This update will not affect review of pending submissions and STNs will not change retroactively.

SE0021835.PD2, SE0022268.PD2, SE0022270.PD2, SE0022271.PD2, SE0022273.PD2, SE0022274.PD2, SE0022276.PD2, SE0022293.PD2, SE0022295.PD2, SE0022296.PD2, SE0022297.PD2, SE0022298.PD2, SE0022299.PD2, SE0022312.PD2, SE0022313.PD2, SE0022317.PD2, SE0022319.PD2, SE0022327.PD2, SE0022329.PD2 and SE0022330.PD2

Change in Product Quantity

SE Report	New Product Quantity per Pouch	Predicate Product Quantity per Pouch	% Change
SE0021835.PD2	3	2	↑25%
SE0022268.PD2	5	8	↓38%
SE0022270.PD2	4	2	↑50%
SE0022271.PD2	5	2	↑75%
SE0022273.PD2	5	2	↑75%
SE0022274.PD2	2	1	↑50%
SE0022276.PD2	2	1	↑50%
SE0022293.PD2	3	2	↑25%
SE0022295.PD2	3	2	↑25%
SE0022296.PD2	5	2	↑75%
SE0022297.PD2	4	2	↑50%
SE0022298.PD2	5	2	↑75%
SE0022299.PD2	3	8	↓63%
SE0022312.PD2	4	2	↑50%
SE0022313.PD2	4	2	↑50%
SE0022317.PD2	4	2	↑50%
SE0022319.PD2	4	2	↑50%
SE0022327.PD2	3	2	↑25%
SE0022329.PD2	3	2	↑25%
SE0022330.PD2	3	2	↑25%

OS prepared memoranda⁶ summarizing its current thinking on product quantity changes. Existing data on product quantity changes are limited and do not address the size threshold (i.e., how much of a change in product quantity) necessary to raise different questions of public health. With respect to product quantity decreases, even though some of the currently available scientific evidence is specific to tobacco products, the studies do not separate out the effect of reduced price from size on consumption or initiation. Thus, based upon the currently available science and CTP's experience in reviewing SE Reports, product quantity changes do not cause new tobacco products to raise different questions of public health. Therefore, scientific review is unnecessary.

Based on regulatory review, the new and corresponding predicate tobacco products are uniquely identified per the April 2021 Unique Identification of Tobacco Products⁷ memo. As TPL, I concur with the recommendation to grant SE Orders for this new tobacco product.

⁶ See memorandum on product quantity changes, dated December 7, 2017, and addendum for deemed tobacco products, dated December 31, 2019.

⁷ See memorandum Unique Identification of Tobacco Products, dated April 20, 2021

SE0021835.PD2, SE0022268.PD2, SE0022270.PD2, SE0022271.PD2, SE0022273.PD2, SE0022274.PD2, SE0022276.PD2, SE0022293.PD2, SE0022295.PD2, SE0022296.PD2, SE0022297.PD2, SE0022298.PD2, SE0022299.PD2, SE0022312.PD2, SE0022313.PD2, SE0022317.PD2, SE0022319.PD2, SE0022327.PD2, SE0022329.PD2 and SE0022330.PD2

4. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Luis Valerio, Ph.D. on February 24, 2023.

The FONSI was supported by an environmental assessment prepared by FDA on February 24, 2023.

5. CONCLUSION AND RECOMMENDATION

The product characteristics of the new and corresponding predicate tobacco products are identical except for a change in product quantity as follows:

- 25% increase in product quantity: SE0021835.PD2, SE0022293.PD2, SE0022295.PD2, SE0022327.PD2, SE0022329.PD2 and SE0022330.PD2
- 50% increase in product quantity: SE0022270.PD2, SE0022274.PD2, SE0022276.PD2, SE0022297.PD2, SE0022312.PD2, SE0022313.PD2, SE0022317.PD2 and SE0022319.PD2
- 75% increase in product quantity: SE0022271.PD2, SE0022273.PD2, SE0022296.PD2 and SE0022298.PD2
- 38% decrease in product quantity: SE0022268.PD2
- 63% decrease in product quantity: SE0022299.PD2

The OS memoranda⁴ concludes that based on OS' experience and the currently available evidence, the difference in product quantity does not cause the new tobacco products to raise different questions of public health. I concur with this conclusion.

The predicate products meet statutory requirements because it was determined that they are pre-existing products (i.e., were commercially marketed in the United States as of February 15, 2007).

The new products are currently in compliance with the FD&C Act. I concur with these reviews and recommend that SE order letters be issued.

FDA examined the environmental effects of finding these new products substantially equivalent and made a finding of no significant impact.

SE0021835.PD2, SE0022268.PD2, SE0022270.PD2, SE0022271.PD2, SE0022273.PD2, SE0022274.PD2, SE0022276.PD2, SE0022293.PD2, SE0022295.PD2, SE0022296.PD2, SE0022297.PD2, SE0022298.PD2, SE0022299.PD2, SE0022312.PD2, SE0022313.PD2, SE0022317.PD2, SE0022319.PD2, SE0022327.PD2, SE0022329.PD2 and SE0022330.PD2

6. APPENDICES

Appendix A. New and Corresponding Predicate Products

Common Attributes ^{8,9,10,11,12}		
Submit date	August 30, 2020 ¹³ , August 31, 2020 ¹⁴ , September 1, 2020 ¹⁵	
Receipt date	September 8, 2020	
Applicant	Blunt Wrap USA Inc.	
Product manufacturer	Emimar S.A.	
Product category	Cigars	
Product subcategory	Cigar Component	
Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0021835.PD2	GF1909080
Product name	BLUNT MASTER CIGAR WRAP - BERRIES	BLUNT WRAP PLATINUM - BERRIES
Eligibility status	Not Applicable	Pre-Existing
Package type	Foil Pouch	Foil Pouch
Package quantity	3 Cigar Wrappers	2 Cigar Wrappers
Characterizing flavor(CF)	Flavored	Flavored
Flavored CF, as identified	Berries	Berries
Nicotine source	Tobacco	Tobacco
Additional properties	Length: 114.3 millimeter (mm) Width: 50.8 mm Mass: 763 milligram (mg) Wrapper material: Tobacco	Length: 114.3 mm Width: 50.8 mm Mass: 763 mg Wrapper material: Tobacco

⁸ We interpret package type to mean container closure system and package quantity to mean product quantity within the container closure system, unless otherwise identified.

⁹ Product name is brand/sub-brand or other commercial name used in commercial distribution.

¹⁰ Nicotine source was not provided by the applicant; however, the applications for these products were received prior to April 14, 2022, or are modifying predicate products that were marketed prior to April 14, 2022. As such, nicotine source is classified as tobacco.

¹¹ FDA updated the term “grandfathered tobacco product” (GF) to “pre-existing tobacco product” (PTP). This update will not affect review of pending submissions and STNs will not change retroactively. You may continue to use the STN (GF or PX) assigned in the FDA Acceptance letter confirming receipt of your submission. Refer to FDA’s website for more information on the GF to PTP update.

¹² Characterizing flavors previously identified as “None” have been updated in FDA records to “Tobacco” to accurately reflect that the products provide a tobacco characterizing flavor. As such, those products do not have any change in characterizing flavor

¹³ For SE0021835.PD2, SE0022270.PD2 – SE0022271.PD2, SE0022273.PD2, SE0022297.PD2, SE0022312.PD2 – SE0022313.PD2, SE0022317.PD2 and SE0022319.PD2.

¹⁴ SE0022274.PD2, SE0022276.PD2, SE0022296.PD2 and SE0022298.PD2.

¹⁵ SE0022268.PD2, SE0022293.PD2, SE0022295.PD2, SE0022299.PD2, SE0022327.PD2 and SE0022329.PD2 – SE0022330.PD2.

SE0021835.PD2, SE0022268.PD2, SE0022270.PD2, SE0022271.PD2, SE0022273.PD2, SE0022274.PD2, SE0022276.PD2, SE0022293.PD2, SE0022295.PD2, SE0022296.PD2, SE0022297.PD2, SE0022298.PD2, SE0022299.PD2, SE0022312.PD2, SE0022313.PD2, SE0022317.PD2, SE0022319.PD2, SE0022327.PD2, SE0022329.PD2 and SE0022330.PD2

Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0022268.PD2	GF2011307
Product name	BLUNT WRAP NATURAL LEAF - BLUEBERRY	JUICY BLUNTS NATURAL LEAF WRAPPER - BLUEBERRY ¹⁶
Eligibility status	Not Applicable	Pre-Existing
Package type	Foil Pouch	Foil Pouch
Package quantity	5 Cigar Wrappers	8 Cigar Wrappers
Characterizing flavor(CF)	Flavored	Flavored
Flavored CF, as identified	Blueberry	Blueberry
Nicotine source	Tobacco	Tobacco
Additional properties	Length: 114.3 mm Width: 50.8 mm Wrapper material: Tobacco	Length: 114.3 mm Width: 50.8 mm Wrapper material: Tobacco
STN	SE0022270.PD2	GF1909080
Product name	BLUNT MASTER CIGAR WRAP - BERRIES	BLUNT WRAP PLATINUM - BERRIES
Eligibility status	Not Applicable	Pre-Existing
Package type	Foil Pouch	Foil Pouch
Package quantity	4 Cigar Wrappers	2 Cigar Wrappers
Characterizing flavor(CF)	Flavored	Flavored
Flavored CF, as identified	Berries	Berries
Nicotine source	Tobacco	Tobacco
Additional properties	Length: 114.3 mm Width: 50.8 mm Mass: 763 mg Wrapper material: Tobacco	Length: 114.3 mm Width: 50.8 mm Mass: 763 mg Wrapper material: Tobacco
STN	SE0022271.PD2	GF1909069
Product name	BLUNT MASTER CIGAR WRAP - MANGO	BLUNT WRAP PLATINUM – MELLO MANGO
Eligibility status	Not Applicable	Pre-Existing
Package type	Foil Pouch	Foil Pouch
Package quantity	5 Cigar Wrappers	2 Cigar Wrappers
Characterizing flavor(CF)	Flavored	Flavored
Flavored CF, as identified	Mango	Mango
Nicotine source	Tobacco	Tobacco
Additional properties	Length: 114.3 mm Width: 50.8 mm Mass: 763 mg Wrapper material: Tobacco	Length: 114.3 mm Width: 50.8 mm Mass: 763 mg Wrapper material: Tobacco

¹⁶ The predicate product is also know as JUICY NATURAL LEAF BLUNT - BLUEBERRY.

SE0021835.PD2, SE0022268.PD2, SE0022270.PD2, SE0022271.PD2, SE0022273.PD2, SE0022274.PD2, SE0022276.PD2, SE0022293.PD2, SE0022295.PD2, SE0022296.PD2, SE0022297.PD2, SE0022298.PD2, SE0022299.PD2, SE0022312.PD2, SE0022313.PD2, SE0022317.PD2, SE0022319.PD2, SE0022327.PD2, SE0022329.PD2 and SE0022330.PD2

Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0022273.PD2	GF1909080
Product name	BLUNT MASTER CIGAR WRAP - BERRIES	BLUNT WRAP PLATINUM – BERRIES
Eligibility status	Not Applicable	Pre-Existing
Package type	Foil Pouch	Foil Pouch
Package quantity	5 Cigar Wrappers	2 Cigar Wrappers
Characterizing flavor(CF)	Flavored	Flavored
Flavored CF, as identified	Berries	Berries
Nicotine source	Tobacco	Tobacco
Additional properties	Length: 114.3 mm Width: 50.8 mm Mass: 763 mg Wrapper material: Tobacco	Length: 114.3 mm Width: 50.8 mm Mass: 763 mg Wrapper material: Tobacco
STN	SE0022274.PD2	GF1909094
Product name	JUICY – CHERRY VANILLA	JUICY – CHERRY VANILLA
Eligibility status	Not Applicable	Pre-Existing
Package type	Foil Pouch	Foil Pouch
Package quantity	2 Cigar Wrappers	1 Cigar Wrapper
Characterizing flavor(CF)	Flavored	Flavored
Flavored CF, as identified	Cherry Vanilla	Cherry Vanilla
Nicotine source	Tobacco	Tobacco
Additional properties	Length: 114.3 mm Width: 60.3 mm Wrapper material: Tobacco	Length: 114.3 mm Width: 60.3 mm Wrapper material: Tobacco
STN	SE0022276.PD2	GF1909041
Product name	JUICY – RASPBERRY	JUICY – RASPBERRY
Eligibility status	Not Applicable	Pre-Existing
Package type	Foil Pouch	Foil Pouch
Package quantity	2 Cigar Wrappers	1 Cigar Wrapper
Characterizing flavor(CF)	Flavored	Flavored
Flavored CF, as identified	Raspberry	Raspberry
Nicotine source	Tobacco	Tobacco
Additional properties	Length: 114.3 mm Width: 60.3 mm Wrapper material: Tobacco	Length: 114.3 mm Width: 60.3 mm Wrapper material: Tobacco

SE0021835.PD2, SE0022268.PD2, SE0022270.PD2, SE0022271.PD2, SE0022273.PD2, SE0022274.PD2, SE0022276.PD2, SE0022293.PD2, SE0022295.PD2, SE0022296.PD2, SE0022297.PD2, SE0022298.PD2, SE0022299.PD2, SE0022312.PD2, SE0022313.PD2, SE0022317.PD2, SE0022319.PD2, SE0022327.PD2, SE0022329.PD2 and SE0022330.PD2

Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0022293.PD2	GF1909083
Product name	Show Diamond Wrap - Chocolate	Blunt Wrap Platinum - Chocolate
Eligibility status	Not Applicable	Pre-Existing
Package type	Foil Pouch	Foil Pouch
Package quantity	3 Cigar Wrappers	2 Cigar Wrappers
Characterizing flavor(CF)	Flavored	Flavored
Flavored CF, as identified	Chocolate	Chocolate
Nicotine source	Tobacco	Tobacco
Additional properties	Length: 114.3 mm Width: 50.8 mm Wrapper material: Tobacco	Length: 114.3 mm Width: 50.8 mm Wrapper material: Tobacco
STN	SE0022295.PD2	GF1909071
Product name	Show Diamond Wrap - Pina Colada	Blunt Wrap Platinum – Pina Colada
Eligibility status	Not Applicable	Pre-Existing
Package type	Foil Pouch	Foil Pouch
Package quantity	3 Cigar Wrappers	2 Cigar Wrappers
Characterizing flavor(CF)	Flavored	Flavored
Flavored CF, as identified	Pina Colada	Pina Colada
Nicotine source	Tobacco	Tobacco
Additional properties	Length: 114.3 mm Width: 50.8 mm Wrapper material: Tobacco	Length: 114.3 mm Width: 50.8 mm Wrapper material: Tobacco
STN	SE0022296.PD2	GF1909071
Product name	BLUNT MASTER CIGAR WRAP - VANILLA	BLUNT WRAP PLATINUM – VANILLA
Eligibility status	Not Applicable	Pre-Existing
Package type	Foil Pouch	Foil Pouch
Package quantity	5 Cigar Wrappers	2 Cigar Wrappers
Characterizing flavor(CF)	Flavored	Flavored
Flavored CF, as identified	Vanilla	Vanilla
Nicotine source	Tobacco	Tobacco
Additional properties	Length: 114.3 mm Width: 50.8 mm Mass: 763 mg Wrapper material: Tobacco	Length: 114.3 mm Width: 50.8 mm Mass: 763 mg Wrapper material: Tobacco

SE0021835.PD2, SE0022268.PD2, SE0022270.PD2, SE0022271.PD2, SE0022273.PD2, SE0022274.PD2, SE0022276.PD2, SE0022293.PD2, SE0022295.PD2, SE0022296.PD2, SE0022297.PD2, SE0022298.PD2, SE0022299.PD2, SE0022312.PD2, SE0022313.PD2, SE0022317.PD2, SE0022319.PD2, SE0022327.PD2, SE0022329.PD2 and SE0022330.PD2

Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0022297.PD2	GF1909068
Product name	BLUNT MASTER CIGAR WRAP - GRAPE	BLUNT WRAP PLATINUM – GRAPE-A-LICIOUS
Eligibility status	Not Applicable	Pre-Existing
Package type	Foil Pouch	Foil Pouch
Package quantity	4 Cigar Wrappers	2 Cigar Wrappers
Characterizing flavor(CF)	Flavored	Flavored
Flavored CF, as identified	Grape	Grape
Nicotine source	Tobacco	Tobacco
Additional properties	Length: 114.3 mm Width: 50.8 mm Mass: 763 mg Wrapper material: Tobacco	Length: 114.3 mm Width: 50.8 mm Mass: 763 mg Wrapper material: Tobacco
STN	SE0022298.PD2	GF1909068
Product name	BLUNT MASTER CIGAR WRAP - GRAPE	BLUNT WRAP PLATINUM – GRAPE-A-LICIOUS
Eligibility status	Not Applicable	Pre-Existing
Package type	Foil Pouch	Foil Pouch
Package quantity	5 Cigar Wrappers	2 Cigar Wrappers
Characterizing flavor(CF)	Flavored	Flavored
Flavored CF, as identified	Grape	Grape
Nicotine source	Tobacco	Tobacco
Additional properties	Length: 114.3 mm Width: 50.8 mm Mass: 763 mg Wrapper material: Tobacco	Length: 114.3 mm Width: 50.8 mm Mass: 763 mg Wrapper material: Tobacco
STN	SE0022299.PD2	GF2011307
Product name	LOADED NATURAL LEAF - BLUEBERRY	JUICY BLUNTS NATURAL LEAF WRAPPER - BLUEBERRY ¹⁶
Eligibility status	Not Applicable	Pre-Existing
Package type	Foil Pouch	Foil Pouch
Package quantity	3 Cigar Wrappers	8 Cigar Wrappers
Characterizing flavor(CF)	Flavored	Flavored
Flavored CF, as identified	Grape	Grape
Nicotine source	Blueberry	Blueberry
Additional properties	Length: 114.3 mm Width: 50.8 mm Wrapper material: Tobacco	Length: 114.3 mm Width: 50.8 mm Wrapper material: Tobacco

SE0021835.PD2, SE0022268.PD2, SE0022270.PD2, SE0022271.PD2, SE0022273.PD2, SE0022274.PD2, SE0022276.PD2, SE0022293.PD2, SE0022295.PD2, SE0022296.PD2, SE0022297.PD2, SE0022298.PD2, SE0022299.PD2, SE0022312.PD2, SE0022313.PD2, SE0022317.PD2, SE0022319.PD2, SE0022327.PD2, SE0022329.PD2 and SE0022330.PD2

Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0022312.PD2	GF1909083
Product name	BLUNT MASTER CIGAR WRAP - CHOCOLATE	BLUNT WRAP PLATINUM-CHOCOLATE
Eligibility status	Not Applicable	Pre-Existing
Package type	Foil Pouch	Foil Pouch
Package quantity	4 Cigar Wrappers	2 Cigar Wrappers
Characterizing flavor(CF)	Flavored	Flavored
Flavored CF, as identified	Chocolate	Chocolate
Nicotine source	Tobacco	Tobacco
Additional properties	Length: 114.3 mm Width: 50.8 mm Mass: 763 mg Wrapper material: Tobacco	Length: 114.3 mm Width: 50.8 mm Mass: 763 mg Wrapper material: Tobacco
STN	SE0022313.PD2	GF1909069
Product name	BLUNT MASTER CIGAR WRAP - MANGO	BLUNT WRAP PLATINUM - MELLO MANGO
Eligibility status	Not Applicable	Pre-Existing
Package type	Foil Pouch	Foil Pouch
Package quantity	4 Cigar Wrappers	2 Cigar Wrappers
Characterizing flavor(CF)	Flavored	Flavored
Flavored CF, as identified	Mango	Mango
Nicotine source	Tobacco	Tobacco
Additional properties	Length: 114.3 mm Width: 50.8 mm Mass: 763 mg Wrapper material: Tobacco	Length: 114.3 mm Width: 50.8 mm Mass: 763 mg Wrapper material: Tobacco
STN	SE0022317.PD2	GF1909027
Product name	BLUNT MASTER CIGAR WRAP - STRAWBERRY KIWI	BLUNT WRAP PLATINUM - STRAWBERRY KIWI
Eligibility status	Not Applicable	Pre-Existing
Package type	Foil Pouch	Foil Pouch
Package quantity	4 Cigar Wrappers	2 Cigar Wrappers
Characterizing flavor(CF)	Flavored	Flavored
Flavored CF, as identified	Strawberry Kiwi	Strawberry Kiwi
Nicotine source	Tobacco	Tobacco
Additional properties	Length: 114.3 mm Width: 50.8 mm Mass: 763 mg Wrapper material: Tobacco	Length: 114.3 mm Width: 50.8 mm Mass: 763 mg Wrapper material: Tobacco

SE0021835.PD2, SE0022268.PD2, SE0022270.PD2, SE0022271.PD2, SE0022273.PD2, SE0022274.PD2, SE0022276.PD2, SE0022293.PD2, SE0022295.PD2, SE0022296.PD2, SE0022297.PD2, SE0022298.PD2, SE0022299.PD2, SE0022312.PD2, SE0022313.PD2, SE0022317.PD2, SE0022319.PD2, SE0022327.PD2, SE0022329.PD2 and SE0022330.PD2

Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0022319.PD2	GF1909028
Product name	BLUNT MASTER CIGAR WRAP - VANILLA	BLUNT WRAP PLATINUM - VANILLA
Eligibility status	Not Applicable	Pre-Existing
Package type	Foil Pouch	Foil Pouch
Package quantity	4 Cigar Wrappers	2 Cigar Wrappers
Characterizing flavor(CF)	Flavored	Flavored
Flavored CF, as identified	Vanilla	Vanilla
Nicotine source	Tobacco	Tobacco
Additional properties	Length: 114.3 mm Width: 50.8 mm Mass: 763 mg Wrapper material: Tobacco	Length: 114.3 mm Width: 50.8 mm Mass: 763 mg Wrapper material: Tobacco
STN	SE0022327.PD2	GF1909072
Product name	Show Diamond Wrap - Purple	Blunt Wrap Platinum-Purple
Eligibility status	Not Applicable	Pre-Existing
Package type	Foil Pouch	Foil Pouch
Package quantity	3 Cigar Wrappers	2 Cigar Wrappers
Characterizing flavor(CF)	Tobacco	Tobacco
Nicotine source	Tobacco	Tobacco
Additional properties	Length: 114.3 mm Width: 50.8 mm Wrapper material: Tobacco	Length: 114.3 mm Width: 50.8 mm Wrapper material: Tobacco
STN	SE0022329.PD2	GF1909028
Product name	Show Diamond Wrap - Vanilla	Blunt Wrap Platinum - Vanilla
Eligibility status	Not Applicable	Pre-Existing
Package type	Foil Pouch	Foil Pouch
Package quantity	3 Cigar Wrappers	2 Cigar Wrappers
Characterizing flavor(CF)	Flavored	Flavored
Flavored CF, as identified	Vanilla	Vanilla
Nicotine source	Tobacco	Tobacco
Additional properties	Length: 114.3 mm Width: 50.8 mm Wrapper material: Tobacco	Length: 114.3 mm Width: 50.8 mm Wrapper material: Tobacco

SE0021835.PD2, SE0022268.PD2, SE0022270.PD2, SE0022271.PD2, SE0022273.PD2, SE0022274.PD2, SE0022276.PD2, SE0022293.PD2, SE0022295.PD2, SE0022296.PD2, SE0022297.PD2, SE0022298.PD2, SE0022299.PD2, SE0022312.PD2, SE0022313.PD2, SE0022317.PD2, SE0022319.PD2, SE0022327.PD2, SE0022329.PD2 and SE0022330.PD2

STN	SE0022330.PD2	GF1909029
Product name	Show Diamond Wrap - Watermelon	Blunt Wrap Platinum- Watermelon
Eligibility status	Not Applicable	Pre-Existing
Package type	Foil Pouch	Foil Pouch
Package quantity	3 Cigar Wrappers	2 Cigar Wrappers
Characterizing flavor(CF)	Flavored	Flavored
Flavored CF, as identified	Watermelon	Watermelon
Nicotine source	Tobacco	Tobacco
Additional properties	Length: 114.3 mm Width: 50.8 mm Wrapper material: Tobacco	Length: 114.3 mm Width: 50.8 mm Wrapper material: Tobacco

SE0021835.PD2, SE0022268.PD2, SE0022270.PD2, SE0022271.PD2, SE0022273.PD2, SE0022274.PD2, SE0022276.PD2, SE0022293.PD2, SE0022295.PD2, SE0022296.PD2, SE0022297.PD2, SE0022298.PD2, SE0022299.PD2, SE0022312.PD2, SE0022313.PD2, SE0022317.PD2, SE0022319.PD2, SE0022327.PD2, SE0022329.PD2 and SE0022330.PD2

Appendix B. Amendments

Table 2. Amendments

Submission Date	Receipt Date	Applications being amended	Reviewed	Brief Description
January 26, 2023	January 27, 2023	All	Yes	Response to January 12, 2023, FDA Information Request