

Technical Project Lead (TPL) Review of SE Reports

New Products Subject of this Review ¹	
STNs	SE0021836.PD2, SE0023107.PD2, SE0023108.PD2, SE0023119.PD2 - SE0023129.PD2, SE0023131.PD2, SE0023133.PD2 - SE0023137.PD2
Common Attributes	
Submission date	September 09, 2020
Receipt date	September 09, 2020
Applicant	National Tobacco Company LP
Product manufacturer	National Tobacco Company LP
Application type	Different Characteristics
Application subtype	Regular
Product category	Cigars
Product subcategory	Cigar Component
Cross-Referenced Submissions	
All STNs	(b) (4) and (b) (4)
Supporting FDA Memoranda Relied Upon in this Review	
All STNs	Equivalence Testing for SE Evaluations (February 24, 2017); Addendum to February 24, 2017, Equivalence Testing for SE Evaluations Memo (April 16, 2019) Product quantity changes in Substantial Equivalence Reports (SE Reports) for statutorily regulated tobacco products (December 07, 2017) and addenda (December 31, 2019, and February 03, 2023)
Recommendation	
Issue Substantially Equivalent (SE) orders for the new tobacco products subject of this review.	

Technical Project Lead (TPL):

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Date: 2024.10.24 12:45:26 -04'00'

Prashanthi Mulinti, Ph.D.
Microbiology Branch Chief,
Division of Product Science
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Signatory Decision:

Concur with TPL recommendation and basis of recommendation

Todd L. Cecil -S Digitally signed by Todd L. Cecil -S
Date: 2024.12.06 10:24:26 -05'00'

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

¹ Product 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).

TABLE OF CONTENTS

1. BACKGROUND.....	3
1.1. NEW AND PREDICATE PRODUCTS	3
1.2. REGULATORY ACTIVITY	3
1.3. SCOPE OF REVIEW	3
2. COMPLIANCE REVIEW	3
3. SCIENTIFIC REVIEW	4
3.1. CHEMISTRY	4
3.2. ENGINEERING	5
3.3. TOXICOLOGY	6
3.4. MICROBIOLOGY	7
4. ENVIRONMENTAL DECISION.....	8
5. CONCLUSION AND RECOMMENDATION	8
6. APPENDICES.....	10
APPENDIX A. NEW AND PREDICATE PRODUCTS.....	10
APPENDIX B. AMENDMENTS AND ADDITIONAL SUBMISSIONS RECEIVED	17

LIST OF TABLES

Table 1. Disciplines reviewed.....	3
Table 2. Consultation	3
Table 3. Amendments	17

1. BACKGROUND

1.1. NEW AND PREDICATE PRODUCTS

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

1.2. REGULATORY ACTIVITY

On September 09, 2020, FDA received SE Reports from National Tobacco Company LP. FDA issued Acceptance letters to the applicant on November 13, 2020.

See Appendix for products and amendments.

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 reviewed²

Discipline	Cycle 1		Cycle 2	
	Reviewer	Review Date	Reviewers	Review Date
Chemistry ³	Yuan-Wei Nei	3/27/2023	Yuan-Wei Nei	1/24/2024
Engineering	Michele Darbeau	3/21/2023	Michele Darbeau	1/22/2024
Toxicology	Sagie Wagage	3/21/2023	Sagie Wagage	1/4/2024
Microbiology	Nikhil Kumar	3/20/2023	Victoria Quadrini	1/26/2024
Environmental Science	Corey DeBoom	3/20/2023	Corey DeBoom	12/29/2023

Table 2. Consultation

Discipline	Reviewer	Review Date
Social Science	Michael Halenar	3/21/2023

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 products⁴ (i.e., were commercially marketed in the United States as of February 15, 2007). The OCE reviews dated November 29, 2023⁵, and November 30, 2023⁶, conclude that the evidence submitted by the applicant is adequate

² N/A: Not applicable

³ The applicant referenced two tobacco product master files (TPMFs), (b) (4) and (b) (4) for tobacco blend information and descriptions of quantitative test protocols including validation reports which were reviewed by Yuan-wei Nei on January 23, 2024, and contain sufficient information to support the chemistry review.

⁴ 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.

⁵ For SE0021836.PD2, SE0023107.PD2, SE0023108.PD2, SE0023120.PD2 - SE0023123.PD2, SE0023125.PD2, SE0023126.PD2, SE0023129.PD2, SE0023131.PD2, SE0023133.PD2

⁶ For SE0023119.PD2, SE0023124.PD2, SE0023127.PD2, SE0023128.PD2, SE0023134.PD2 - SE0023137.PD2

to demonstrate that the predicate products are pre-existing products and, therefore, are eligible predicate products.

OCE also completed a review 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 review dated January 16, 2024, conclude that the new products are in compliance with the FD&C Act.

3. SCIENTIFIC REVIEW

Scientific reviews were completed by the Office of Science (OS) for the following disciplines:

3.1. CHEMISTRY

The final chemistry review concludes that the new products have different characteristics compared to the corresponding predicate products, but the differences do not cause the new products to raise different questions of public health from a chemistry perspective.

The new and corresponding predicate products are cigar components (wrappers). The applicant provided certification statements for all SE Reports stating that all new products differ from the corresponding predicate products in increased product quantity, reduced target length and target width (and thus a reduced product mass), and different quantities and types of flavoring additive ingredients. Additionally, the new products in SE0021836.PD2, SE0023107.PD2, and SE0023108.PD2 differ from the predicate product in packaging materials (blister pack and foil vs foil), additions of a small amount (b) (4) milligram) of adhesive, and a paperboard tip. The paperboard tip is not intended to be combusted during normal usage of the product and therefore not expected to contribute HPHC smoke yields of the new products compared to the predicate product and does not cause the new products to raise different questions of public health. However, differences in wrapper size and ingredients (i.e., adhesive, and complex flavoring ingredients) could potentially affect the mainstream smoke (MSS) yields of the new products compared to the corresponding predicate products. The applicant provided complete data sets and method information for all HPHC (i.e., tar, nicotine, carbon monoxide [TNCO], (b) (4), and total particulate matter [TPM] yields) testing performed under CORESTA (Cooperation Centre for Scientific Research Relative to Tobacco) smoking regimen. The smoke yields of each analyte were determined to be analytically inequivalent but lower (15 – 95%) in the new products, using a two one sided t-test (TOST) approach combined with a Horwitz-Thompson estimation, compared to the corresponding predicate products. The applicant also provided complete ingredient information for the adhesive added to the new products in SE0021836.PD2, SE0023107.PD2, and SE0023108.PD2 and screened the adhesive for the presence of polycyclic aromatic hydrocarbons (PAHs). The test results indicate that the adhesive used in these new products does not contain detectable levels of PAHs in the new products. Therefore, the addition of adhesive to the new products in SE0021836.PD2, SE0023107.PD2, and SE0023108.PD2 is acceptable and does not cause the new products to raise different questions of public health from a chemistry perspective. A toxicological evaluation of the ingredients in the adhesive is included in section 3.3 of this review. The applicant also provided the tobacco filler weight ratio between the new and corresponding predicate products from when the products are rolled with unidentified tobacco filler and machine smoked by a third-

party contract laboratory. For SE0023119.PD2-SE0023129.PD2, SE0023131.PD2, and SE0023133.PD2-SE0023137.PD2, the predicate products required 1.6-1.9 times more tobacco filler by weight than the corresponding new products. However, for SE0021836.PD2, SE0023107.PD2, and SE0023108.PD2, the predicate product required 5.5-5.6 times more tobacco filler by weight than the corresponding new products. Although a reduction of tobacco filler by weight in the new products is likely to reduce MSS yields of HPHCs in the new products, as supported by the smoke HPHC data provided by the applicant, these significant decreases in tobacco filler weight in the new products of SE0021836.PD2, SE0023107.PD2, and SE0023108.PD2 compared to the predicate product may influence consumers' use behavior when switching from the predicate product to the corresponding new products. A social science consultation was initiated, and it was concluded that based on currently available scientific evidence on the influence of the size of cigar wrapper cones on consumer perceptions, use intentions, or product use, the reductions in product size in SE0021836.PD2, SE0023107.PD2, and SE0023108.PD2, do not cause the new products to raise different questions of public health from a Social Science perspective.

Therefore, the differences in characteristics between the new and corresponding predicate products do not cause the new products to raise different questions of public health from a chemistry perspective.

3.2. ENGINEERING

The final engineering review concludes that the new products have different characteristics compared to the corresponding predicate products, but the differences do not cause the new products to raise different questions of public health from an engineering perspective.

The applicant provided design parameter target specifications and range limits for cigar wrapper length and width. All new products show decreases in length and width compared to the corresponding predicate products which could directly influence the area through which air is permitted to enter the tobacco column, which, in turn, may affect puff count and smoke constituent (TNCO) yields. However, per discussion in section 3.1 above on smoke HPHC data, these differences in wrapper length and width are acceptable for new products and do not cause the new products to raise different questions of public health. For wrapper porosity and basis weight, the applicant did not provide target specifications and range limits for new and corresponding predicate products. However, the applicant stated that the same base homogenized sheet wrapper is used for both products and indicated that the supplier does not use target specifications for either of these parameters. Instead, they use an acceptable tolerance range for wrapper porosity and for basis weight they use target bone dry sheet weight (g/ft²) as well as a target moisture (%) with acceptable tolerance ranges. The manufacturer data sheet specification (MDSS) provided by the applicant identifies that the manufacturer's acceptable tolerance range for wrapper porosity (0 to 50 CORESTA Unit [CU]) and for bone dry sheet weight and moisture used for basis weight are identical for all new and corresponding predicate products, which indicates that the manufacture of new products is as well-controlled as the corresponding predicate products for wrapper porosity and basis weight. The applicant also provided test data for wrapper porosity and basis weight. The average test data and acceptance criteria provided by the applicant for porosity and basis weight are used as target specifications and the upper and lower range limits for each parameter. The test data for wrapper porosity falls within the manufacturer's acceptable tolerance range for all new and

corresponding predicate products. However, except for SE0023108. PD2 and SE0023133. PD2, the target specification for wrapper porosity of all new products either increased or decreased substantially ($\geq 5\%$) compared to the corresponding predicate products. Additionally, the new products in SE0023119.PD2, SE0023128.PD2, SE0023135.PD2, SE0023136. PD2, and SE0023137. PD2 also showed decreases ($\geq 5\%$) in target specification for basis weight compared to the predicate product. These differences could potentially affect puff count and smoke constituent yields. However, per discussion in section 3.1 above on smoke HPHC data, these differences in wrapper porosity and basis weight are acceptable for new products and do not cause the new products to raise different questions of public health.

Therefore, the differences in characteristics between the new and corresponding predicate products do not cause the new products to raise different questions of public health from an engineering perspective.

3.3. TOXICOLOGY

The final toxicology review concludes that the new products have different characteristics compared to the corresponding predicate products, but the differences do not cause the new products to raise different questions of public health from a toxicology perspective.

The new products include lower levels of total complex flavor ingredients compared to the corresponding predicate products. Additionally, multiple individual flavor ingredients are either added or removed or used at higher or lower levels in the new products compared to the corresponding predicate products. The ingredients that are used at higher or lower levels in the new products include potential genotoxicants, irritants, and/or permeation enhancers. However, the mass of all new products is lower than the mass of the corresponding predicate products. Given their smaller sizes, the new products are expected to be used with lower amounts of tobacco filler, which is likely to impact their total HPHC yields. Based on the discussion in section 3.1 above on smoke HPHC data, these differences in complex flavor ingredients are acceptable for new products and do not cause the new products to raise different questions of public health from a toxicological perspective. For SE0021836.PD2, SE0023107.PD2, and SE0023108.PD2, the difference in packaging materials (bister pack and foil pouch vs foil pouch) between the new and predicate products and the additions of paperboard tip and adhesive to the new products could be a concern for toxicology. The blister pack used for the new products consists of polyethylene terephthalate, which has the potential to leach antimony and endocrine disrupters. The applicant stated that the material used in the blister pack complies with 21 C.F.R. §177.1630. Although this section of the Code of Federal Regulations applies to polyethylene phthalate polymers that contact food and does not apply to tobacco products, it indicates that the packaging material does not produce high total levels of extractables under the conditions required for compliance with 21 C.F.R. §177.1630. Therefore, the packaging material used for the new products in SE0021836.PD2, SE0023107.PD2, and SE0023108.PD2 does not cause the new products to raise different questions of public health from a toxicology perspective. The paperboard tip used in the new products is inserted into the conical wrappers and is not intended to be combusted. Therefore, direct oral or dermal contact with the tip is expected to be minimal and the use of the tip in the new products is not expected to substantially impact HPHC yields. Additionally, direct oral or dermal contact with the adhesive is not expected due to the location of the applied adhesive in the new products. However, the adhesive is applied to the combusted portion of the new products, which may result in user

inhalation exposure to adhesive ingredients. Inhalation of one the ingredients used in the adhesive, (b) (4) has the potential to result in severe respiratory toxicity. The applicant used a no observed adverse effect concentration (NOAEC) derived from a 28-day rat inhalation study to calculate a margin of exposure of (b) (4) for (b) (4) from new product use. The applicant did not provide information to demonstrate that the calculated margin of exposure to (b) (4) adequately accounts for the uncertainties associated with extrapolating from an acute rodent study to chronic exposures in human populations. However, (b) (4) is likely to be pyrolyzed during product use, potentially limiting user exposure. Additionally, the new products in SE0021836.PD2, SE0023107.PD2, and SE0023108.PD2 have a smaller mass than the predicate product and are expected to be used with lower amounts of tobacco filler, which is likely to impact their HPHC yields and toxicant exposures. Therefore, although the predicate product in SE0021836.PD2, SE0023107.PD2, and SE0023108.PD2 does not contain (b) (4) the smaller size of the new products could potentially affect cumulative toxic effects due to new product use. Based on the levels of (b) (4) in the finished new products (up to (b) (4) µg), the potential for pyrolysis of (b) (4) and the overall differences between the new and predicate products, (b) (4) from the adhesive added to the new products in SE0021836.PD2, SE0023107.PD2, and SE0023108.PD2 and the use of adhesive in these new products is unlikely to raise different questions of public health from a toxicological perspective.

Therefore, the differences in characteristics between the new and corresponding predicate products do not cause the new products to raise different questions of public health from a toxicology perspective.

3.4. MICROBIOLOGY

The final microbiology review concludes that the new products have different characteristics compared to the corresponding predicate products, but the differences do not cause the new products to raise different questions of public health from a microbiology perspective.

The new and corresponding predicate products differ in complex flavor ingredients which result in differences in humectants (i.e., (b) (4) and (b) (4)) that could potentially affect microbial growth and product stability of the new products. Additionally, the new products compared to the corresponding predicate products also show decreases in (b) (4) (b) (4), a humectant, that is added as an ingredient to both products. However, the amounts of (b) (4) or (b) (4) contributed by the complex flavors, or the amount of (b) (4) added is ≤2% of the total product mass of the new and corresponding predicate products. Further, between the new and corresponding predicate products, the difference in the amounts of (b) (4) or (b) (4) or (b) (4) as a percentage of total product mass is ≤0.7%. Therefore, these differences in (b) (4), and (b) (4) are not expected to impact microbial stability of the new products and do not cause the new products to raise different questions of public health from a microbiology perspective. The new and corresponding predicate products in SE0023119.PD2–SE0023129.PD2, SE0023131.PD2, and SE0023133.PD2–SE0023137.PD2) have identical container closure system (CCS) (foil pouch) which is acceptable for microbiology. However, the new products in SE0021836.PD2, SE0023107.PD2, and SE0023108.PD2 are packaged in a blister pack within a foil pouch, while the predicate product is packaged in a foil pouch. Difference in CCS could potentially and water activity (a_w). Increases in a_w could impact microbial growth which in turn could impact levels of carcinogenic tobacco specific nitrosamines (TSNAs) in the products. However, in response to the

Deficiency letter, the applicant clarified that the blister pack within the foil pouch of the new products is intended to help maintain the shape of the product in the foil pouch and provided photographs that substantiated that the blister pack is only closed by tucking one edge of the pack under another edge but not sealed. Therefore, the new and predicate products in SE0021836.PD2, SE0023107.PD2, and SE0023108.PD2 have identical CCS (i.e., foil pouch). The applicant also provided a_w data which showed decreases (16 – 18%) in the new products compared to the predicate product which are acceptable and do not cause the new products to raise different questions of public health from a microbiology perspective.

Therefore, the differences in characteristics between the new and corresponding predicate products do not cause the new products to raise different questions of public health from a microbiology perspective.

4. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Luis Valerio, Ph.D. on January 5, 2024. The FONSI was supported by an environmental assessment prepared by FDA on January 4, 2024.

5. CONCLUSION AND RECOMMENDATION

The new and corresponding predicate products have the following characteristics:

- All SE Reports:
 - 52 -54% decrease in length; 62 – 73% decrease in width; 81 – 90% decrease in mass, and 69-89% decrease in complex flavor ingredients
- SE0023120.PD2, SE0023124.PD2, SE0023125.PD2, SE0023127.PD2, SE0023134.PD2
 - 7 -23% decrease in porosity
- SE0023119.PD2, SE0023135.PD2, and SE0023137.PD2
 - 7 – 23% decrease in porosity; 5 – 10% decrease in basis weight
- SE0023128.PD2, and SE0023136.PD2
 - 16 – 95% increase in porosity; 5 – 10% decrease in basis weight
- SE0021836.PD2, SE0023107.PD2, SE0023121.PD2-SE0023123.PD2, SE0023126.PD2, SE0023129.PD2, and SE0023131.PD2
 - 16 – 95% increase in wrapper porosity
- SE0021836.PD2, SE0023107.PD2, and SE0023108.PD2
 - addition of adhesive
 - addition of a non-combusted paperboard tip
 - difference in packaging material (blister pack and foil pouch vs foil pouch)
 - package quantity of two pre-formed cones vs one cigar wrapper
- SE0023119.PD2 - SE0023129.PD2, SE0023131.PD2, SE0023133.PD2 - SE0023137.PD2
 - package quantity of two or four cigar wrappers vs one cigar wrapper

I concur with the conclusions of all the scientific reviews that the applicant has demonstrated that these differences in characteristics do not cause the new products to raise different questions of public health as described in sections 3.1-3.4 above. The new products have differences in product quantity, design parameters (i.e., length, width, mass, porosity and basis weight), and ingredients (i.e., packaging materials, adhesive and flavors) when compared to the corresponding predicate products that could potentially impact smoke HPHC yields. Differences in design parameters and

ingredients are adequately addressed based on the lower smoke HPHC yields in the new products compared to the corresponding predicate products. Additionally, the differences in ingredients are also acceptable from a toxicology perspective as discussed in section 3.3 above. Further, based on the memos cited in this review, at this time there is insufficient social science evidence to determine that product quantity changes between any new and corresponding predicate product would cause the new products to raise different questions of public health. Therefore, the differences in characteristics between the new and corresponding predicate products do not cause the new products to raise different questions of public health.

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.

6. APPENDICES

Appendix A. New and predicate products

Common Attributes ^{7,8,9,10,11,12}	
Submission date	September 09, 2020
Receipt date	September 09, 2020
Applicant	National Tobacco Company LP
Product manufacturer	National Tobacco Company LP
Product category	Cigars
Product subcategory	Cigar Component

⁷ We interpret package type to mean container closure system and package quantity to mean product quantity within the container closure system, unless otherwise identified.

⁸ Product name is brand/sub-brand or other commercial name used in commercial distribution.

⁹ Effective April 14, 2022, FDA's authority to regulate tobacco products was extended to include tobacco products containing nicotine from any source. Therefore, nicotine source should be included in future submissions.

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

¹¹ Attributes in Appendix A may display converted values.

¹² 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.

Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0021836.PD2	GF1909047
Product name	ZIG-ZAG CONES BLUEBERRY	Super Juicy - Black n Blueberry
Eligibility status	Not Applicable (N/A)	Pre-Existing Tobacco Product
Package type	Blister Pack Inside a Foil Pouch	Foil Pouch
Product quantity	2 Cones	1 Wrapper
Characterizing flavor (CF)	Flavored	Flavored
Flavored CF, as identified	Blueberry	Black n Blueberry
Nicotine source	Tobacco	Tobacco
Length: ¹³	105 millimeter (mm)	228.6 mm
Width: ¹³	48 mm	127 mm
Diameter:	13.29 mm	N/A
Additional Property:	Mass: 663 milligram (mg)	Mass: 4380 mg
STN	SE0023107.PD2	GF1909047
Product name	ZIG-ZAG CONES DRAGONBERRY	Super Juicy - Black n Blueberry
Eligibility status	N/A	Pre-Existing Tobacco Product
Package type	Blister Pack Inside a Foil Pouch	Foil Pouch
Product quantity	2 Cones	1 Wrapper
Characterizing flavor (CF)	Flavored	Flavored
Flavored CF, as identified	Dragonberry	Black n Blueberry
Nicotine source	Tobacco	Tobacco
Length: ¹³	105 mm	228.6 mm
Width: ¹³	48 mm	127 mm
Diameter:	13.29 mm	N/A
Additional Property:	Mass: 815 mg	Mass: 4380 mg
STN	SE0023108.PD2	GF1909047
Product name	ZIG-ZAG CONES GRAPE	Super Juicy - Black n Blueberry
Eligibility status	N/A	Pre-Existing Tobacco Product
Package type	Blister Pack Inside a Foil Pouch	Foil Pouch
Product quantity	2 Cones	1 Wrapper
Characterizing flavor (CF)	Flavored	Flavored
Flavored CF, as identified	Grape	Black n Blueberry
Nicotine source	Tobacco	Tobacco
Length: ¹³	105 mm	228.6 mm
Width: ¹³	48 mm	127 mm
Diameter:	13.29 mm	N/A
Additional Property:	Mass: 821 mg	Mass: 4380 mg

¹³ Applicant submitted the length and width of each product unrolled. The new product was subsequently rolled into a conical shape for filling.

Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0023119.PD2	GF1909048
Product name	ZIG-ZAG WRAPS BLUE 'RILLO SIZE	Super Juicy - Blunt & Mild
Eligibility status	N/A	Pre-Existing Tobacco Product
Package type	Foil Pouch	Foil Pouch
Product quantity	4 Wrappers	1 Wrapper
Characterizing flavor (CF)	Tobacco	Tobacco
Nicotine source	Tobacco	Tobacco
Length:	108 mm	228.6 mm
Width:	34 mm	127 mm
Additional Property:	Mass: 456 mg	Mass: 4315 mg
STN	SE0023120.PD2	GF1909047
Product name	ZIG-ZAG WRAPS BLUEBERRY 'RILLO SIZE	Super Juicy - Black n Blueberry
Eligibility status	N/A	Pre-Existing Tobacco Product
Package type	Foil Pouch	Foil Pouch
Product quantity	4 Wrappers	1 Wrapper
Characterizing flavor (CF)	Flavored	Flavored
Flavored CF, as identified	Blueberry	Black n Blueberry
Nicotine source	Tobacco	Tobacco
Length:	108 mm	228.6 mm
Width:	34 mm	127 mm
Additional Property:	Mass: 430 mg	Mass: 4380 mg
STN	SE0023121.PD2	GF1909047
Product name	ZIG-ZAG WRAPS BLUEBERRY	Super Juicy - Black n Blueberry
Eligibility status	N/A	Pre-Existing Tobacco Product
Package type	Foil Pouch	Foil Pouch
Product quantity	2 Wrappers	1 Wrapper
Characterizing flavor (CF)	Flavored	Flavored
Flavored CF, as identified	Blueberry	Black n Blueberry
Nicotine source	Tobacco	Tobacco
Length:	110 mm	228.6 mm
Width:	48 mm	127 mm
Additional Property:	Mass: 800 mg	Mass: 4380 mg
STN	SE0023122.PD2	GF1909047
Product name	ZIG-ZAG WRAPS CHERRY	Super Juicy - Black n Blueberry
Eligibility status	N/A	Pre-Existing Tobacco Product
Package type	Foil Pouch	Foil Pouch
Product quantity	2 Wrappers	1 Wrapper
Characterizing flavor (CF)	Flavored	Flavored
Flavored CF, as identified	Cherry	Black n Blueberry
Nicotine source	Tobacco	Tobacco
Length:	110 mm	228.6 mm
Width:	48 mm	127 mm
Additional Property:	Mass: 758 mg	Mass: 4380 mg

Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0023123.PD2	GF1909047
Product name	ZIG-ZAG WRAPS DRAGONBERRY	Super Juicy - Black n Blueberry
Eligibility status	N/A	Pre-Existing Tobacco Product
Package type	Foil Pouch	Foil Pouch
Product quantity	2 Wrappers	1 Wrapper
Characterizing flavor (CF)	Flavored	Flavored
Flavored CF, as identified	Dragonberry	Black n Blueberry
Nicotine source	Tobacco	Tobacco
Length:	105 mm	228.6 mm
Width:	48 mm	127 mm
Additional Property:	Mass: 722 mg	Mass: 4380 mg
STN	SE0023124.PD2	GF1909048
Product name	ZIG-ZAG WRAPS GOLD 'RILLO SIZE	Super Juicy - Blunt & Mild
Eligibility status	N/A	Pre-Existing Tobacco Product
Package type	Foil Pouch	Foil Pouch
Product quantity	4 Wrappers	1 Wrapper
Characterizing flavor (CF)	Tobacco	Tobacco
Nicotine source	Tobacco	Tobacco
Length:	108 mm	228.6 mm
Width:	34 mm	127 mm
Additional Property:	Mass: 462 mg	Mass: 4315 mg
STN	SE0023125.PD2	GF1909047
Product name	ZIG-ZAG WRAPS GRAPE 'RILLO SIZE	Super Juicy - Black n Blueberry
Eligibility status	N/A	Pre-Existing Tobacco Product
Package type	Foil Pouch	Foil Pouch
Product quantity	4 Wrappers	1 Wrapper
Characterizing flavor (CF)	Flavored	Flavored
Flavored CF, as identified	Grape	Black n Blueberry
Nicotine source	Tobacco	Tobacco
Length:	108 mm	228.6 mm
Width:	34 mm	127 mm
Additional Property:	Mass: 510 mg	Mass: 4380 mg
STN	SE0023126.PD2	GF1909047
Product name	ZIG-ZAG WRAPS GRAPE	Super Juicy - Black n Blueberry
Eligibility status	N/A	Pre-Existing Tobacco Product
Package type	Foil Pouch	Foil Pouch
Product quantity	2 Wrappers	1 Wrapper
Characterizing flavor (CF)	Flavored	Flavored
Flavored CF, as identified	Grape	Black n Blueberry
Nicotine source	Tobacco	Tobacco
Length:	110 mm	228.6 mm
Width:	48 mm	127 mm
Additional Property:	Mass: 699 mg	Mass: 4380 mg

Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0023127.PD2	GF1909047
Product name	ZIG-ZAG WRAPS GREEN 'RILLO SIZE	Super Juicy - Blunt & Mild
Eligibility status	N/A	Pre-Existing Tobacco Product
Package type	Foil Pouch	Foil Pouch
Product quantity	4 Wrappers	1 Wrapper
Characterizing flavor (CF)	Tobacco	Tobacco
Nicotine source	Tobacco	Tobacco
Length:	108 mm	228.6 mm
Width:	34 mm	127 mm
Additional Property:	Mass: 484 mg	Mass: 4315 mg
STN	SE0023128.PD2	GF1909048
Product name	ZIG-ZAG WRAPS ISLAND	Super Juicy - Blunt & Mild
Eligibility status	N/A	Pre-Existing Tobacco Product
Package type	Foil Pouch	Foil Pouch
Product quantity	2 Wrappers	1 Wrapper
Characterizing flavor (CF)	Tobacco	Tobacco
Nicotine source	Tobacco	Tobacco
Length:	105 mm	228.6 mm
Width:	48 mm	127 mm
Additional Property:	Mass: 604 mg	Mass: 4315 mg
STN	SE0023129.PD2	GF1909047
Product name	ZIG-ZAG WRAPS MANGO	Super Juicy - Black n Blueberry
Eligibility status	N/A	Pre-Existing Tobacco Product
Package type	Foil Pouch	Foil Pouch
Product quantity	2 Wrappers	1 Wrapper
Characterizing flavor (CF)	Flavored	Flavored
Flavored CF, as identified	Mango	Black n Blueberry
Nicotine source	Tobacco	Tobacco
Length:	110 mm	228.6 mm
Width:	48 mm	127 mm
Additional Property:	Mass: 725 mg	Mass: 4380 mg
STN	SE0023131.PD2	GF1909047
Product name	ZIG-ZAG WRAPS ORANGE	Super Juicy - Black n Blueberry
Eligibility status	N/A	Pre-Existing Tobacco Product
Package type	Foil Pouch	Foil Pouch
Product quantity	2 Wrappers	1 Wrapper
Characterizing flavor (CF)	Flavored	Flavored
Flavored CF, as identified	Orange	Black n Blueberry
Nicotine source	Tobacco	Tobacco
Length:	105 mm	228.6 mm
Width:	48 mm	127 mm
Additional Property:	Mass: 706 mg	Mass: 4380 mg

Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0023133.PD2	GF1909047
Product name	ZIG-ZAG WRAPS PINEAPPLE	Super Juicy - Black n Blueberry
Eligibility status	N/A	Pre-Existing Tobacco Product
Package type	Foil Pouch	Foil Pouch
Product quantity	2 Wrappers	1 Wrapper
Characterizing flavor (CF)	Flavored	Flavored
Flavored CF, as identified	Pineapple	Black n Blueberry
Nicotine source	Tobacco	Tobacco
Length:	105 mm	228.6 mm
Width:	48 mm	127 mm
Additional Property:	Mass: 692 mg	Mass: 4380 mg
STN	SE0023134.PD2	GF1909048
Product name	ZIG-ZAG WRAPS PINK 'RILLO SIZE	Super Juicy - Blunt & Mild
Eligibility status	N/A	Pre-Existing Tobacco Product
Package type	Foil Pouch	Foil Pouch
Product quantity	4 Wrappers	1 Wrapper
Characterizing flavor (CF)	Tobacco	Tobacco
Nicotine source	Tobacco	Tobacco
Length:	108 mm	228.6 mm
Width:	34 mm	127 mm
Additional Property:	Mass: 547 mg	Mass: 4315 mg
STN	SE0023135.PD2	GF1909048
Product name	ZIG-ZAG WRAPS PURPLE 'RILLO SIZE	Super Juicy - Blunt & Mild
Eligibility status	N/A	Pre-Existing Tobacco Product
Package type	Foil Pouch	Foil Pouch
Product quantity	4 Wrappers	1 Wrapper
Characterizing flavor (CF)	Tobacco	Tobacco
Nicotine source	Tobacco	Tobacco
Length:	108 mm	228.6 mm
Width:	34 mm	127 mm
Additional Property:	Mass: 460 mg	Mass: 4315 mg
STN	SE0023136.PD2	GF1909048
Product name	ZIG-ZAG WRAPS STRAIGHT UP 'RILLO SIZE	Super Juicy - Blunt & Mild
Eligibility status	N/A	Pre-Existing Tobacco Product
Package type	Foil Pouch	Foil Pouch
Product quantity	4 Wrappers	1 Wrapper
Characterizing flavor (CF)	Tobacco	Tobacco
Nicotine source	Tobacco	Tobacco
Length:	108 mm	228.6 mm
Width:	34 mm	127 mm
Additional Property:	Mass: 538 mg	Mass: 4315 mg

Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0023137.PD2	GF1909048
Product name	ZIG-ZAG WRAPS STRAIGHT UP	Super Juicy - Blunt & Mild
Eligibility status	N/A	Pre-Existing Tobacco Product
Package type	Foil Pouch	Foil Pouch
Product quantity	2 Wrappers	1 Wrapper
Characterizing flavor (CF)	Tobacco	Tobacco
Nicotine source	Tobacco	Tobacco
Length:	110 mm	228.6 mm
Width:	48 mm	127 mm
Additional Property:	Mass: 761 mg	Mass: 4315 mg

Appendix B. Amendments and additional submissions received**Table 3. Amendments**

Submission Date	Receipt Date	Application being amended	Reviewed	Brief Description
February 01, 2021	February 01, 2021	SE0023119.PD2	Yes	Updated product characteristics (length, width, diameter, and product mass)
February 01, 2021	February 01, 2021	SE0023120.PD2	Yes	
February 01, 2021	February 01, 2021	SE0023121.PD2	Yes	
February 01, 2021	February 01, 2021	SE0023122.PD2	Yes	
February 01, 2021	February 01, 2021	SE0023123.PD2	Yes	
February 01, 2021	February 01, 2021	SE0023124.PD2	Yes	
February 01, 2021	February 01, 2021	SE0023125.PD2	Yes	
February 01, 2021	February 01, 2021	SE0023126.PD2	Yes	
February 02, 2021	February 02, 2021	SE0023127.PD2	Yes	
February 02, 2021	February 02, 2021	SE0023128.PD2	Yes	
February 02, 2021	February 02, 2021	SE0023129.PD2	Yes	
February 02, 2021	February 02, 2021	SE0023131.PD2	Yes	
February 02, 2021	February 02, 2021	SE0023133.PD2	Yes	
February 02, 2021	February 02, 2021	SE0023134.PD2	Yes	
February 02, 2021	February 02, 2021	SE0023135.PD2	Yes	
February 02, 2021	February 02, 2021	SE0023136.PD2	Yes	
February 02, 2021	February 02, 2021	SE0023137.PD2	Yes	
March 15, 2021	March 15, 2021	SE0023107.PD2	Yes	
March 15, 2021	March 15, 2021	SE0023107.PD2	Yes	
March 15, 2021	March 15, 2021	SE0023108.PD2	Yes	

SE0021836.PD2, SE0023107.PD2, SE0023108.PD2, SE0023119.PD2 - SE0023129.PD2, SE0023131.PD2, SE0023133.PD2 - SE0023137.PD2

Submission Date	Receipt Date	Application being amended	Reviewed	Brief Description
March 15, 2021	March 15, 2021	SE0021836.PD2	Yes	Updated product characteristics (length, width, diameter, and product mass)
August 31, 2023	August 31, 2023	SE0021836.PD2, SE0023107.PD2, SE0023108.PD2, SE0023119.PD2 - SE0023129.PD2, SE0023131.PD2, SE0023133.PD2 - SE0023137.PD2	Yes	Response to June 02, 2023, Deficiency Letter
October 10, 2023	October 10, 2023	SE0021836.PD2, SE0023107.PD2, SE0023108.PD2, SE0023119.PD2 - SE0023129.PD2, SE0023131.PD2, SE0023133.PD2 - SE0023137.PD2	Yes	Supplemental response to June 02, 2023, Deficiency Letter

Additional Submission(s) Received for This Applicant

Submit Date	Receipt Date	Reviewed	Brief Description
Not applicable (N/A)	N/A	N/A	N/A