



December 6, 2024

SUBSTANTIALLY EQUIVALENT

National Tobacco Company LP
Attention: Brittani Cushman, General Counsel & Secretary
Turning Point Brands Inc.
5201 Interchange Way
Louisville, KY 40229

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

Dear Brittani Cushman:

We have completed our review of your SE Reports¹ and determined that the new tobacco products are substantially equivalent to the corresponding predicate tobacco products listed in Appendix A² and are in compliance with the requirements of the FD&C Act. Under the provisions of section 910 and 905(j) of the FD&C Act, you may introduce or deliver for introduction into interstate commerce the new tobacco products subject of this letter. Refer to Appendix B for a list of amendments and additional submissions received.

Our findings do not constitute FDA approval of the new products specified in Appendix A; therefore, you may not, in any way, promote, include in labeling or represent the new tobacco products, specified in Appendix A, as being “approved” by FDA (see section 301(tt) of the FD&C Act).

In accordance with 40 CFR 1506.6, we will make your Environmental Assessment (EA) publicly available.

All regulated tobacco products, including the tobacco products specified in Appendix A, are subject to the requirements of the FD&C Act and its implementing regulations. It is your responsibility to ensure the tobacco products specified in Appendix A complies with all applicable statutory and regulatory requirements. FDA will monitor your compliance with all applicable statutes and regulations.

¹ Substantially Equivalent (SE) Reports submitted under section 905(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

² In addition to comparing the new tobacco products to the predicate tobacco products named by the applicant, FDA also compared the new tobacco products in these SE Reports to the grandfathered tobacco products in GF1909047 and GF1909048. Although the new products have different characteristics than the grandfathered tobacco products in SE0021836, SE0023107, SE0023108, SE0023119-SE0023129, SE0023131, SE0023133-SE0023137, FDA found that those differences do not cause the new tobacco products to raise different questions of public health, and thus the new tobacco products are also substantially equivalent to the grandfathered products in GF1909047 and GF1909048.

If you have any questions, please contact Elizabeth Do, Regulatory Health Project Manager, at 301-796-5205 or Elizabeth.Do@fda.hhs.gov.

Sincerely,

Todd L. Cecil - Digitally signed by Todd L.
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Date: 2024.12.06 10:28:29
-05'00'

Todd Cecil, Ph.D.
Deputy Director
Office of Science
Center for Tobacco Products

Enclosures:

Appendix A – New and Corresponding Predicate Tobacco Products Subject of This Letter
Appendix B – Amendments and Additional Submissions Received for This Applicant
Appendix C – Health Information Summary

Appendix A
New and Corresponding Predicate Tobacco Products Subject of This Letter

Common Attributes^{3,4,5,6,7,8}	
Submit date	September 9, 2020
Receipt date	September 9, 2020
Applicant	National Tobacco Company L.P.
Product manufacturer	Parque Industrial Emimar
Product category	Cigars
Product subcategory	Cigar Component

³ We interpret package type to mean container closure system and package quantity to mean product quantity within the container closure system, unless otherwise identified.

⁴ Product name is brand/sub-brand or other commercial name used in commercial distribution.

⁵ 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.

⁶ 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.

⁷ Attributes in Appendix A may display converted values.

⁸ 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: ⁹	105 millimeter (mm)	228.6 mm
Width: ⁹	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: ⁹	105 mm	228.6 mm
Width: ⁹	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: ⁹	105 mm	228.6 mm
Width: ⁹	48 mm	127 mm
Diameter:	13.29 mm	N/A
Additional Property:	Mass: 821 mg	Mass: 4380 mg

⁹ 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 for This Applicant

Amendments Received for These Applications

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	

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

Appendix C

Health Information Summary

Your SE Reports did not provide a summary of any health information related to the new tobacco products, required by section 910(a)(4) of the FD&C Act; however, your SE Reports stated that such information will be available upon request to any person. Consistent with the requirements of section 910(a)(4), you may wish to consider providing the following when information is requested:

- A. A copy of your final SE Reports upon which the Substantially Equivalent order was based, redacted only to the extent necessary to exclude patient identifiers and trade secret and confidential commercial information as defined in 21 CFR 20.61 and 20.63.
- B. Any research or data you have in your possession or otherwise know of specifically regarding the adverse health effects of the new tobacco products, or the following statement if such statement is accurate: “[Insert manufacturer name] does not have or know of any research or data regarding any adverse health effects specifically related to [insert tobacco product name].”

Alternatively, you may provide the following when information is requested:

- Description of the new tobacco products
- Description of the predicate tobacco products
- List of all differences in characteristics between the new and predicate tobacco products
- Summary of the evidence and scientific rationale concerning why the differences in characteristics do not raise different questions of public health
- Any research or data you have in your possession or otherwise know of regarding the adverse health effects of the new tobacco product, or the following statement if such statement is accurate: “[Insert manufacturer name] does not have or know of any research or data regarding any adverse health effects specifically related to [insert tobacco product name].”

There may be other accurate, complete, and not false or misleading ways to satisfy the requirements of section 910(a)(4) not included above. If you wish to discuss other ways to meet the requirements of section 910(a)(4), submit a meeting request to us.