



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

September 29, 2021

SUBSTANTIALLY EQUIVALENT

National Tobacco Company, L.P.
Attention: Brittani Cushman, Senior Vice President, External Affairs
Turning Point Brands, Inc.
5201 Interchange Way
Louisville, KY 40229

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

Dear Brittani Cushman:

We 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.

Our finding does not mean we “approved” the new products specified in Appendix A; therefore, you may not promote or in any way represent the new tobacco products specified in Appendix A, or the labeling, as being “approved” by FDA (see Section 301(tt) of the FD&C Act).

For information on how to fulfill the provisions of section 910(a)(4) of the FD&C Act, refer to Appendix B.

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)

Multiple STNs, see Appendix A

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If you have any questions, please contact Fredris Wiley, Regulatory Health Project Manager at (301) 348-1499 or Fredris.Wiley@fda.hhs.gov.

Sincerely,

Digitally signed by Matthew R. Holman -S

Date: 2021.09.29 12:13:29 -04'00'

Matthew R. Holman, Ph.D.

Director

Office of Science

Center for Tobacco Products

Enclosures:

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

Appendix B – Health Information Summary

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

Common Attributes of SE Reports		
Submission date	July 1, 2020	
Receipt date	July 1, 2020	
Product manufacturer	National Tobacco Company, L.P.	
Product category	Cigars	
Product subcategory	Cigar Component	
Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0016758	N/A
Product name	ZIG-ZAG NATURAL LEAF WRAPS-Watermelon ^{2,3}	Miami Blunts- Watermelon ^{2,3}
Eligibility status	Not applicable	Grandfathered
Package type	Foil Pouch	Foil Pouch
Package quantity	2 wrappers Per pouch	6 wrappers Per pouch
Chracterizing flavor	Watermelon	Watermelon
Width	70 mm	70 mm
Length	125 mm	125 mm
STN	SE0016759	N/A
Product name	ZIG-ZAG NATURAL LEAF WRAPS-Vanilla ^{2,3}	Miami Blunts - Vanilla ^{2,3}
Eligibility status	Not applicable	Grandfathered
Package type	Foil Pouch	Foil Pouch
Package quantity	2 wrappers Per pouch	6 wrappers Per pouch
Chracterizing flavor	Vanilla	Vanilla
Width	70 mm	70 mm
Length	125 mm	125 mm
STN	SE0016760	N/A
Product name	ZIG-ZAG NATURAL LEAF WRAPS-Strawberry ^{2,3}	Miami Blunts-Strawberry ^{2,3}
Eligibility status	Not applicable	Grandfathered
Package type	Foil Pouch	Foil Pouch
Package quantity	2 wrappers Per pouch	6 wrappers Per pouch
Chracterizing flavor	Strawberry	Strawberry
Width	70 mm	70 mm
Length	125 mm	125 mm

² Brand/sub-brand or other commercial name used in commercial distribution.

³ As stated by the applicant, each wrapper has a trapezoidal shape, and the provided target width and length reflect the target for the widest and the longest points of the trapezoid, respectively.

STN	SE0016761	N/A
Product name	ZIG-ZAG NATURAL LEAF WRAPS-Rum ^{2,3}	Miami Blunts - Rum ^{2,3}
Eligibility status	Not applicable	Grandfathered
Package type	Foil Pouch	Foil Pouch
Package quantity	2 wrappers Per pouch	6 wrappers Per pouch
Characterizing flavor	Rum	Rum
Width	70 mm	70 mm
Length	125 mm	125 mm
STN	SE0016762	N/A
Product name	ZIG-ZAG NATURAL LEAF WRAPS-Passion ^{2,3}	Miami Blunts - Thug Passion ^{2,3}
Eligibility status	Not applicable	Grandfathered
Package type	Foil Pouch	Foil Pouch
Package quantity	2 wrappers Per pouch	6 wrappers Per pouch
Characterizing flavor	None	None
Width	70 mm	70 mm
Length	125 mm	125 mm
STN	SE0016763	N/A
Product name	ZIG-ZAG NATURAL LEAF WRAPS-Original ^{2,3}	Miami Blunts - Natural ^{2,3}
Eligibility status	Not applicable	Grandfathered
Package type	Foil Pouch	Foil Pouch
Package quantity	2 wrappers Per pouch	6 wrappers Per pouch
Characterizing flavor	None	None
Width	70 mm	70 mm
Length	125 mm	125 mm
STN	SE0016764	N/A
Product name	ZIG-ZAG NATURAL LEAF WRAPS-Mint ^{2,3}	Miami Blunts - Mint ^{2,3}
Eligibility status	Not applicable	Grandfathered
Package type	Foil Pouch	Foil Pouch
Package quantity	2 wrappers Per pouch	6 wrappers Per pouch
Characterizing flavor	Mint	Mint
Width	70 mm	70 mm
Length	125 mm	125 mm
STN	SE0016765	N/A
Product name	ZIG-ZAG NATURAL LEAF WRAPS-Honey ^{2,3}	Miami Blunts - Honey ^{2,3}
Eligibility status	Not applicable	Grandfathered
Package type	Foil Pouch	Foil Pouch
Package quantity	2 wrappers Per pouch	6 wrappers Per pouch
Characterizing flavor	Honey	Honey
Width	70 mm	70 mm
Length	125 mm	125 mm

STN	SE0016766	N/A
Product name	ZIG-ZAG NATURAL LEAF WRAPS-Cognac ^{2,3}	Miami Blunts - Cognac ^{2,3}
Eligibility status	Not applicable	Grandfathered
Package type	Foil Pouch	Foil Pouch
Package quantity	2 wrappers Per pouch	6 wrappers Per pouch
Characterizing flavor	Cognac	Cognac
Width	70 mm	70 mm
Length	125 mm	125 mm
STN	SE0016767	N/A
Product name	ZIG-ZAG NATURAL LEAF WRAPS-Chocolate ^{2,3}	Miami Blunts - Chocolate ^{2,3}
Eligibility status	Not applicable	Grandfathered
Package type	Foil Pouch	Foil Pouch
Package quantity	2 wrappers Per pouch	6 wrappers Per pouch
Characterizing flavor	Chocolate	Chocolate
Width	70 mm	70 mm
Length	125 mm	125 mm
STN	SE0016768	N/A
Product name	ZIG-ZAG NATURAL LEAF WRAPS - Cherry ^{2,3}	Miami Blunts - Cherry ^{2,3}
Eligibility status	Not applicable	Grandfathered
Package type	Foil Pouch	Foil Pouch
Package quantity	2 wrappers Per pouch	6 wrappers Per pouch
Characterizing flavor	Cherry	Cherry
Width	70 mm	70 mm
Length	125 mm	125 mm
STN	SE0016769	N/A
Product name	ZIG-ZAG NATURAL LEAF WRAPS-Champagne ^{2,3}	Miami Blunts - Champagne ^{2,3}
Eligibility status	Not applicable	Grandfathered
Package type	Foil Pouch	Foil Pouch
Package quantity	2 wrappers Per pouch	6 wrappers Per pouch
Characterizing flavor	Champagne	Champagne
Width	70 mm	70 mm
Length	125 mm	125 mm

Appendix B

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.