



September 29, 2023

SUBSTANTIALLY EQUIVALENT

National Tobacco Company LP
Attention: Brittani Cushman
Senior Vice President, General Counsel, & Secretary
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 A. Under the provisions of sections 910 and 905(j) of the FD&C Act, you may continue to legally market 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).

To fulfill the provisions of section 910(a)(4) of the FD&C Act, you submitted a health information summary in your SE Reports. It is your responsibility under section 910(a)(4) to make your health information summary available upon request by any person.

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.

In accordance with 40 CFR 1506.6, we will make publicly available our finding that these marketing authorizations are in a class of actions categorically excluded under 21 CFR 25.35(a). No extraordinary circumstances exist for this action.

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)

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

Sincerely,

**Todd L.
Cecil -S**

Digitally signed by
Todd L. Cecil -S
Date: 2023.09.29
15:33:15 -04'00'

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 – Health Information Summary

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

Common Attributes of SE Reports^{2,3,4,5}		
Submission date	September 6, 2020	
Receipt date	September 6, 2020	
Applicant	National Tobacco Company LP	
Product manufacturer	Rab Exports E.I.R.L.	
Product category	Cigars	
Product subcategory	Unfiltered, Sheet-Wrapped Cigar	
Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0018473.PD1	GF1702364
Product name	Trivo Cigarillo Mango 2 Pk	Royal Blunts Wet Mango EZ-Duz-It
Eligibility status	Not applicable (N/A)	Pre-Existing
Package type	Foil Pouch	Foil Pouch
Product quantity	2 Cigars	1 Cigar
Characterizing flavor	Mango	Mango
Length	112 millimeter (mm)	112 mm
Diameter	11 mm	11 mm
Tip	None	None
Nicotine Source	Tobacco	Tobacco
Additional property	N/A	Ring Gauge: (b) (4)
STN	SE0018474.PD1	GF1702364
Product name	Trivo Cigarillo Mango 3 Pk	Royal Blunts Wet Mango EZ-Duz-It
Grandfathered	N/A	Pre-Existing
Package type	Foil Pouch	Foil Pouch
Product quantity	3 Cigars	1 Cigar
Characterizing flavor	Mango	Mango
Length	112 mm	112 mm
Diameter	11 mm	11 mm
Tip	None	None
Nicotine Source	Tobacco	Tobacco
Additional property	N/A	Ring Gauge: (b) (4)

²We interpret package type to mean container closure system and package quantity to mean product quantity within the container closure system, unless otherwise identified.

³ Brand/sub-brand or other commercial name used in commercial distribution.

⁴Nicotine source was not provided by the applicant; however, the application for this product was received prior to April 14, 2022, or is modifying a predicate product that was marketed prior to April 14, 2022. As such, nicotine source is classified as tobacco.

⁵FDA 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	SE0018475.PD1	GF1702365
Product name	Hype Cigarillo Purple Reserve 4 Pk	Royal Blunts Purple Haze EZ-Duz-It
Eligibility status	N/A	Pre-Existing
Package type	Foil Pouch	Foil Pouch
Product quantity	4 Cigars	1 Cigar
Characterizing flavor	None	None
Length	112 mm	112 mm
Diameter	11 mm	11 mm
Tip	None	None
Nicotine Source	Tobacco	Tobacco
Additional property	N/A	Ring Gauge: (b) (4)
STN	SE0018476.PD1	GF1702365
Product name	HI-FI Cigarillo Purple Rush 5 Pk	Royal Blunts Purple Haze EZ-Duz-It
Eligibility status	N/A	Pre-Existing
Package type	Foil Pouch	Foil Pouch
Product quantity	5 Cigars	1 Cigar
Characterizing flavor	None	None
Length	112 mm	112 mm
Diameter	11 mm	11 mm
Tip	None	None
Nicotine Source	Tobacco	Tobacco
Additional property	N/A	Ring Gauge: (b) (4)
STN	SE0018478.PD1	GF1702365
Product name	Trivo Cigarillo Purple 3 Pk	Royal Blunts Purple Haze EZ-Duz-It
Eligibility status	N/A	Pre-Existing
Package type	Foil Pouch	Foil Pouch
Product quantity	3 Cigars	1 Cigar
Characterizing flavor	None	None
Length	112 mm	112 mm
Diameter	11 mm	11 mm
Tip	None	None
Nicotine Source	Tobacco	Tobacco
Additional property	N/A	Ring Gauge: (b) (4)
STN	SE0018479.PD1	GF1702365
Product name	Trivo Cigarillo Purple 2 Pk	Royal Blunts Purple Haze EZ-Duz-It
Eligibility status	N/A	Pre-Existing
Package type	Foil Pouch	Foil Pouch
Product quantity	2 Cigars	1 Cigar
Characterizing flavor	None	None
Length	112 mm	112 mm
Diameter	11 mm	11 mm
Tip	None	None
Nicotine Source	Tobacco	Tobacco
Additional property	N/A	Ring Gauge: (b) (4)

Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0018482.PD1	GF1702339
Product name	Trivo Cigarillo Xotic Lush 2 Pk	Royal Blunts Kush EZ-Duz-It
Eligibility status	N/A	Pre-Existing
Package type	Foil Pouch	Foil Pouch
Product quantity	2 Cigars	1 Cigar
Characterizing flavor	None	None
Length	112 mm	112 mm
Diameter	11 mm	11 mm
Tip	None	None
Nicotine Source	Tobacco	Tobacco
Additional property	N/A	Ring Gauge: (b) (4)
STN	SE0018483.PD1	GF1702339
Product name	Hype Cigarillo Xotic Lush 4 Pk	Royal Blunts Kush EZ-Duz-It
Eligibility status	N/A	Pre-Existing
Package type	Foil Pouch	Foil Pouch
Product quantity	4 Cigars	1 Cigar
Characterizing flavor	None	None
Length	112 mm	112 mm
Diameter	11 mm	11 mm
Tip	None	None
Nicotine Source	Tobacco	Tobacco
Additional property	N/A	Ring Gauge: (b) (4)
STN	SE0018484.PD1	GF1702339
Product name	HI-FI Cigarillo Xotic Mix 5 Pk	Royal Blunts Kush EZ-Duz-It
Eligibility status	N/A	Pre-Existing
Package type	Foil Pouch	Foil Pouch
Product quantity	5 Cigars	1 Cigar
Characterizing flavor	None	None
Length	112 mm	112 mm
Diameter	11 mm	11 mm
Tip	None	None
Nicotine Source	Tobacco	Tobacco
Additional property	N/A	Ring Gauge: (b) (4)
STN	SE0018486.PD1	GF1702339
Product name	Trivo Cigarillo Xotic Lush 3 Pk	Royal Blunts Kush EZ-Duz-It
Eligibility status	N/A	Pre-Existing
Package type	Foil Pouch	Foil Pouch
Product quantity	3 Cigars	1 Cigar
Characterizing flavor	None	None
Length	112 mm	112 mm
Diameter	11 mm	11 mm
Tip	None	None
Nicotine Source	Tobacco	Tobacco
Additional property	N/A	Ring Gauge: (b) (4)

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.