

Technical Project Lead (TPL) Review of SE Reports

New Products Subject of this Review ¹	
STNs	SE0018473, SE0018474, SE0018475, SE0018476, SE0018478, SE0018479, SE0018482, SE0018483, SE0018484, SE0018486
Common Attributes	
Submission date	September 06, 2020
Receipt date	September 06, 2020
Applicant	National Tobacco Company LP
Product manufacturer	Rab Exports E.I.R.L.
Application type	Same Characteristics
Application subtype	Regular
Product category	Cigar
Product subcategory	Unfiltered, Sheet-Wrapped
Cross-Referenced Submissions	
All new tobacco products	None
Supporting FDA Memoranda Relied Upon in this Review	
All new tobacco products	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):

Lauren A. Deberry -S Lauren A. Deberry -S
2023.09.29 11:19:22 -04'00'

Lauren DeBerry, MPH
Senior Regulatory Health Project Manager
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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: 2023.09.29 11:41:26 -04'00'

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(s) including product static identification number (PD) if applicable SE means substantial equivalence (report).

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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

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 reviewed

Discipline	Cycle 1	
	Reviewers	Review Date
Regulatory	Sequoia Bacon	9/16/2022
Environmental science	Dilip Venugopal	8/26/2022

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 products² (i.e., were commercially marketed in the United States as of February 15, 2007). The OCE reviews, dated July 13, 2022 and May 26, 2023, conclude that the evidence submitted by the applicant is adequate to demonstrate that the predicate products are pre-existing tobacco 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 July 25, 2023, concludes 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 change in product quantity:

SE Report	New Product Quantity	Predicate Product Quantity	% Change
SE0018473, SE0018479, SE0018482	2 Cigars	1 Cigar	↑100
SE0018474, SE0018478, SE0018486	3 Cigars	1 Cigar	↑200

² 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.

SE Report	New Product Quantity	Predicate Product Quantity	% Change
SE0018475, SE0018483	4 Cigars	1 Cigar	↑300
SE0018476, SE0018484	5 Cigars	1 Cigar	↑400

OS prepared memoranda³ 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.

4. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Luis Valerio, Ph.D. on June 9, 2023. The FONSI was supported by an environmental assessment prepared by FDA on June 9, 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 in the following:

- 100% increase (1 Cigar to 2 Cigars): SE0018473, SE0018479, SE0018482
- 200% increase (1 Cigar to 3 Cigars): SE0018474, SE0018478, SE0018486
- 300% increase (1 Cigar to 4 Cigars): SE0018475, SE0018483
- 400% increase (1 Cigar to 5 Cigars): SE0018476, SE0018484

The OS memoranda³ conclude 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 tobacco products meet statutory requirements because it was determined that they are grandfathered products (i.e., were commercially marketed in the United States as of February 15, 2007).

The new tobacco 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.

³ See memorandum on product quantity changes, dated December 7, 2017, and addendum for deemed tobacco products, dated December 30, 2019.

6. APPENDICES

Appendix A. New and predicate products

Common Attributes of SE Reports ^{4,5,6}		
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)

⁴ We interpret package type to mean container closure system and package quantity to mean product quantity within the container closure system, unless otherwise identified.

⁵ Brand/sub-brand or other commercial name used in commercial distribution.

⁶ Nicotine 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.

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. Amendments

Submission Date	Receipt Date	Applications Being Amended	Reviewed	Brief Description
September 6, 2020	April 30, 2021	SE0018473	Yes	Amends original submission by submitting a signed cover letter
September 6, 2020	April 30, 2021	SE0018473	Yes	Amends original submission by submitting a signed cover letter