

Technical Project Lead (TPL) Review of SE Reports

New Products Subject of this Review	
Submission tracking numbers (STNs)	SE0016758-SE0016769
Common Attributes	
Submission date	July 1, 2020
Receipt date	July 1, 2020
Applicant	National Tobacco Company LP
Product manufacturer	National Tobacco Company LP
Application type	Regular Product Quantity
Product category	Cigars
Product subcategory	Cigar Component
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):

Digitally signed by Marcella W. Dolling -S
 Date: 2021.09.29 11:36:18 -04'00'

Marcella W. Dolling, M.S., MBA
 Chief, Regulatory Project Management Branch
 Division of Regulatory Project Management
 Office of Science

Signatory Decision:

Concur with TPL recommendation and basis of recommendation

Digitally signed by Matthew R. Holman -S
 Date: 2021.09.29 12:12:42 -04'00'

Matthew R. Holman, Ph.D.
 Director
 Office of Science

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 3

4. ENVIRONMENTAL DECISION..... 4

5. CONCLUSION AND RECOMMENDATION 4

6. APPENDICES 5

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

See Appendices for products and amendments.

1.3. SCOPE OF REVIEW

This review captures all compliance, regulatory, and scientific reviews completed for the new products that are the subject of this review.

Table 1. Disciplines reviewed

Discipline	Cycle 1	
	Reviewers	Review Date
Regulatory	Ravi Choudhuri	7/8/2020
	Rida Tariq	9/28/2021
Environmental Science	Chad Baisden	6/22/2021

2. COMPLIANCE REVIEW

The Office of Compliance and Enforcement (OCE) completed reviews to determine whether the applicant established that the predicate products are grandfathered products (i.e., were commercially marketed in the United States as of February 15, 2007). The OCE reviews dated June 1, 2021¹ and June 7, 2021² conclude that the evidence submitted by the applicant is adequate to demonstrate that the predicate products are grandfathered and, therefore, are eligible predicate products.

OCE also completed reviews 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 7, 2021 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
SE0016758-SE0016769	2 wrappers	6 wrappers	↓66.7

¹ For SE0016758-SE00016762 and SE0016764-SE0016769

² For SE0016763

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 16, 2021. The FONSI was supported by an environmental assessment prepared by FDA on June 16, 2021.

5. CONCLUSION AND RECOMMENDATION

The product characteristics of the new and corresponding predicate tobacco products are identical except for a change in product quantity from 6 wrappers per pouch to 2 wrappers per pouch.

The OS memoranda³ concludes 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 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 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 31, 2019.

6. APPENDICES

Appendix A. New and predicate products

Common Attributes		
Submission date	July 1, 2020	
Receipt date	July 1, 2020	
Applicant	National Tobacco Company LP	
Product manufacturer	National Tobacco Company LP	
Product category	Cigars	
Product subcategory	Cigar Component	
Attributes	New Product	Predicate Product
STN	SE0016758	Not Applicable
Product name ⁴	ZIG-ZAG NATURAL LEAF WRAPS- Watermelon	Miami Blunts- Watermelon
Eligibility status	Not applicable	Grandfathered
Package type	Foil pouch	Foil pouch
Package quantity	2 wrappers	6 wrappers
Characterizing flavor ⁵	Watermelon	Watermelon
Additional property ⁶	Width: 70 mm Length: 125 mm	Width: 70 mm Length: 125 mm
STN	SE0016759	Not Applicable
Product name ⁴	ZIG-ZAG NATURAL LEAF WRAPS- Vanilla	Miami Blunts- Vanilla
Eligibility status	Not applicable	Grandfathered
Package type	Foil pouch	Foil pouch
Package quantity	2 wrappers	6 wrappers
Characterizing flavor ⁵	Vanilla	Vanilla
Additional property ⁶	Width: 70 mm Length: 125 mm	Width: 70 mm Length: 125 mm
STN	SE0016760	Not Applicable
Product name ⁴	ZIG-ZAG NATURAL LEAF WRAPS- Strawberry	Miami Blunts- Strawberry
Eligibility status	Not applicable	Grandfathered
Package type	Foil pouch	Foil pouch
Package quantity	2 wrappers	6 wrappers
Characterizing flavor ⁵	Strawberry	Strawberry
Additional property ⁶	Width: 70 mm Length: 125 mm	Width: 70 mm Length: 125 mm

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

⁵ As provided by the applicant's certification statement. For product quantity change SE Reports, FDA does not conduct substantive scientific review to evaluate the information contained in the applicant's certification statement.

⁶ The applicant stated that each wrapper has a trapezoidal shape, and provided target width and length for the widest and the longest points of the trapezoid, respectively.

Attributes	New Product	Predicate Product
STN	SE0016761	Not Applicable
Product name ⁴	ZIG-ZAG NATURAL LEAF WRAPS- Rum	Miami Blunts- Rum
Eligibility status	Not applicable	Grandfathered
Package type	Foil pouch	Foil pouch
Package quantity	2 wrappers	6 wrappers
Characterizing flavor ⁵	Rum	Rum
Additional property ⁶	Width: 70 mm Length: 125 mm	Width: 70 mm Length: 125 mm
STN	SE0016762	Not Applicable
Product name ⁴	ZIG-ZAG NATURAL LEAF WRAPS- Passion	Miami Blunts- Thug Passion
Eligibility status	Not applicable	Grandfathered
Package type	Foil pouch	Foil pouch
Package quantity	2 wrappers	6 wrappers
Characterizing flavor ⁵	None	None
Additional property ⁶	Width: 70 mm Length: 125 mm	Width: 70 mm Length: 125 mm
STN	SE0016763	Not Applicable
Product name ⁴	ZIG-ZAG NATURAL LEAF WRAPS- Original	Miami Blunts- Natural
Eligibility status	Not applicable	Grandfathered
Package type	Foil pouch	Foil pouch
Package quantity	2 wrappers	6 wrappers
Characterizing flavor ⁵	None	None
Additional property ⁶	Width: 70 mm Length: 125 mm	Width: 70 mm Length: 125 mm
STN	SE0016764	Not Applicable
Product name ⁴	ZIG-ZAG NATURAL LEAF WRAPS- Mint	Miami Blunts- Mint
Eligibility status	Not applicable	Grandfathered
Package type	Foil pouch	Foil pouch
Package quantity	2 wrappers	6 wrappers
Characterizing flavor ⁵	Mint	Mint
Additional property ⁶	Width: 70 mm Length: 125 mm	Width: 70 mm Length: 125 mm
STN	SE0016765	Not Applicable
Product name ⁴	ZIG-ZAG NATURAL LEAF WRAPS- Honey	Miami Blunts- Honey
Eligibility status	Not applicable	Grandfathered
Package type	Foil pouch	Foil pouch
Package quantity	2 wrappers	6 wrappers
Characterizing flavor ⁵	Honey	Honey
Additional property ⁶	Width: 70 mm Length: 125 mm	Width: 70 mm Length: 125 mm

Attributes	New Product	Predicate Product
STN	SE0016766	Not Applicable
Product name ⁴	ZIG-ZAG NATURAL LEAF WRAPS-Cognac	Miami Blunts- Cognac
Eligibility status	Not applicable	Grandfathered
Package type	Foil pouch	Foil pouch
Package quantity	2 wrappers	6 wrappers
Characterizing flavor ⁵	Cognac	Cognac
Additional property ⁶	Width: 70 mm Length: 125 mm	Width: 70 mm Length: 125 mm
STN	SE0016767	Not Applicable
Product name ⁴	ZIG-ZAG NATURAL LEAF WRAPS-Chocolate	Miami Blunts- Chocolate
Eligibility status	Not applicable	Grandfathered
Package type	Foil pouch	Foil pouch
Package quantity	2 wrappers	6 wrappers
Characterizing flavor ⁵	Chocolate	Chocolate
Additional property ⁶	Width: 70 mm Length: 125 mm	Width: 70 mm Length: 125 mm
STN	SE0016768	Not Applicable
Product name ⁴	ZIG-ZAG NATURAL LEAF WRAPS-Cherry	Miami Blunts- Cherry
Eligibility status	Not applicable	Grandfathered
Package type	Foil pouch	Foil pouch
Package quantity	2 wrappers	6 wrappers
Characterizing flavor ⁵	Cherry	Cherry
Additional property ⁶	Width: 70 mm Length: 125 mm	Width: 70 mm Length: 125 mm
STN	SE0016769	Not Applicable
Product name ⁴	ZIG-ZAG NATURAL LEAF WRAPS-Champagne	Miami Blunts- Champagne
Eligibility status	Not applicable	Grandfathered
Package type	Foil pouch	Foil pouch
Package quantity	2 wrappers	6 wrappers
Characterizing flavor ⁵	Champagne	Champagne
Additional property ⁶	Width: 70 mm Length: 125 mm	Width: 70 mm Length: 125 mm

Appendix B. Amendment

Submission Date	Receipt Date	Application being amended	Reviewed	Brief Description
June 4, 2021	June 4, 2021	SE0016763	Yes	Response to June 2, 2021 FDA Information Request