

Technical Project Lead (TPL) Review of SE Reports

New Products Subject of this Review	
Submission tracking numbers (STNs)	SE0018372, SE0018374-SE0018379
Common Attributes	
Submission date	September 5, 2020
Receipt date	September 5, 2020
Applicant	New Image Global Inc.
Product manufacturer	New Image Mexico S.A. de C.V.
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):

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Date: 2021.12.20 10:00:58 -05'00'

Marcella W. Dolling, M.S., M.B.A.
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 Todd L. Cecil -S
Date: 2021.12.20 12:49:28 -05'00'

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

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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 that are the subject of this review.

Table 1. Disciplines reviewed

Discipline	Cycle 1	
	Reviewers	Review Date
Regulatory	Riandra Bates	11/19/2020
	Fiona Kiprop	12/20/2021
Environmental Science	Christy Leppanen	10/19/2021

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 October 11, 2021¹, 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 reviews dated November 2, 2021, conclude 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
SE0018372, SE0018374-SE0018379	2 wrappers	1 wrapper	↑100%

¹ OCE completed an addendum to the review on October 22, 2021 for SE0018377 to provide the FDA-assigned STN of related submissions. The addendum did not change the conclusions of the initial review.

OS prepared memoranda² 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

The final environmental review found the applicant did not provide current year market volume information for the predicate products. Additionally, for SE0018372 confidential appendices containing market volume, manufacturer, and packaging information were not included. This information is needed to evaluate environmental impacts of the new and predicate products. Therefore, additional information is needed to determine whether to prepare an Environmental Impact Statement (EIS) or Finding of No Significant Impact (FONSI).

5. CONCLUSION AND RECOMMENDATION

The product characteristics of the new and corresponding predicate products are identical except for an increase in product quantity from 1 cigar wrapper to 2 cigar wrappers.

The OS memoranda 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.

FDA examined the environmental effects of finding these new products substantially equivalent and found additional information is necessary to determine the impact of the action. Without this information, FDA is precluded from issuing an SE order.

An Environmental Information Request letter should be issued requesting the following information:

1. All of your SE Reports do not provide current year market volume information for the predicate products. This information is needed to evaluate environmental impacts of the new and predicate products. In the table to follow, provide current year market volumes and associated weights in metric tons for all predicate products.

² See memorandum on product quantity changes, dated December 7, 2017, and addendum for deemed tobacco products, dated December 31, 2019.

Table. Current year market volume information for predicate products

STN	Number of Units ⁱ	Metric Tons
SE0018372		
SE0018373		
SE0018374		
SE0018375		
SE0018376		
SE0018377		
SE0018378		
SE0018379		

ⁱ Unit = 1 cigar wrapper

- The SE Report for SE0018372 is missing Confidential Appendices 1, 2, and 3, that are reported to include market volume, manufacturer, and packaging information. This information is needed to evaluate environmental impacts of the new and predicate products. Provide Confidential Appendices 1, 2, and 3 for SE0018372.

If the applicant adequately responds to the request and an EIS or FONSI is completed, SE order letters should be issued for the new products, as identified in the Appendix of this review.

6. APPENDICES

Appendix A. New and predicate products

Common Attributes		
Submission date	September 5, 2020	
Receipt date	September 5, 2020	
Applicant	New Image Global Inc.	
Product manufacturer	New Image Mexico S.A. de C.V.	
Product category	Cigars	
Product subcategory	Cigar Component	
Attributes	New Product	Predicate Product
STN	SE0018372	GF1702358
Product name ³	Royal Blunts XXL Sour Apple	Royal Blunts EZ Roll Sour Apple
Eligibility status	Not applicable	Grandfathered
Package type	Foil pouch	Foil pouch
Package quantity	2 Wrappers	1 Wrapper
Characterizing flavor ⁴	Apple	Apple
Additional Property	Length: 107.95 millimeters (mm) Width: 66.675 mm Mass: 866.459 milligrams (mg)	Length: 107.95 mm Width: 66.675 mm Mass: 866.459 mg

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

⁴ 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.

STN	SE0018374	GF1702350
Product name ³	Royal Blunts XXL Peach	Royal Blunts EZ Roll Georgia Peach
Eligibility status	Not applicable	Grandfathered
Package type	Foil pouch	Foil pouch
Package quantity	2 Wrappers	1 Wrapper
Characterizing flavor ⁴	Peach	Peach
Additional Property	Length: 107.95 mm Width: 66.675 mm	Length: 107.95 mm Width: 66.675 mm
STN	SE0018375	GF1702352
Product name ³	Royal Blunts XXL Blueberry	Royal Blunts EZ Roll Blueberry
Eligibility status	Not applicable	Grandfathered
Package type	Foil pouch	Foil pouch
Package quantity	2 Wrappers	1 Wrapper
Characterizing flavor ⁴	Blueberry	Blueberry
Additional Property	Length: 107.95 mm Width: 66.675 mm	Length: 107.95 mm Width: 66.675 mm
STN	SE0018376	GF1702360
Product name ³	Royal Blunts XXL Purple Haze	Royal Blunts EZ Roll Purple Haze
Eligibility status	Not applicable	Grandfathered
Package type	Foil pouch	Foil pouch
Package quantity	2 Wrappers	1 Wrapper
Characterizing flavor ⁴	Grape	Grape
Additional Property	Length: 107.95 mm Width: 66.675 mm	Length: 107.95 mm Width: 66.675 mm
STN	SE0018377	GF1702341
Product name ³	Royal Blunts XXL Wet Mango	Royal Blunts EZ Roll Wet Mango
Eligibility status	Not applicable	Grandfathered
Package type	Foil pouch	Foil pouch
Package quantity	2 Wrappers	1 Wrapper
Characterizing flavor ⁴	Mango	Mango
Additional Property	Length: 107.95 mm Width: 66.675 mm	Length: 107.95 mm Width: 66.675 mm
STN	SE0018378	GF1702361
Product name ³	Royal Blunts XXL Passion Fruit	Royal Blunts EZ Roll Passion Fruit
Eligibility status	Not applicable	Grandfathered
Package type	Foil pouch	Foil pouch
Package quantity	2 Wrappers	1 Wrapper
Characterizing flavor ⁴	Passion Fruit	Passion Fruit
Additional Property	Length: 107.95 mm Width: 66.675 mm	Length: 107.95 mm Width: 66.675 mm

STN	SE0018379	GF1702333
Product name ³	Royal Blunts XXL OGK	True Blunt EZ Roll Kush
Eligibility status	Not applicable	Grandfathered
Package type	Foil pouch	Foil pouch
Package quantity	2 Wrappers	1 Wrapper
Characterizing flavor ⁴	None	None
Additional Property	Length: 107.95 mm Width: 66.675 mm	Length: 107.95 mm Width: 66.675 mm

Appendix B. Amendment

Submission Date	Receipt Date	Application being amended	Reviewed	Brief Description
September 29, 2021	September 29, 2021	SE0018377	Yes	Response to September 27, 2021 FDA Information Request