



May 25, 2022

SUBSTANTIALLY EQUIVALENT

New Image Global Inc.
Attention: Jeffrey M. Clark, Chief Financial Officer
15265 Alton Parkway Suite 120
Irvine, CA 92618

FDA Submission Tracking Numbers (STNs): SE0018372.PD1 and SE0018374.PD1 - SE0018379.PD1

Dear Jeffrey M. Clark:

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 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 9050) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)

If you have any questions, please contact Eric Cruz, Regulatory Health Project Manager, at (240) 402 -8289 or Eric.Cruz@fda.hhs.gov.

Sincerely,

Digitally signed by Benjamin
Apelberg -S

For

Date: 2022.05.25 16:43:21 -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^{2,3,4}

New and Corresponding Predicate Tobacco Products Subject of This Letter

Common Attributes of SE Reports		
Submission date	September 5, 2020	
Receipt date	September 5, 2020	
Product manufacturer	New Image Mexico S.A. de C.V	
Product category	Cigars	
Product subcategory	Cigar Component	
Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0018372.PD1	GF1702358
Product name	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	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
STN	SE0018374.PD1	GF1702350
Product name	Royal Blunts XXL Peach	Royal Blunts EZ Roll Georgia
Eligibility status	Not applicable	Grandfathered
Package type	Foil pouch	Foil pouch
Package quantity	2 Wrappers	1 Wrapper
Characterizing flavor	Peach	Peach
Additional property	Length: 107.95 mm Width: 66.675 mm	Length: 107.95 mm Width: 66.675 mm
STN	SE0018375.PD1	GF1702352
Product name	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	Blueberry	Blueberry
Additional property	Length: 107.95 mm Width: 66.675 mm	Length: 107.95 mm Width: 66.675 mm

² PD numbers were not used in the previously issued letters.

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	SE0018376.PD1	GF1702360
Product name	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	Grape	Grape
Additional property	Length: 107.95 mm Width: 66.675 mm	Length: 107.95 mm Width: 66.675 mm
STN	SE0018377.PD1	GF1702362
Product name	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	Mango	Mango
Additional property	Length: 107.95 mm Width: 66.675 mm	Length: 107.95 mm Width: 66.675 mm
STN	SE0018378.PD1	GF1702361
Product name	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	Passion Fruit	Passion Fruit
Additional property	Length: 107.95 mm Width: 66.675 mm	Length: 107.95 mm Width: 66.675 mm
STN	SE0018379.PD1	GF1702333
Product name	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	None	None
Additional property	Length: 107.95 mm Width: 66.675 mm	Length: 107.95 mm Width: 66.675 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.