

Technical Project Lead (TPL) Review of SE Reports

New Products Subject of this Review ¹	
STNs.PDs	SE0022688.PD2, SE0022693.PD2, SE0022778.PD2, SE0022779.PD2, SE0022802.PD2, SE0022846.PD2, SE0022848.PD2, SE0022851.PD2, SE0022853.PD2, SE0022885.PD2, SE0022945.PD2, See Appendix A
Common Attributes	
Submit date	August 30, 2020 ² , August 31, 2020 ³
Receipt date	September 9, 2020
Applicant	Blunt Wrap USA Inc.
Product manufacturer	Emimar S.A.
Application type	Same Characteristics
Application subtype	Regular
Product category	Cigars
Product subcategory	Cigar Component
Cross-Referenced Submissions	
All STNs.PDs	None
Supporting FDA Memoranda Relied Upon in this Review	
All STNs.PDs	Product quantity changes in Substantial Equivalence Reports (SE Reports) for statutorily regulated tobacco products (February 3, 2023)
Recommendation	
Issue Substantially Equivalent (SE) orders for the new tobacco products subject of this review.	

Technical Project Lead (TPL):

Digitally signed by Habibah M. Jackson -S
Date: 2024.09.27 20:27:00 -04'00'

Habibah Jackson
Supervisory Regulatory Health Project Manager
Division of Regulatory Project Management

Signatory Decision:

Concur with TPL recommendation and basis of recommendation

Todd L. Cecil -S Digitally signed by Todd L. Cecil -S
Date: 2024.09.30 09:45:17 -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).

² For SE0022846.PD2, SE0022848.PD2, SE0022851.PD2, SE0022853.PD2

³ For SE0022688.PD2, SE0022693.PD2, SE0022778.PD2, SE0022779.PD2, SE0022802.PD2, SE0022885.PD2, SE0022945.PD2

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.....	6
APPENDIX A. NEW AND PREDICATE PRODUCTS.....	6
APPENDIX B. AMENDMENTS AND ADDITIONAL SUBMISSIONS RECEIVED	10

LIST OF TABLES

Table 1. Disciplines reviewed.....	3
Table 3. Amendments	10
Table 4. Additional submissions.....	10

1. BACKGROUND

1.1. NEW AND PREDICATE PRODUCTS

The applicant submitted information for the new and predicate products listed in detail in the Appendix A.

1.2. REGULATORY ACTIVITY

On September 8, 2020, FDA received two SE Reports from Blunt Wrap USA Inc. FDA issued an Acceptance letter⁴ to the applicant on November 24, 2020.

Refer to Appendix B for a list of amendments and additional submissions received by FDA.

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	
	Reviewer(s)	Review Date
Regulatory	Joy Arellano	8/30/2024
Environmental Science	Yasmin Termeh-Zonoozi	1/24/2024

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 products⁵ (i.e., were commercially marketed in the United States as of February 15, 2007). The OCE reviews dated December 28, 2023⁶ and January 16, 2024⁷ conclude that the evidence submitted by the applicant is adequate to demonstrate that the predicate products are pre-existing products 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 February 22, 2024, and September 20, 2024 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:

⁴ On November 24, 2020, regulatory reviews were completed by Riandra Bates.

⁵ 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.

⁶ For SE0022688.PD2, SE0022802.PD2, SE0022846.PD2, SE0022848.PD2, SE0022851.PD2, SE0022853.PD2, SE0022885.PD2, SE0022945.PD2

⁷ For SE0022693.PD2, SE0022778.PD2, SE0022779.PD2

SE Report	New Product Quantity	Predicate Product Quantity	% Change
SE0022688.PD2	2 wrappers	1 wrapper	↑100
SE0022693.PD2	5 wrappers	8 wrappers	↓38
SE0022778.PD2	5 wrappers	8 wrappers	↓38
SE0022779.PD2	5 wrappers	8 wrappers	↓38
SE0022802.PD2	3 wrappers	2 wrappers	↑50
SE0022846.PD2	3 wrappers	2 wrappers	↑50
SE0022848.PD2	3 wrappers	2 wrappers	↑50
SE0022851.PD2	3 wrappers	2 wrappers	↑50
SE0022853.PD2	3 wrappers	2 wrappers	↑50
SE0022885.PD2	3 wrappers	2 wrappers	↑50
SE0022945.PD2	3 wrappers	2 wrappers	↑50

OS prepared memoranda⁸ 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 January 25, 2024. The FONSI was supported by an environmental assessment prepared by FDA on January 24, 2024.

5. CONCLUSION AND RECOMMENDATION

The product characteristics of the new and corresponding predicate tobacco products are identical except for a change in product quantity as follows:

- 100% increase in product quantity: SE0022688.PD2
- 38% decrease in product quantity: SE0022693.PD2, SE0022778.PD2, SE0022779.PD2
- 50% increase in product quantity: SE0022802.PD2, SE0022846.PD2, SE0022848.PD2, SE0022851.PD2, SE0022853.PD2, SE0022885.PD2, SE0022945.PD2

⁸ See memorandum on product quantity changes, dated December 7, 2017, and addendum for deemed tobacco products, dated December 30, 2019 and February 3, 2023.

The OS memorandum 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 they were determined that they are pre-existing tobacco 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 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.

6. APPENDICES

Appendix A. New and predicate products

Common Attributes^{9, 10, 11, 12}		
Submit date	August 30, 2020 ² , August 31, 2020 ³	
Receipt date	September 9, 2020	
Applicant	Blunt Wrap USA Inc.	
Product manufacturer	Emimar S.A.	
Product category	Cigars	
Product subcategory	Cigar Component	
Attributes	New Product	Predicate Product
STN.PD	SE0022688.PD2	GF1909037
Product name	JUICY - MANGO PAPAYA	JUICY - MANGO PAPAYA
Eligibility status	N/A	Pre-Existing Tobacco Product
Package type	Foil	Foil
Product quantity	2 Wrappers	1 Wrappers
Characterizing flavor (CF)	Flavored	Flavored
Flavored CF, as identified	Mango Papaya	Mango Papaya
Nicotine source	Tobacco	Tobacco
Additional Property:	Length: 114.3 millimeter (mm), Width: 60.3 mm	Length: 114.3 mm, Width: 60.3 mm
STN.PD	SE0022693.PD2	GF2011307
Product name	LOADED NATURAL LEAF - BLUEBERRY	JUICY NATURAL LEAF BLUNT - BLUEBERRY
Eligibility status	N/A	Pre-Existing Tobacco Product
Package type	Foil	Foil
Product quantity	5 Wrappers	8 Wrappers
Characterizing flavor (CF)	Flavored	Flavored
Flavored CF, as identified	BLUEBERRY	BLUEBERRY
Nicotine source	Tobacco	Tobacco
Additional Property:	Length: 114.3 mm, Width: 50.8 mm	Length: 114.3 mm, Width: 50.8 mm

⁹ Product name is the brand/sub-brand or other commercial name used in commercial distribution.

¹⁰ We interpret package type to mean container closure system and package quantity to mean product quantity within the container closure system, unless otherwise identified.

¹¹ Nicotine source was not provided by the applicant; however, the applications for these products were received prior to April 14, 2022, or is modifying predicate products that were marketed prior to April 14, 2022. As such, nicotine source is classified as tobacco.

¹² 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. 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.

SE0022688.PD2, SE0022693.PD2, SE0022778.PD2, SE0022779.PD2, SE0022802.PD2, SE0022846.PD2, SE0022848.PD2, SE0022851.PD2, SE0022853.PD2, SE0022885.PD2, SE0022945.PD2

STN.PD	SE0022778.PD2	GF2011316
Product name	LOADED NATURAL LEAF - MANGO	JUICY NATURAL LEAF BLUNT - SWEET MANGO
Eligibility status	N/A	Pre-Existing Tobacco Product
Package type	Foil	Foil
Product quantity	5 Wrappers	8 Wrappers
Characterizing flavor (CF)	Flavored	Flavored
Flavored CF, as identified	MANGO	MANGO
Nicotine source	Tobacco	Tobacco
Additional Property:	Length: 114.3 mm, Width: 50.8 mm	Length: 114.3 mm, Width: 50.8 mm
STN.PD	SE0022779.PD2	GF2011312
Product name	LOADED NATURAL LEAF - PEACH	JUICY NATURAL LEAF BLUNT - PEACH
Eligibility status	N/A	Pre-Existing Tobacco Product
Package type	Foil	Foil
Product quantity	5 Wrappers	8 Wrappers
Characterizing flavor (CF)	Flavored	Flavored
Flavored CF, as identified	PEACH	PEACH
Nicotine source	Tobacco	Tobacco
Additional Property:	Length: 114.3 mm, Width: 50.8 mm	Length: 114.3 mm, Width: 50.8 mm
STN.PD	SE0022802.PD2	GF1909029
Product name	BLUNT MASTER CIGAR WRAP - WATERMELON	BLUNT WRAP PLATINUM-WATERMELON
Eligibility status	N/A	Pre-Existing Tobacco Product
Package type	Foil	Foil
Product quantity	3 Wrappers	2 Wrappers
Characterizing flavor (CF)	Flavored	Flavored
Flavored CF, as identified	WATERMELON	WATERMELON
Nicotine source	Tobacco	Tobacco
Additional Property:	Length: 114.3 mm, Width: 50.8 mm	Length: 114.3 mm, Width: 50.8 mm
STN.PD	SE0022846.PD2	GF1909068
Product name	BLUNT MASTER CIGAR WRAP - GRAPE	BLUNT WRAP PLATINUM - GRAPE-A-LICIOUS
Eligibility status	N/A	Pre-Existing Tobacco Product
Package type	Foil	Foil
Product quantity	3 Wrappers	2 Wrappers
Characterizing flavor (CF)	Flavored	Flavored
Flavored CF, as identified	Grape	Grape
Nicotine source	Tobacco	Tobacco
Additional Property:	Length: 114.3 mm, Width: 50.8 mm	Length: 114.3 mm, Width: 50.8 mm

SE0022688.PD2, SE0022693.PD2, SE0022778.PD2, SE0022779.PD2, SE0022802.PD2, SE0022846.PD2, SE0022848.PD2, SE0022851.PD2, SE0022853.PD2, SE0022885.PD2, SE0022945.PD2

STN.PD	SE0022848.PD2	GF1909069
Product name	BLUNT MASTER CIGAR WRAP - MANGO	BLUNT WRAP PLATINUM - MELLO MANGO
Eligibility status	N/A	Pre-Existing Tobacco Product
Package type	Foil	Foil
Product quantity	3 Wrappers	2 Wrappers
Characterizing flavor (CF)	Flavored	Flavored
Flavored CF, as identified	Mango	Mango
Nicotine source	Tobacco	Tobacco
Additional Property:	Length: 114.3 mm, Width: 50.8 mm	Length: 114.3 mm, Width: 50.8 mm
STN.PD	SE0022851.PD2	GF1909027
Product name	BLUNT MASTER CIGAR WRAP - STRAWBERRY KIWI	BLUNT WRAP PLATINUM - STRAWBERRY KIWI
Eligibility status	N/A	Pre-Existing Tobacco Product
Package type	Foil	Foil
Product quantity	3 Wrappers	2 Wrappers
Characterizing flavor (CF)	Flavored	Flavored
Flavored CF, as identified	Strawberry Kiwi	Strawberry Kiwi
Nicotine source	Tobacco	Tobacco
Additional Property:	Length: 114.3 mm, Width: 50.8 mm	Length: 114.3 mm, Width: 50.8 mm
STN.PD	SE0022853.PD2	GF1909028
Product name	BLUNT MASTER CIGAR WRAP - VANILLA	BLUNT WRAP PLATINUM - VANILLA
Eligibility status	N/A	Pre-Existing Tobacco Product
Package type	Foil	Foil
Product quantity	3 Wrappers	2 Wrappers
Characterizing flavor (CF)	Flavored	Flavored
Flavored CF, as identified	VANILLA	VANILLA
Nicotine source	Tobacco	Tobacco
Additional Property:	Length: 114.3 mm, Width: 50.8 mm	Length: 114.3 mm, Width: 50.8 mm
STN.PD	SE0022885.PD2	GF1909068
Product name	Show Flat Wraps - White Grapes	BLUNT WRAP PLATINUM - GRAPE-A-LICIOUS
Eligibility status	N/A	Pre-Existing Tobacco Product
Package type	Foil	Foil
Product quantity	3 Wrappers	2 Wrappers
Characterizing flavor (CF)	Flavored	Flavored
Flavored CF, as identified	Grape	Grape
Nicotine source	Tobacco	Tobacco
Additional Property:	Length: 114.3 mm, Width: 50.8 mm	Length: 114.3 mm, Width: 50.8 mm

SE0022688.PD2, SE0022693.PD2, SE0022778.PD2, SE0022779.PD2, SE0022802.PD2, SE0022846.PD2, SE0022848.PD2, SE0022851.PD2, SE0022853.PD2, SE0022885.PD2, SE0022945.PD2

STN.PD	SE0022945.PD2	GF1909068
Product name	BLUNT MASTER CIGAR WRAP - WHITE GRAPE	BLUNT WRAP PLATINUM - GRAPE-A-LICIOUS
Eligibility status	N/A	Pre-Existing Tobacco Product
Package type	Foil	Foil
Product quantity	3 Wrappers	2 Wrappers
Characterizing flavor (CF)	Flavored	Flavored
Flavored CF, as identified	Grape	Grape
Nicotine source	Tobacco	Tobacco
Additional Property:	Length: 114.3 mm, Width: 50.8 mm	Length: 114.3 mm, Width: 50.8 mm

Appendix B. Amendments and additional submissions received**Table 2. Amendments Received for These Applications**

Submit Date	Receipt Date	Applications being amended	Reviewed	Brief Description
January 4, 2024	January 5, 2024	SE0022693.PD2, SE0022778.PD2, SE0022779.PD2	Yes	Response to December 26, 2023 FDA Information Request

Table 3. Additional Submission(s) Received for This Applicant

Submit Date	Receipt Date	Reviewed	Brief Description
N/A	N/A	N/A	N/A