



September 30, 2024

**SUBSTANTIALLY EQUIVALENT**

Blunt Wrap USA Inc.  
Attention: Ronald Tully  
TNV Ventures LLC  
2846 East Palo Verde Court  
Gilbert, AZ 85296

**FDA Submission Tracking Numbers (STNs.PDs):** Multiple STNs.PDs, see Appendix A

Dear Ronald Tully:

We completed our review of your SE Reports<sup>1</sup> 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. Refer to Appendix B for a list of amendments received in support of your applications.

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 C.

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.

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<sup>1</sup> Substantially Equivalent (SE) Reports submitted under section 905(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)

If you have any questions, please contact Nala Jackson, Regulatory Health Project Manager, at (240) 402-8583 or [Nala.Jackson@fda.hhs.gov](mailto:Nala.Jackson@fda.hhs.gov).

Sincerely,

**Todd L. Cecil -** Digitally signed by Todd L.  
Cecil -S  
S Date: 2024.09.30 10:07:56  
-04'00'

Todd Cecil, Ph.D.  
Deputy Director  
Office of Science  
Center for Tobacco Products

**Enclosures:**

Appendix A – New and Corresponding Predicate Tobacco Products Subject of This Letter

Appendix B – Amendments and Additional Submissions Received for This Applicant

Appendix C – Health Information Summary

**Appendix A**  
New and Corresponding Predicate Tobacco Products Subject of This Letter

| <b>Common Attributes<sup>2,3,4,5</sup></b> |   |                                      |
|--|---|--------------------------------------|
| Submit date                                | August 30, 2020 <sup>6</sup> , August 31, 2020 <sup>7</sup> |                                      |
| Receipt date                               | September 8, 2020   |                                      |
| Applicant                                  | Blunt Wrap USA Inc.   |                                      |
| Product manufacturer                       | Emimar S.A.   |                                      |
| Product category                           | Cigars  |                                      |
| Product subcategory                        | Cigar Component   |                                      |
| <b>STN.PD</b>                              | <b>SE0022688.PD2</b>  | <b>GF1909037</b>                     |
| 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 Wrapper                            |
| Characterizing flavor (CF)                 | Flavored  | Flavored                             |
| Flavored CF, as identified                 | Mango Papaya  | Mango Papaya                         |
| Nicotine source                            | Tobacco   | Tobacco                              |
| Additional Property                        | Length: 114.3 Millimeters (mm)<br>Width: 60.3 mm            | Length: 114.3 mm<br>Width: 60.3 mm   |
| <b>STN.PD</b>                              | <b>SE0022693.PD2</b>  | <b>GF2011307</b>                     |
| 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<br>Width: 50.8 mm                          | Length: 114.3 mm<br>Width: 50.8 mm   |

<sup>2</sup> We interpret package type to mean container closure system and package quantity to mean product quantity within the container closure system, unless otherwise identified.

<sup>3</sup> Product name is brand/sub-brand or other commercial name used in commercial distribution.

<sup>4</sup> 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.

<sup>5</sup> 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.

<sup>6</sup> For SE0022846.PD2, SE0022848.PD2, SE0022851.PD2, SE0022853.PD2

<sup>7</sup> For SE0022688.PD2, SE0022693.PD2, SE0022778.PD2, SE0022779.PD2, SE0022802.PD2, SE0022885.PD2, SE0022945.PD2

| <b>STN.PD</b>              | <b>SE0022778.PD2</b>                | <b>GF2011316</b>                       |
|----------------------------|-------------------------------------|--|
| 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<br>Width: 50.8 mm  | Length: 114.3 mm<br>Width: 50.8 mm     |
| <b>STN.PD</b>              | <b>SE0022779.PD2</b>                | <b>GF2011312</b>                       |
| 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<br>Width: 50.8 mm  | Length: 114.3 mm<br>Width: 50.8 mm     |
| <b>STN.PD</b>              | <b>SE0022802.PD2</b>                | <b>GF1909029</b>                       |
| 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<br>Width: 50.8 mm  | Length: 114.3 mm<br>Width: 50.8 mm     |
| <b>STN.PD</b>              | <b>SE0022846.PD2</b>                | <b>GF1909068</b>                       |
| 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<br>Width: 50.8 mm  | Length: 114.3 mm<br>Width: 50.8 mm     |

| <b>STN.PD</b>              | <b>SE0022848.PD2</b>                    | <b>GF1909069</b>                    |
|----------------------------|---|-------------------------------------|
| 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<br>Width: 50.8 mm      | Length: 114.3 mm<br>Width: 50.8 mm  |
| <b>STN.PD</b>              | <b>SE0022851.PD2</b>                    | <b>GF1909027</b>                    |
| 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                         | Watermelon                          |
| Nicotine source            | Tobacco                                 | Tobacco                             |
| Additional Property        | Length: 114.3 mm<br>Width: 50.8 mm      | Length: 114.3 mm<br>Width: 50.8 mm  |
| <b>STN.PD</b>              | <b>SE0022853.PD2</b>                    | <b>GF1909028</b>                    |
| 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<br>Width: 50.8 mm      | Length: 114.3 mm<br>Width: 50.8 mm  |
| <b>STN.PD</b>              | <b>SE0022885.PD2</b>                    | <b>GF1909068</b>                    |
| Product name               | Show Flat Wraps- White Grape            | BLUNT WRAP PLATINUM- GRAPE-ALICIOUS |
| 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<br>Width: 50.8 mm      | Length: 114.3 mm<br>Width: 50.8 mm  |

| <b>STN.PD</b>              | <b>SE0022945.PD2</b>                    | <b>GF1909068</b>                         |
|----------------------------|---|--|
| Product name               | BLUNT MASTER CIGAR WRAP-<br>WHITE GRAPE | BLUNT WRAP PLATINUM- GRAPE-A-<br>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<br>Width: 50.8 mm      | Length: 114.3 mm<br>Width: 50.8 mm       |

**Appendix B**

Amendments and Additional Submissions Received for This Applicant

Amendment Received for These Applications

| Submit Date     | Receipt Date    | Amendment STN | Applications Being Amended                  | Reviewed | Brief Description                                      |
|-----------------|-----------------|---------------|---|----------|--|
| January 4, 2024 | January 5, 2024 | SE0025794     | SE0022693.PD2, SE0022778.PD2, SE0022779.PD2 | Yes      | Response to December 26, 2023, FDA Information Request |

Additional Submission Received for This Applicant

| Submit Date | Receipt Date | STN | Reviewed | Brief Description |
|-------------|--------------|-----|----------|-------------------|
| N/A         | N/A          | N/A | N/A      | N/A               |

### **Appendix C**

#### 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.