



December 22, 2023

**SUBSTANTIALLY EQUIVALENT**

Blunt Wrap USA Inc.  
Attention: Daniel S. Sinclair, President  
629 Village Lane S  
Mandeville, LA 70471

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

Dear Daniel Sinclair:

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.

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 comply 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 - 8535 or [Nala.Jackson@fda.hhs.gov](mailto:Nala.Jackson@fda.hhs.gov).

Sincerely,

**Todd L.  
Cecil -S**

Digitally signed by  
Todd L. Cecil -S  
Date: 2023.12.22  
11:37:17 -05'00'

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 – Health Information Summary

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

| <b>Common Attributes</b> <sup>2,3,4,5,6</sup> |                                                                                              |                                                                                 |
|-----------------------------------------------|----------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------|
| Submit date                                   | August 30, 2020 <sup>7</sup> , August 31, 2020 <sup>8</sup> , September 1, 2020 <sup>9</sup> |                                                                                 |
| Receipt date                                  | September 8, 2020                                                                            |                                                                                 |
| Applicant                                     | Blunt Wrap USA Inc.                                                                          |                                                                                 |
| Product manufacturer                          | Emimar S.A.                                                                                  |                                                                                 |
| Product category                              | Cigars                                                                                       |                                                                                 |
| Product subcategory                           | Cigar Component                                                                              |                                                                                 |
| Attributes                                    | New Tobacco Product                                                                          | Predicate Tobacco Product                                                       |
| STN                                           | SE0021835.PD2                                                                                | GF1909080                                                                       |
| Product name                                  | BLUNT MASTER CIGAR<br>WRAP - BERRIES                                                         | BLUNT WRAP PLATINUM - BERRIES                                                   |
| Eligibility status                            | Not Applicable                                                                               | Pre-Existing                                                                    |
| Package type                                  | Foil Pouch                                                                                   | Foil Pouch                                                                      |
| Package quantity                              | 3 Cigar Wrappers                                                                             | 2 Cigar Wrappers                                                                |
| Characterizing flavor(CF)                     | Flavored                                                                                     | Flavored                                                                        |
| Flavored CF, as identified                    | Berries                                                                                      | Berries                                                                         |
| Nicotine source                               | Tobacco                                                                                      | Tobacco                                                                         |
| Additional properties                         | Length: 114.3 mm<br>Width: 50.8 mm<br>Mass: 763 mg<br>Wrapper Material: Tobacco              | Length: 114.3 mm<br>Width: 50.8 mm<br>Mass: 763 mg<br>Wrapper Material: Tobacco |

<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 are 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> Characterizing flavors previously identified as “None” have been updated in FDA records to “Tobacco” to accurately reflect that the products provide a tobacco characterizing flavor. As such, those products do not have any change in characterizing flavor

<sup>7</sup> For SE0021835.PD2, SE0022270.PD2 – SE0022271.PD2, SE0022273.PD2, SE0022297.PD2, SE0022312.PD2 – SE0022313.PD2, SE0022317.PD2 and SE0022319.PD2.

<sup>8</sup> SE0022274.PD2, SE0022276.PD2, SE0022296.PD2 and SE0022298.PD2.

<sup>9</sup> SE0022268.PD2, SE0022293.PD2, SE0022295.PD2, SE0022299.PD2, SE0022327.PD2 and SE0022329.PD2 – SE0022330.PD2.

| Attributes                 | New Tobacco Product                                                             | Predicate Tobacco Product                                                       |
|----------------------------|---------------------------------------------------------------------------------|---------------------------------------------------------------------------------|
| <b>STN</b>                 | <b>SE0022268.PD2</b>                                                            | <b>GF2011307</b>                                                                |
| Product name               | BLUNT WRAP NATURAL LEAF - BLUEBERRY                                             | JUICY BLUNTS NATURAL LEAF WRAPPER - BLUEBERRY <sup>10</sup>                     |
| Eligibility status         | Not Applicable                                                                  | Pre-Existing                                                                    |
| Package type               | Foil Pouch                                                                      | Foil Pouch                                                                      |
| Package quantity           | 5 Cigar Wrappers                                                                | 8 Cigar Wrappers                                                                |
| Characterizing flavor(CF)  | Flavored                                                                        | Flavored                                                                        |
| Flavored CF, as identified | Blueberry                                                                       | Blueberry                                                                       |
| Nicotine source            | Tobacco                                                                         | Tobacco                                                                         |
| Additional properties      | Length: 114.3 mm<br>Width: 50.8 mm<br>Wrapper Material: Tobacco                 | Length: 114.3 mm<br>Width: 50.8 mm<br>Wrapper Material: Tobacco                 |
| <b>STN</b>                 | <b>SE0022270.PD2</b>                                                            | <b>GF1909080</b>                                                                |
| Product name               | BLUNT MASTER CIGAR WRAP - BERRIES                                               | BLUNT WRAP PLATINUM - BERRIES                                                   |
| Eligibility status         | Not Applicable                                                                  | Pre-Existing                                                                    |
| Package type               | Foil Pouch                                                                      | Foil Pouch                                                                      |
| Package quantity           | 4 Cigar Wrappers                                                                | 2 Cigar Wrappers                                                                |
| Characterizing flavor(CF)  | Flavored                                                                        | Flavored                                                                        |
| Flavored CF, as identified | Berries                                                                         | Berries                                                                         |
| Nicotine source            | Tobacco                                                                         | Tobacco                                                                         |
| Additional properties      | Length: 114.3 mm<br>Width: 50.8 mm<br>Mass: 763 mg<br>Wrapper Material: Tobacco | Length: 114.3 mm<br>Width: 50.8 mm<br>Mass: 763 mg<br>Wrapper Material: Tobacco |
| <b>STN</b>                 | <b>SE0022271.PD2</b>                                                            | <b>GF1909069</b>                                                                |
| Product name               | BLUNT MASTER CIGAR WRAP - MANGO                                                 | BLUNT WRAP PLATINUM – MELLO MANGO                                               |
| Eligibility status         | Not Applicable                                                                  | Pre-Existing                                                                    |
| Package type               | Foil Pouch                                                                      | Foil Pouch                                                                      |
| Package quantity           | 5 Cigar Wrappers                                                                | 2 Cigar Wrappers                                                                |
| Characterizing flavor(CF)  | Flavored                                                                        | Flavored                                                                        |
| Flavored CF, as identified | Mango                                                                           | Mango                                                                           |
| Nicotine source            | Tobacco                                                                         | Tobacco                                                                         |
| Additional properties      | Length: 114.3 mm<br>Width: 50.8 mm<br>Mass: 763 mg<br>Wrapper Material: Tobacco | Length: 114.3 mm<br>Width: 50.8 mm<br>Mass: 763 mg<br>Wrapper Material: Tobacco |

<sup>10</sup> The predicate product is also know as JUICY NATURAL LEAF BLUNT - BLUEBERRY.

| Attributes                 | New Tobacco Product                                                             | Predicate Tobacco Product                                                       |
|----------------------------|---------------------------------------------------------------------------------|---------------------------------------------------------------------------------|
| <b>STN</b>                 | <b>SE0022273.PD2</b>                                                            | <b>GF1909080</b>                                                                |
| Product name               | BLUNT MASTER CIGAR WRAP - BERRIES                                               | BLUNT WRAP PLATINUM – BERRIES                                                   |
| Eligibility status         | Not Applicable                                                                  | Pre-Existing                                                                    |
| Package type               | Foil Pouch                                                                      | Foil Pouch                                                                      |
| Package quantity           | 5 Cigar Wrappers                                                                | 2 Cigar Wrappers                                                                |
| Characterizing flavor(CF)  | Flavored                                                                        | Flavored                                                                        |
| Flavored CF, as identified | Berries                                                                         | Berries                                                                         |
| Nicotine source            | Tobacco                                                                         | Tobacco                                                                         |
| Additional properties      | Length: 114.3 mm<br>Width: 50.8 mm<br>Mass: 763 mg<br>Wrapper Material: Tobacco | Length: 114.3 mm<br>Width: 50.8 mm<br>Mass: 763 mg<br>Wrapper Material: Tobacco |
| <b>STN</b>                 | <b>SE0022274.PD2</b>                                                            | <b>GF1909094</b>                                                                |
| Product name               | JUICY – CHERRY VANILLA                                                          | JUICY – CHERRY VANILLA                                                          |
| Eligibility status         | Not Applicable                                                                  | Pre-Existing                                                                    |
| Package type               | Foil Pouch                                                                      | Foil Pouch                                                                      |
| Package quantity           | 2 Cigar Wrappers                                                                | 1 Cigar Wrapper                                                                 |
| Characterizing flavor(CF)  | Flavored                                                                        | Flavored                                                                        |
| Flavored CF, as identified | Cherry Vanilla                                                                  | Cherry Vanilla                                                                  |
| Nicotine source            | Tobacco                                                                         | Tobacco                                                                         |
| Additional properties      | Length: 114.3 mm<br>Width: 60.3 mm<br>Wrapper Material: Tobacco                 | Length: 114.3 mm<br>Width: 60.3 mm<br>Wrapper Material: Tobacco                 |
| <b>STN</b>                 | <b>SE0022276.PD2</b>                                                            | <b>GF1909041</b>                                                                |
| Product name               | JUICY – RASPBERRY                                                               | JUICY – RASPBERRY                                                               |
| Eligibility status         | Not Applicable                                                                  | Pre-Existing                                                                    |
| Package type               | Foil Pouch                                                                      | Foil Pouch                                                                      |
| Package quantity           | 2 Cigar Wrappers                                                                | 1 Cigar Wrapper                                                                 |
| Characterizing flavor(CF)  | Flavored                                                                        | Flavored                                                                        |
| Flavored CF, as identified | Raspberry                                                                       | Raspberry                                                                       |
| Nicotine source            | Tobacco                                                                         | Tobacco                                                                         |
| Additional properties      | Length: 114.3 mm<br>Width: 60.3 mm<br>Wrapper Material: Tobacco                 | Length: 114.3 mm<br>Width: 60.3 mm<br>Wrapper Material: Tobacco                 |

| Attributes                 | New Tobacco Product                                                             | Predicate Tobacco Product                                                       |
|----------------------------|---------------------------------------------------------------------------------|---------------------------------------------------------------------------------|
| <b>STN</b>                 | <b>SE0022293.PD2</b>                                                            | <b>GF1909083</b>                                                                |
| Product name               | Show Diamond Wrap - Chocolate                                                   | Blunt Wrap Platinum - Chocolate                                                 |
| Eligibility status         | Not Applicable                                                                  | Pre-Existing                                                                    |
| Package type               | Foil Pouch                                                                      | Foil Pouch                                                                      |
| Package quantity           | 3 Cigar Wrappers                                                                | 2 Cigar Wrappers                                                                |
| Characterizing flavor(CF)  | Flavored                                                                        | Flavored                                                                        |
| Flavored CF, as identified | Chocolate                                                                       | Chocolate                                                                       |
| Nicotine source            | Tobacco                                                                         | Tobacco                                                                         |
| Additional properties      | Length: 114.3 mm<br>Width: 50.8 mm<br>Wrapper Material: Tobacco                 | Length: 114.3 mm<br>Width: 50.8 mm<br>Wrapper Material: Tobacco                 |
| <b>STN</b>                 | <b>SE0022295.PD2</b>                                                            | <b>GF1909071</b>                                                                |
| Product name               | Show Diamond Wrap - Pina Colada                                                 | Blunt Wrap Platinum – Pina Colada                                               |
| Eligibility status         | Not Applicable                                                                  | Pre-Existing                                                                    |
| Package type               | Foil Pouch                                                                      | Foil Pouch                                                                      |
| Package quantity           | 3 Cigar Wrappers                                                                | 2 Cigar Wrappers                                                                |
| Characterizing flavor(CF)  | Flavored                                                                        | Flavored                                                                        |
| Flavored CF, as identified | Pina Colada                                                                     | Pina Colada                                                                     |
| Nicotine source            | Tobacco                                                                         | Tobacco                                                                         |
| Additional properties      | Length: 114.3 mm<br>Width: 50.8 mm<br>Wrapper Material: Tobacco                 | Length: 114.3 mm<br>Width: 50.8 mm<br>Wrapper Material: Tobacco                 |
| <b>STN</b>                 | <b>SE0022296.PD2</b>                                                            | <b>GF1909071</b>                                                                |
| Product name               | BLUNT MASTER CIGAR WRAP - VANILLA                                               | BLUNT WRAP PLATINUM – VANILLA                                                   |
| Eligibility status         | Not Applicable                                                                  | Pre-Existing                                                                    |
| Package type               | Foil Pouch                                                                      | Foil Pouch                                                                      |
| Package quantity           | 5 Cigar Wrappers                                                                | 2 Cigar Wrappers                                                                |
| Characterizing flavor(CF)  | Flavored                                                                        | Flavored                                                                        |
| Flavored CF, as identified | Vanilla                                                                         | Vanilla                                                                         |
| Nicotine source            | Tobacco                                                                         | Tobacco                                                                         |
| Additional properties      | Length: 114.3 mm<br>Width: 50.8 mm<br>Mass: 763 mg<br>Wrapper Material: Tobacco | Length: 114.3 mm<br>Width: 50.8 mm<br>Mass: 763 mg<br>Wrapper Material: Tobacco |

| Attributes                 | New Tobacco Product                                                             | Predicate Tobacco Product                                                       |
|----------------------------|---------------------------------------------------------------------------------|---------------------------------------------------------------------------------|
| <b>STN</b>                 | <b>SE0022297.PD2</b>                                                            | <b>GF1909068</b>                                                                |
| Product name               | BLUNT MASTER CIGAR WRAP - GRAPE                                                 | BLUNT WRAP PLATINUM – GRAPE-A-LICIOUS                                           |
| Eligibility status         | Not Applicable                                                                  | Pre-Existing                                                                    |
| Package type               | Foil Pouch                                                                      | Foil Pouch                                                                      |
| Package quantity           | 4 Cigar Wrappers                                                                | 2 Cigar Wrappers                                                                |
| Characterizing flavor(CF)  | Flavored                                                                        | Flavored                                                                        |
| Flavored CF, as identified | Grape                                                                           | Grape                                                                           |
| Nicotine source            | Tobacco                                                                         | Tobacco                                                                         |
| Additional properties      | Length: 114.3 mm<br>Width: 50.8 mm<br>Mass: 763 mg<br>Wrapper Material: Tobacco | Length: 114.3 mm<br>Width: 50.8 mm<br>Mass: 763 mg<br>Wrapper Material: Tobacco |
| <b>STN</b>                 | <b>SE0022298.PD2</b>                                                            | <b>GF1909068</b>                                                                |
| Product name               | BLUNT MASTER CIGAR WRAP - GRAPE                                                 | BLUNT WRAP PLATINUM – GRAPE-A-LICIOUS                                           |
| Eligibility status         | Not Applicable                                                                  | Pre-Existing                                                                    |
| Package type               | Foil Pouch                                                                      | Foil Pouch                                                                      |
| Package quantity           | 5 Cigar Wrappers                                                                | 2 Cigar Wrappers                                                                |
| Characterizing flavor(CF)  | Flavored                                                                        | Flavored                                                                        |
| Flavored CF, as identified | Grape                                                                           | Grape                                                                           |
| Nicotine source            | Tobacco                                                                         | Tobacco                                                                         |
| Additional properties      | Length: 114.3 mm<br>Width: 50.8 mm<br>Mass: 763 mg<br>Wrapper Material: Tobacco | Length: 114.3 mm<br>Width: 50.8 mm<br>Mass: 763 mg<br>Wrapper Material: Tobacco |
| <b>STN</b>                 | <b>SE0022299.PD2</b>                                                            | <b>GF2011307</b>                                                                |
| Product name               | LOADED NATURAL LEAF - BLUEBERRY                                                 | JUICY BLUNTS NATURAL LEAF WRAPPER - BLUEBERRY <sup>10</sup>                     |
| Eligibility status         | Not Applicable                                                                  | Pre-Existing                                                                    |
| Package type               | Foil Pouch                                                                      | Foil Pouch                                                                      |
| Package quantity           | 3 Cigar Wrappers                                                                | 8 Cigar Wrappers                                                                |
| Characterizing flavor(CF)  | Flavored                                                                        | Flavored                                                                        |
| Flavored CF, as identified | Grape                                                                           | Grape                                                                           |
| Nicotine source            | Blueberry                                                                       | Blueberry                                                                       |
| Additional properties      | Length: 114.3 mm<br>Width: 50.8 mm<br>Wrapper Material: Tobacco                 | Length: 114.3 mm<br>Width: 50.8 mm<br>Wrapper Material: Tobacco                 |

| Attributes                 | New Tobacco Product                                                             | Predicate Tobacco Product                                                       |
|----------------------------|---------------------------------------------------------------------------------|---------------------------------------------------------------------------------|
| <b>STN</b>                 | <b>SE0022312.PD2</b>                                                            | <b>GF1909083</b>                                                                |
| Product name               | BLUNT MASTER CIGAR WRAP - CHOCOLATE                                             | BLUNT WRAP PLATINUM-CHOCOLATE                                                   |
| Eligibility status         | Not Applicable                                                                  | Pre-Existing                                                                    |
| Package type               | Foil Pouch                                                                      | Foil Pouch                                                                      |
| Package quantity           | 4 Cigar Wrappers                                                                | 2 Cigar Wrappers                                                                |
| Characterizing flavor(CF)  | Flavored                                                                        | Flavored                                                                        |
| Flavored CF, as identified | Chocolate                                                                       | Chocolate                                                                       |
| Nicotine source            | Tobacco                                                                         | Tobacco                                                                         |
| Additional properties      | Length: 114.3 mm<br>Width: 50.8 mm<br>Mass: 763 mg<br>Wrapper Material: Tobacco | Length: 114.3 mm<br>Width: 50.8 mm<br>Mass: 763 mg<br>Wrapper Material: Tobacco |
| <b>STN</b>                 | <b>SE0022313.PD2</b>                                                            | <b>GF1909069</b>                                                                |
| Product name               | BLUNT MASTER CIGAR WRAP - MANGO                                                 | BLUNT WRAP PLATINUM - MELLO MANGO                                               |
| Eligibility status         | Not Applicable                                                                  | Pre-Existing                                                                    |
| Package type               | Foil Pouch                                                                      | Foil Pouch                                                                      |
| Package quantity           | 4 Cigar Wrappers                                                                | 2 Cigar Wrappers                                                                |
| Characterizing flavor(CF)  | Flavored                                                                        | Flavored                                                                        |
| Flavored CF, as identified | Mango                                                                           | Mango                                                                           |
| Nicotine source            | Tobacco                                                                         | Tobacco                                                                         |
| Additional properties      | Length: 114.3 mm<br>Width: 50.8 mm<br>Mass: 763 mg<br>Wrapper Material: Tobacco | Length: 114.3 mm<br>Width: 50.8 mm<br>Mass: 763 mg<br>Wrapper Material: Tobacco |
| <b>STN</b>                 | <b>SE0022317.PD2</b>                                                            | <b>GF1909027</b>                                                                |
| Product name               | BLUNT MASTER CIGAR WRAP - STRAWBERRY KIWI                                       | BLUNT WRAP PLATINUM - STRAWBERRY KIWI                                           |
| Eligibility status         | Not Applicable                                                                  | Pre-Existing                                                                    |
| Package type               | Foil Pouch                                                                      | Foil Pouch                                                                      |
| Package quantity           | 4 Cigar Wrappers                                                                | 2 Cigar Wrappers                                                                |
| Characterizing flavor(CF)  | Flavored                                                                        | Flavored                                                                        |
| Flavored CF, as identified | Strawberry Kiwi                                                                 | Strawberry Kiwi                                                                 |
| Nicotine source            | Tobacco                                                                         | Tobacco                                                                         |
| Additional properties      | Length: 114.3 mm<br>Width: 50.8 mm<br>Mass: 763 mg<br>Wrapper Material: Tobacco | Length: 114.3 mm<br>Width: 50.8 mm<br>Mass: 763 mg<br>Wrapper Material: Tobacco |

| Attributes                 | New Tobacco Product                                                             | Predicate Tobacco Product                                                       |
|----------------------------|---------------------------------------------------------------------------------|---------------------------------------------------------------------------------|
| <b>STN</b>                 | <b>SE0022319.PD2</b>                                                            | <b>GF1909028</b>                                                                |
| Product name               | BLUNT MASTER CIGAR WRAP - VANILLA                                               | BLUNT WRAP PLATINUM - VANILLA                                                   |
| Eligibility status         | Not Applicable                                                                  | Pre-Existing                                                                    |
| Package type               | Foil Pouch                                                                      | Foil Pouch                                                                      |
| Package quantity           | 4 Cigar Wrappers                                                                | 2 Cigar Wrappers                                                                |
| Characterizing flavor(CF)  | Flavored                                                                        | Flavored                                                                        |
| Flavored CF, as identified | Vanilla                                                                         | Vanilla                                                                         |
| Nicotine source            | Tobacco                                                                         | Tobacco                                                                         |
| Additional properties      | Length: 114.3 mm<br>Width: 50.8 mm<br>Mass: 763 mg<br>Wrapper Material: Tobacco | Length: 114.3 mm<br>Width: 50.8 mm<br>Mass: 763 mg<br>Wrapper Material: Tobacco |
| <b>STN</b>                 | <b>SE0022327.PD2</b>                                                            | <b>GF1909072</b>                                                                |
| Product name               | Show Diamond Wrap - Purple                                                      | Blunt Wrap Platinum-Purple                                                      |
| Eligibility status         | Not Applicable                                                                  | Pre-Existing                                                                    |
| Package type               | Foil Pouch                                                                      | Foil Pouch                                                                      |
| Package quantity           | 3 Cigar Wrappers                                                                | 2 Cigar Wrappers                                                                |
| Characterizing flavor(CF)  | Tobacco                                                                         | Tobacco                                                                         |
| Nicotine source            | Tobacco                                                                         | Tobacco                                                                         |
| Additional properties      | Length: 114.3 mm<br>Width: 50.8 mm<br>Wrapper Material: Tobacco                 | Length: 114.3 mm<br>Width: 50.8 mm<br>Wrapper Material: Tobacco                 |
| <b>STN</b>                 | <b>SE0022329.PD2</b>                                                            | <b>GF1909028</b>                                                                |
| Product name               | Show Diamond Wrap - Vanilla                                                     | Blunt Wrap Platinum - Vanilla                                                   |
| Eligibility status         | Not Applicable                                                                  | Pre-Existing                                                                    |
| Package type               | Foil Pouch                                                                      | Foil Pouch                                                                      |
| Package quantity           | 3 Cigar Wrappers                                                                | 2 Cigar Wrappers                                                                |
| Characterizing flavor(CF)  | Flavored                                                                        | Flavored                                                                        |
| Flavored CF, as identified | Vanilla                                                                         | Vanilla                                                                         |
| Nicotine source            | Tobacco                                                                         | Tobacco                                                                         |
| Additional properties      | Length: 114.3 mm<br>Width: 50.8 mm<br>Wrapper Material: Tobacco                 | Length: 114.3 mm<br>Width: 50.8 mm<br>Wrapper Material: Tobacco                 |

| STN                        | SE0022330.PD2                                                   | GF1909029                                                       |
|----------------------------|-----------------------------------------------------------------|-----------------------------------------------------------------|
| Product name               | Show Diamond Wrap - Watermelon                                  | Blunt Wrap Platinum- Watermelon                                 |
| Eligibility status         | Not Applicable                                                  | Pre-Existing                                                    |
| Package type               | Foil Pouch                                                      | Foil Pouch                                                      |
| Package quantity           | 3 Cigar Wrappers                                                | 2 Cigar Wrappers                                                |
| Characterizing flavor(CF)  | Flavored                                                        | Flavored                                                        |
| Flavored CF, as identified | Watermelon                                                      | Watermelon                                                      |
| Nicotine source            | Tobacco                                                         | Tobacco                                                         |
| Additional properties      | Length: 114.3 mm<br>Width: 50.8 mm<br>Wrapper Material: Tobacco | Length: 114.3 mm<br>Width: 50.8 mm<br>Wrapper Material: Tobacco |

## **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.