

## Technical Project Lead (TPL) Review of Exemption Requests

| New Products Subject of this Review <sup>1</sup>                              |                                                                                                         |
|-------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------|
| STNs                                                                          | EX0002050.PD1, EX0002051.PD1, EX0002052.PD1, EX0002053.PD1, EX0002056.PD1, EX0002058.PD1, EX0002059.PD1 |
| Common Attributes                                                             |                                                                                                         |
| Submission date                                                               | June 15, 2021                                                                                           |
| Receipt date                                                                  | June 15, 2021                                                                                           |
| Applicant                                                                     | Joseph Anderson dba Smokin Joes                                                                         |
| Product manufacturer                                                          | Joseph Anderson dba Smokin Joes                                                                         |
| Product category                                                              | Cigars                                                                                                  |
| Product subcategory                                                           | Filtered, Sheet-Wrapped                                                                                 |
| Cross-Referenced Submissions                                                  |                                                                                                         |
| All STNs                                                                      | None                                                                                                    |
| Supporting FDA Memoranda Relied Upon in this Review                           |                                                                                                         |
| All STNs                                                                      | Social science evaluation of design of cigarette tipping paper (May 11, 2017)                           |
| Recommendation                                                                |                                                                                                         |
| Issue Exempt (EX) orders for the new tobacco products subject of this review. |                                                                                                         |

Technical Project Lead (TPL):

Digitally signed by Jenna F. Dumond -S  
Date: 2022.11.14 09:18:25 -05'00'

Matthew Hassink, Ph.D.  
Team Supervisor  
Division of Product Science

Signing for Matthew Hassink  
November 14, 2022

Signatory Decision:

Concur with TPL recommendation and basis of recommendation

Todd L. Cecil -S Digitally signed by Todd L. Cecil -S  
Date: 2022.11.14 13:39:38 -05'00'

Todd L. Cecil, Ph.D.  
Deputy Director  
Office of Science

<sup>1</sup> Product details, amendments, and dates provided in the Appendix. EX means exemption (request) from substantial equivalence. STN means submission tracking number.

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## 1. BACKGROUND

### 1.1. NEW AND ORIGINAL PRODUCTS

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

### 1.2. REGULATORY ACTIVITY

See appendices 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               |             | Cycle 2        |                |
|-----------------------|-----------------------|-------------|----------------|----------------|
|                       | Reviewer(s)           | Review Date | Reviewer(s)    | Review Date    |
| Regulatory            | Kristopher Van Amburg | 8/26/2021   | Not Applicable | Not Applicable |
| Chemistry             | Ling Zhang            | 5/19/2022   | Not Applicable | Not Applicable |
| Environmental Science | Carla Figueroa        | 5/19/2022   | Carla Figueroa | 10/11/2022     |

## 2. COMPLIANCE REVIEW

The Office of Compliance and Enforcement (OCE) completed a review to determine whether the applicant established that the original products are pre-existing products (i.e., were commercially marketed in the United States as of February 15, 2007). The OCE reviews dated September 29, 2022 (for EX0002051.PD1, EX0002056.PD1 and EX0002058.PD1) and September 30, 2022 (for EX0002050.PD1, EX0002052.PD1, EX0002053.PD1, and EX0002059.PD1) conclude that the evidence submitted by the applicant is adequate to demonstrate original products are pre-existing products.

Therefore, the original products are eligible for modification under the Exemption Request pathway.<sup>2</sup>

## 3. TOBACCO ADDITIVE MODIFICATION

The applicant claims that the modification of the original products compared to the corresponding new products is the result of:

- deleting an additive (Tipping paper: (b) (4) ) in all the EX Requests
- adding an additive (Tipping paper: (b) (4) ) in all the EX Requests

<sup>2</sup> Any product that can be sold under the FD&C Act (e.g., legally marketed in the United States) is eligible for modification under the Exemption Request pathway.

#### 4. SCIENTIFIC REVIEW

The review finds the modified ingredient (see Section 3) is an additive because the intended use may reasonably be expected to result, directly or indirectly, in their becoming a component or otherwise affecting the characteristics of the products. The review concludes that the modification is a minor modification of a product in accordance with section 905(j)(3)(A)(i) of the FD&C Act.

#### 5. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Luis Valerio, Ph.D. on October 12, 2022. The FONSI was supported by an environmental assessment prepared by FDA on October 11, 2022.

#### 6. CONCLUSION AND RECOMMENDATION

I concur with the conclusion of the scientific review that this modification (see Section 3) is a minor modification of a product in accordance with section 905(j)(3)(A)(i) of the FD&C Act. I concur that the modified ingredients are “additives” as defined in section 900(1) of the FD&C Act. In addition, it is my conclusion that, consistent with section 905(j)(3)(A)(ii) of the FD&C Act, an SE Report is not necessary to ensure that permitting the new products to be marketed would be appropriate for the protection of the public health. The applicant proposes to modify the corresponding original products by deleting tipping paper (b) (4)

and adding tipping paper TP (b) (4) in the new products. There is limited scientific data on the influence of consumer perception on changes in cigarette tipping paper, and therefore any change in consumer behavior such as increased initiation or use solely due to cigarette tipping paper design (e.g., line color) are likely to be minimal.<sup>1</sup> The tipping paper of the original products contains (b) (4), which are not present in the tipping paper of the corresponding new products.

Moreover, there are no differences between the reported characterizing flavors of all new and corresponding original products. Therefore, the deletion of the small quantity of (b) (4) (b) (4) mg/g) in the new products is not expected to have measurable impact on product characteristics. The other ingredient differences in the base paper and ink between the new and corresponding original products are all very small quantity differences. In addition, tipping paper is a non-combusted component, and the tipping paper ingredients do not combust, volatilize, or otherwise release during normal consumption. Therefore, change in tipping paper is not expected to contribute to the smoke chemistry or consumer exposure to smoke constituents. All the new and corresponding original products are unventilated. There are no modifications to the tipping papers that affect product ventilation. The identical ventilation between the new and corresponding original products does not raise any concerns. Lastly, I find that an exemption for this modification is otherwise appropriate as required by section 905(j)(3)(A)(iii) of the FD&C Act. Therefore, the new products should be found exempt from the requirements of substantial equivalence under section 910(a)(3)(A) of the FD&C Act.

The original products are eligible for modification through the Exemption Request pathway because they can be legally marketed in the United States. The original products are pre-existing products; i.e., were commercially marketed in the United States as of February 15, 2007.

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<sup>1</sup> FDA memorandum: Social science evaluation of design of cigarette tipping paper, signed on May 16, 2017

FDA has examined the environmental effects of finding the new products exempt and made a finding of no significant impact.

An exempt order should be issued for the new products, as identified on the cover page of this review.

## 7. APPENDICES

### Appendix A. New and original products

| Common Attributes            |                                                                                                                                                                        |                                     |
|------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|
| Submission date              | June 15, 2021                                                                                                                                                          |                                     |
| Receipt date                 | June 15, 2021                                                                                                                                                          |                                     |
| Applicant                    | Joseph Anderson dba Smokin Joes                                                                                                                                        |                                     |
| Product manufacturer         | Joseph Anderson dba Smokin Joes                                                                                                                                        |                                     |
| Product category             | Cigars                                                                                                                                                                 |                                     |
| Product subcategory          | Filtered, Sheet-Wrapped                                                                                                                                                |                                     |
| Attributes                   | New Product                                                                                                                                                            | Original Product                    |
| STN                          | EX0002050.PD1                                                                                                                                                          | GF1909408                           |
| Product name                 | Exacta Filtered Cigars Menthol                                                                                                                                         | Smokin Time Filtered Cigars Menthol |
| Eligibility status           | Not Applicable                                                                                                                                                         | Pre-Existing                        |
| Marketing authorization date | Not Applicable                                                                                                                                                         | Not Applicable                      |
| Abbreviated report date      | Not Applicable                                                                                                                                                         | Not Applicable                      |
| Package type                 | Soft Pack                                                                                                                                                              | Soft Pack                           |
| Package quantity             | 20 Cigars                                                                                                                                                              | 20 Cigars                           |
| Characterizing flavor (CF)   | Menthol                                                                                                                                                                | Menthol                             |
| Nicotine Source              | Tobacco                                                                                                                                                                | Tobacco                             |
| Length                       | 99 mm                                                                                                                                                                  | 99 mm                               |
| Diameter                     | 7.9 mm                                                                                                                                                                 | 7.9 mm                              |
| Ventilation                  | None                                                                                                                                                                   | None                                |
| Product modifications        | Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>Deletion of Tipping paper (b) (4)</li> <li>Addition of Tipping paper (b) (4)</li> </ul> |                                     |

| Attributes                   | New Product                                                                                                                                                                | Original Product                   |
|------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|
| STN                          | EX0002051.PD1                                                                                                                                                              | GF1909407                          |
| Product name                 | Bogar Filtered Cigars Cherry                                                                                                                                               | Smokin Time Filtered Cigars Cherry |
| Eligibility status           | Not Applicable                                                                                                                                                             | Pre-Existing                       |
| Marketing authorization date | Not Applicable                                                                                                                                                             | Not Applicable                     |
| Abbreviated report date      | Not Applicable                                                                                                                                                             | Not Applicable                     |
| Package type                 | Soft Pack                                                                                                                                                                  | Soft Pack                          |
| Package quantity             | 20 Cigars                                                                                                                                                                  | 20 Cigars                          |
| Characterizing flavor (CF)   | Flavored                                                                                                                                                                   | Flavored                           |
| Flavored CF                  | Cherry                                                                                                                                                                     | Cherry                             |
| Nicotine Source              | Tobacco                                                                                                                                                                    | Tobacco                            |
| Length                       | 99 mm                                                                                                                                                                      | 99 mm                              |
| Diameter                     | 7.9 mm                                                                                                                                                                     | 7.9 mm                             |
| Ventilation                  | None                                                                                                                                                                       | None                               |
| Product modifications        | Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of Tipping paper (b) (4)</li> <li>• Addition of Tipping paper (b) (4)</li> </ul> |                                    |
| Attributes                   | New Product                                                                                                                                                                | Original Product                   |
| STN                          | EX0002052.PD1                                                                                                                                                              | GF1909405                          |
| Product name                 | No Limit Filtered Cigars Grape                                                                                                                                             | Smokin Time Filtered Cigars Grape  |
| Eligibility status           | Not Applicable                                                                                                                                                             | Pre-Existing                       |
| Marketing authorization date | Not Applicable                                                                                                                                                             | Not Applicable                     |
| Abbreviated report date      | Not Applicable                                                                                                                                                             | Not Applicable                     |
| Package type                 | Soft Pack                                                                                                                                                                  | Soft Pack                          |
| Package quantity             | 20 Cigars                                                                                                                                                                  | 20 Cigars                          |
| Characterizing flavor (CF)   | Flavored                                                                                                                                                                   | Flavored                           |
| Flavored CF                  | Grape                                                                                                                                                                      | Grape                              |
| Nicotine Source              | Tobacco                                                                                                                                                                    | Tobacco                            |
| Length                       | 99 mm                                                                                                                                                                      | 99 mm                              |
| Diameter                     | 7.9 mm                                                                                                                                                                     | 7.9 mm                             |
| Ventilation                  | None                                                                                                                                                                       | None                               |
| Product modifications        | Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of Tipping paper (b) (4)</li> <li>• Addition of Tipping paper (b) (4)</li> </ul> |                                    |

| Attributes                   | New Product                                                                                                                                                                | Original Product                        |
|------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------|
| STN                          | EX0002053.PD1                                                                                                                                                              | GF1909404                               |
| Product name                 | No Limit Filtered Cigars Ultra Smooth                                                                                                                                      | Smokin Time Filtered Cigars Ultra Light |
| Eligibility status           | Not Applicable                                                                                                                                                             | Pre-Existing                            |
| Marketing authorization date | Not Applicable                                                                                                                                                             | Not Applicable                          |
| Abbreviated report date      | Not Applicable                                                                                                                                                             | Not Applicable                          |
| Package type                 | Soft Pack                                                                                                                                                                  | Soft Pack                               |
| Package quantity             | 20 Cigars                                                                                                                                                                  | 20 Cigars                               |
| Characterizing flavor (CF)   | Tobacco                                                                                                                                                                    | Tobacco                                 |
| Nicotine Source              | Tobacco                                                                                                                                                                    | Tobacco                                 |
| Length                       | 99 mm                                                                                                                                                                      | 99 mm                                   |
| Diameter                     | 7.9 mm                                                                                                                                                                     | 7.9 mm                                  |
| Ventilation                  | None                                                                                                                                                                       | None                                    |
| Product modifications        | Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of Tipping paper (b) (4)</li> <li>• Addition of Tipping paper (b) (4)</li> </ul> |                                         |
| Attributes                   | New Product                                                                                                                                                                | Original Product                        |
| STN                          | EX0002056.PD1                                                                                                                                                              | GF1909409                               |
| Product name                 | No Limit Filtered Cigars Full Flavor                                                                                                                                       | Smokin Time Filtered Cigars Full Flavor |
| Eligibility status           | Not Applicable                                                                                                                                                             | Pre-Existing                            |
| Marketing authorization date | Not Applicable                                                                                                                                                             | Not Applicable                          |
| Abbreviated report date      | Not Applicable                                                                                                                                                             | Not Applicable                          |
| Package type                 | Soft Pack                                                                                                                                                                  | Soft Pack                               |
| Package quantity             | 20 Cigars                                                                                                                                                                  | 20 Cigars                               |
| Characterizing flavor (CF)   | Tobacco                                                                                                                                                                    | Tobacco                                 |
| Nicotine Source              | Tobacco                                                                                                                                                                    | Tobacco                                 |
| Length                       | 99 mm                                                                                                                                                                      | 99 mm                                   |
| Diameter                     | 7.9 mm                                                                                                                                                                     | 7.9 mm                                  |
| Ventilation                  | None                                                                                                                                                                       | None                                    |
| Product modifications        | Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of Tipping paper (b) (4)</li> <li>• Addition of Tipping paper (b) (4)</li> </ul> |                                         |

| Attributes                   | New Product                                                                                                                                                                | Original Product                    |
|------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|
| STN                          | EX0002058.PD1                                                                                                                                                              | GF1909406                           |
| Product name                 | No Limit Filtered Cigars Vanilla                                                                                                                                           | Smokin Time Filtered Cigars Vanilla |
| Eligibility status           | Not Applicable                                                                                                                                                             | Pre-Existing                        |
| Marketing authorization date | Not Applicable                                                                                                                                                             | Not Applicable                      |
| Abbreviated report date      | Not Applicable                                                                                                                                                             | Not Applicable                      |
| Package type                 | Soft Pack                                                                                                                                                                  | Soft Pack                           |
| Package quantity             | 20 Cigars                                                                                                                                                                  | 20 Cigars                           |
| Characterizing flavor (CF)   | Flavored                                                                                                                                                                   | Flavored                            |
| Flavored CF                  | Vanilla                                                                                                                                                                    | Vanilla                             |
| Nicotine Source              | Tobacco                                                                                                                                                                    | Tobacco                             |
| Length                       | 99 mm                                                                                                                                                                      | 99 mm                               |
| Diameter                     | 7.9 mm                                                                                                                                                                     | 7.9 mm                              |
| Ventilation                  | None                                                                                                                                                                       | None                                |
| Product modifications        | Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of Tipping paper (b) (4)</li> <li>• Addition of Tipping paper (b) (4)</li> </ul> |                                     |
| Attributes                   | New Product                                                                                                                                                                | Original Product                    |
| STN                          | EX0002059.PD1                                                                                                                                                              | GF1909403                           |
| Product name                 | Bogar Filtered Cigar Smooth                                                                                                                                                | Smokin Time Filtered Cigar Light    |
| Eligibility status           | Not Applicable                                                                                                                                                             | Pre-Existing                        |
| Marketing authorization date | Not Applicable                                                                                                                                                             | Not Applicable                      |
| Abbreviated report date      | Not Applicable                                                                                                                                                             | Not Applicable                      |
| Package type                 | Soft Pack                                                                                                                                                                  | Soft Pack                           |
| Package quantity             | 20 Cigars                                                                                                                                                                  | 20 Cigars                           |
| Characterizing flavor (CF)   | Tobacco                                                                                                                                                                    | Tobacco                             |
| Nicotine Source              | Tobacco                                                                                                                                                                    | Tobacco                             |
| Length                       | 99 mm                                                                                                                                                                      | 99 mm                               |
| Diameter                     | 7.9 mm                                                                                                                                                                     | 7.9 mm                              |
| Ventilation                  | None                                                                                                                                                                       | None                                |
| Product modifications        | Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of Tipping paper (b) (4)</li> <li>• Addition of Tipping paper (b) (4)</li> </ul> |                                     |

**Appendix B. Amendments**

| Submission Date | Receipt Date   | Applications being amended | Reviewed | Brief Description                            |
|-----------------|----------------|----------------------------|----------|----------------------------------------------|
| August 9, 2022  | August 9, 2022 | All STNs                   | Yes      | Response to July 22, 2022, Deficiency letter |