

**Technical Project Lead (TPL) Review:
Exemption Requests EX0000798 – EX0000803**

| EX0000798: Misty Rose Slim 100 | |
|--|---|
| Length | 99 mm |
| Diameter | 7.3 mm |
| Ventilation | 62% |
| Characterizing Flavor | None |
| Product Modifications | <p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> • Deletion of filter center line adhesive (b) (4) • Addition of filter center line adhesive (b) (4) • Deletion of tipping paper adhesive (b) (4) • Addition of tipping paper adhesive (b) (4) • Deletion of white tipping paper (b) (4) • (b) (4) • Addition of white tipping paper (b) (4) • (b) (4) • Deletion of filter tow (b) (4) • Addition of filter tow (b) (4) <p>Increasing/Decreasing the quantity of existing tobacco additives:</p> <ul style="list-style-type: none"> • Increase in the quantity of filter sideseam adhesive |
| EX0000799: Misty Menthol Green Slim 100 | |
| Length | 99 mm |
| Diameter | 7.3 mm |
| Ventilation | 45% |
| Characterizing Flavor | Menthol |
| Product Modifications | <p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> • Deletion of filter center line adhesive (b) (4) • Addition of filter center line adhesive (b) (4) • Deletion of tipping paper adhesive (b) (4) • Addition of tipping paper adhesive (b) (4) • Deletion of white tipping paper (b) (4) • (b) (4) • Addition of white tipping paper (b) (4) • (b) (4) • Deletion of filter tow (b) (4) • Addition of filter tow (b) (4) <p>Increasing/Decreasing the quantity of existing tobacco additives:</p> <ul style="list-style-type: none"> • Increase in the quantity of filter sideseam adhesive |
| EX0000800: Misty Menthol Silver Slim 100 | |
| Length | 99 mm |
| Diameter | 7.3 mm |
| Ventilation | 62% |
| Characterizing Flavor | Menthol |
| Product Modifications | Addition/Deletion of tobacco additives: |

| | |
|--|---|
| | <ul style="list-style-type: none"> • Deletion of filter center line adhesive (RJRT <i>In-House</i>) • Addition of filter center line adhesive (b) (4) • Deletion of white tipping paper (b) (4) • Addition of white tipping paper (b) (4) • Deletion of filter tow (b) (4) • Addition of filter tow (b) (4) |
| EX0000801: Misty Menthol Green Slim 120 | |
| Length | 119 mm |
| Diameter | 7.3 mm |
| Ventilation | 48% |
| Characterizing Flavor | Menthol |
| Product Modifications | <p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> • Deletion of filter center line adhesive (b) (4) • Addition of filter center line adhesive (b) (4) • Deletion of tipping paper adhesive (b) (4) • Addition of tipping paper adhesive (b) (4) • Deletion of white tipping paper (b) (4) • Addition of white tipping paper (b) (4) • Deletion of filter tow (b) (4) • Addition of filter tow (b) (4) <p>Increasing/Decreasing the quantity of existing tobacco additives:</p> <ul style="list-style-type: none"> • Increase in the quantity of filter sideseam adhesive |
| EX0000802: Misty Blue Slim 120 | |
| Length | 119 mm |
| Diameter | 7.3 mm |
| Ventilation | 48% |
| Characterizing Flavor | None |
| Product Modifications | <p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> • Deletion of filter center line adhesive (b) (4) • Addition of filter center line adhesive (b) (4) • Deletion of tipping paper adhesive (b) (4) • Addition of tipping paper adhesive (b) (4) • Deletion of white tipping paper (b) (4) • Addition of white tipping paper (b) (4) • Deletion of filter tow (b) (4) • Addition of filter tow (b) (4) <p>Increasing/Decreasing the quantity of existing tobacco additives:</p> <ul style="list-style-type: none"> • Increase in the quantity of filter sideseam adhesive |
| EX0000803: Misty Blue Slim 100 | |
| Length | 99 mm |

| | |
|--|---|
| Diameter | 7.3 mm |
| Ventilation | 45% |
| Characterizing Flavor | None |
| Product Modifications | <p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> • Deletion of filter center line adhesive (b) (4) • Addition of filter center line adhesive (b) (4) • Deletion of tipping paper adhesive (b) (4) • Addition of tipping paper adhesive (b) (4) • Deletion of white tipping paper (b) (4) : • Addition of (b) (4) • Deletion of filter tow (b) (4) • Addition of filter tow (b) (4) <p>Increasing/Decreasing the quantity of existing tobacco additives:</p> <ul style="list-style-type: none"> • Increase in the quantity of filter sideseam adhesive |
| Common Attributes of Exemption Requests | |
| Applicant | R.J. Reynolds Tobacco Company |
| Product Category | Cigarette |
| Product Sub-Category | Combusted Filtered |
| Package Quantity | 20 cigarettes |
| Package Type | Box |
| Conclusion | |
| Issue Exempt order letter. | |

Technical Project Lead (TPL):

Digitally signed by Todd L. Cecil -S
Date: 2019.12.03 08:25:04 -05'00'

Todd L. Cecil, Ph.D.
Associate Director
Division of Product Science

Signatory Decision:

- Concur with TPL recommendation and basis of recommendation
- Concur with TPL recommendation with additional comments (see separate memo)
- Do not concur with TPL recommendation (see separate memo)

Digitally signed by Matthew R. Holman -S
Date: 2019.12.03 12:50:26 -05'00'

Matthew R. Holman, Ph.D.
Director
Office of Science

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1. BACKGROUND

1.1. ORIGINAL TOBACCO PRODUCTS

The applicant submitted the following original tobacco products:

Table 1. Original Tobacco Products

| | |
|---|--|
| EX0000798: Misty Rose Slim 100 | |
| Product Name | Misty Slims Ultra Light 100s Box |
| Package Type | Box |
| Package Quantity | 20 Cigarettes |
| Length | 99 mm |
| Diameter | 7.3 mm |
| Ventilation | 62% |
| Characterizing Flavor | None |
| EX0000799: Misty Menthol Green Slim 100 | |
| Product Name | Misty Slims Light Menthol 100s Box |
| Package Type | Box |
| Package Quantity | 20 Cigarettes |
| Length | 99 mm |
| Diameter | 7.3 mm |
| Ventilation | 45% |
| Characterizing Flavor | Menthol |
| EX0000800: Misty Menthol Silver Slim 100 | |
| Product Name | Misty Slims Ultra Light Menthol 100s Box |
| Package Type | Box |
| Package Quantity | 20 Cigarettes |
| Length | 99 mm |
| Diameter | 7.3 mm |
| Ventilation | 62% |
| Characterizing Flavor | Menthol |
| EX0000801: Misty Menthol Green Slim 120 | |
| Product Name | Misty Slims Light Menthol 120s Box |
| Package Type | Box |
| Package Quantity | 20 Cigarettes |
| Length | 119 mm |
| Diameter | 7.3 mm |
| Ventilation | 48% |
| Characterizing Flavor | Menthol |
| EX0000802: Misty Blue Slim 120 | |
| Product Name | Misty Slims Light 120s Box |
| Package Type | Box |
| Package Quantity | 20 Cigarettes |
| Length | 119 mm |

| | |
|---------------------------------------|----------------------------|
| Diameter | 7.3 mm |
| Ventilation | 48% |
| Characterizing Flavor | None |
| EX0000803: Misty Blue Slim 100 | |
| Product Name | Misty Slims Light 100s Box |
| Package Type | Box |
| Package Quantity | 20 Cigarettes |
| Length | 99 mm |
| Diameter | 7.3 mm |
| Ventilation | 45% |
| Characterizing Flavor | None |

The applicant manufactures the original tobacco products and claims that they are grandfathered.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On October 4, 2019, FDA received six Exemption Requests (EX0000798-EX0000803) from RAI Services Company on behalf of R.J. Reynolds Tobacco Company. FDA issued the applicant an Acceptance letter for these Exemption Requests on October 9, 2019.

1.3. SCOPE OF REVIEW

This review captures all regulatory, compliance, and scientific reviews completed for these Exemption Requests.

1.4. TOBACCO ADDITIVE MODIFICATIONS

The new tobacco products contain the following modifications compared to the corresponding original tobacco products:

- Deletion of filter center line adhesive (b) (4) (EX0000798-EX0000799, EX0000801-EX0000803)
- Deletion of filter center line adhesive (RJRT In-house) (EX0000800)
- Addition of filter center line adhesive (b) (4) (EX0000798-803)
- Deletion of tipping paper adhesive (b) (4) (EX0000798-EX0000799, EX0000801-EX0000803)
- Addition of tipping paper adhesive (b) (4) (EX0000798-EX0000799, EX0000801-EX0000803)
- Deletion of white tipping paper (b) (4) (EX0000798-803)
- Addition of white tipping paper (b) (4) (EX0000798-803)
- Deletion of filter tow (b) (4) (EX0000798-EX0000800, EX0000803)
- Addition of filter tow (b) (4) (EX0000798-EX0000800, EX0000803)
- Deletion of filter tow (b) (4) (EX0000801-EX0000802)

- Addition of filter tow (b) (4) (EX0000801-EX0000802)
- Increase in the quantity of filter seam adhesive (EX0000798-EX0000799, EX0000801-EX0000803)

2. ADMINISTRATIVE REVIEW

Acceptance reviews were completed by Nikole Ayala-Agosto on October 9, 2019. The review concludes that the Exemption Requests are administratively complete.

3. COMPLIANCE REVIEW

The Office of Compliance and Enforcement (OCE) completed reviews to determine whether the applicant established that the original tobacco products are grandfathered products (i.e., were commercially marketed in the United States, other than exclusively in test markets, as of February 15, 2007). The OCE reviews dated November 4, 2019, conclude that the original tobacco products are grandfathered products. Therefore, the original products are eligible for modification under the Exemption Request pathway.¹

4. SCIENTIFIC REVIEW

A scientific review was completed by Scott Wasdo on December 3, 2019.

The review concludes that the new tobacco products have been modified by adding or deleting tobacco additives and increasing or decreasing tobacco additives. Filter center line adhesive, filter sideseam adhesive², tipping paper adhesive², tipping paper, and filter tow are substances used in the manufacture of the original tobacco products' filters and are additives because their intended use may reasonably be expected to result, directly or indirectly, in their becoming a component or otherwise affecting the characteristics of the tobacco products. The review concludes that the modifications are minor modification of tobacco additives in accordance with section 905(j)(3)(A)(i) of the FD&C Act. For EX0000798-EX0000803, the review concludes, the deletion of filter center line adhesive in the original products and the addition of an alternate filter center line adhesive in the new products is a minor modification. Because the filter centerline adhesive is not combusted, volatilized, or otherwise released during normal cigarette consumption, the modifications of these ingredients in the filter are not expected to significantly alter the smoke chemistry or consumer exposure to chemical constituents while smoking. For EX0000798-EX0000799, EX0000801-EX0000803, the review also concludes that the deletion of tipping paper and filter sideseam adhesive in the original products and the addition of an alternate tipping paper and filter sideseam adhesive and the increase in the filter sideseam adhesive in the new products are minor modifications. These changes are made to the filter of the tobacco product, which is not combusted, volatilized, or otherwise released during normal cigarette consumption, therefore the ingredient differences and relatively small increase in content between the tipping adhesive of the new and original products are not expected to significantly alter the relative smoke chemistry or consumer exposure to chemical constituents of the new product relative to the original product. The review also concludes that the deletion of white tipping paper and the addition of white tipping paper is a minor modification. These changes are not expected to have any significant effects on

¹ Any tobacco 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.

² EX0000798, EX0000799, EX0000801-EX0000803 only.

consumer perception as outlined in the May 16, 2017, social science memo. Furthermore, the review concludes that the deletion of filter tow and the addition of an alternative filter tow is a minor modification and is not expected to materially affect any other characteristic (materials, ingredients, design, composition, heating source, or other features) of the products. The differences in the filter tow in the original and new tobacco products is the quantity of (b) (4) used in the new products is lower than the amount used in the original products. The difference in the relative quantities of (b) (4) are not expected to have a meaningful impact on the relative performance of the new and original product filters. As a result, the ingredient differences between the tipping paper of the new and original products are not expected to significantly alter the relative smoke chemistry or consumer exposure to chemical constituents of the new product relative to the original tobacco product.

5. ENVIRONMENTAL DECISION

An environmental review was completed by Shannon Hanna, Ph.D. on October 29, 2019.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on November 7, 2019. The FONSI was supported by an environmental assessment prepared by FDA on November 7, 2019.

6. CONCLUSION AND RECOMMENDATION

The new tobacco products contain the following modifications compared to the corresponding original tobacco products:

- Deletion of filter center line adhesive (b) (4) (EX0000798-EX0000799, EX0000801-EX0000803)
- Deletion of filter center line adhesive (RJRT In-house) (EX0000800)
- Addition of filter center line adhesive (b) (4) (EX0000798-803)
- Deletion of tipping paper adhesive (b) (4) (EX0000798-EX0000799, EX0000801-EX0000803)
- Addition of tipping paper adhesive (b) (4) (EX0000798-EX0000799, EX0000801-EX0000803)
- Deletion of white tipping paper (b) (4) (EX0000798-803)
- Addition of white tipping paper (b) (4) (EX0000798-803)
- Deletion of filter tow (b) (4) (EX0000798-EX0000800, EX0000803)
- Addition of filter tow (b) (4) (EX0000798-EX0000800, EX0000803)
- Deletion of filter tow (b) (4) (EX0000801-EX0000802)
- Addition of filter tow (b) (4) (EX0000801-EX0000802)
- Increase in the quantity of filter seam adhesive (EX0000798-EX0000799, EX0000801-EX0000803)

I concur with the conclusion of the scientific review that these modifications are minor modification involving tobacco additives in accordance with section 905(j)(3)(A)(i) of the FD&C Act. Section 900(1) of the FD&C Act defines 'additive' as "any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristic of any tobacco product (including any substances intended for use as a flavoring or coloring or in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding), . . ." I agree with the scientific review that the new tobacco products have been modified by adding or deleting tobacco additives and increasing or decreasing tobacco additives. Filter center line adhesive, filter sideseam adhesive², tipping paper adhesive², tipping paper, and filter tow are substances used in the manufacture of the original tobacco products' filters and are additives because their intended use may reasonably be expected to result, directly or indirectly, in their becoming a component or otherwise affecting the characteristics of the tobacco products. 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 tobacco product to be marketed would be appropriate for protection of the public health. For EX0000798-EX0000803, I also agree with the conclusion that the deletion of filter center line adhesive in the original products and the addition of an alternate filter center line adhesive in the new products is a minor modification. Because the filter centerline adhesive is not combusted, volatilized, or otherwise released during normal cigarette consumption, the modifications of these ingredients in the filter are not expected to significantly alter the smoke chemistry or consumer exposure to chemical constituents while smoking. For EX0000798-EX0000799, EX0000801-EX0000803, I agree with the scientific review conclusion that the deletion of tipping paper adhesive in the original products and the addition of an alternate tipping paper adhesive and the increase in the filter sideseam adhesive in the new products are minor modifications. These changes are made to the filter of the tobacco product, which is not combusted, volatilized, or otherwise released during normal cigarette consumption, therefore the ingredient differences and relatively small increase in content between the tipping adhesive of the new and original products are not expected to significantly alter the relative smoke chemistry or consumer exposure to chemical constituents of the new product relative to the original product. I also agree that the deletion of white tipping paper and the addition of white tipping paper is a minor modification. These changes are not expected to have any significant effects on consumer perception as outlined in the May 16, 2017, social science memo. I agree with the review's conclusion that the deletion of filter tow and the addition of an alternative filter tow is a minor modification and is not expected to materially affect any other characteristic (materials, ingredients, design, composition, heating source, or other features) of the products. The differences in the filter tow in the original and new tobacco products is the quantity of (b) (4) used in the new products is lower than the amount used in the original products. The difference in the relative quantities of (b) (4) are not expected to have a meaningful impact on the relative performance of the new and original product filters. As a result, the ingredient differences between the tipping paper of the new and original products are not expected to significantly alter the relative smoke chemistry or consumer exposure to chemical constituents of the new product relative to the original tobacco product. Lastly, FDA finds, based on the information contained in the Exemption Request and CTP's scientific understanding, 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 tobacco product should be found exempt from the requirements of substantial equivalence under section 910(a)(3)(A) of the FD&C Act.

The original tobacco products meet statutory requirements because they are legally marketed in the United States. The original products are grandfathered products (i.e., were commercially marketed in the United States, other than exclusively in test markets, as of February 15, 2007).

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

Exempt order letters should be issued for the new tobacco products in EX0000798-EX0000803 as identified on the cover page of this review.