

**Technical Project Lead (TPL) Review:
Exemption Requests EX0000901 – EX0000904**

EX0000901: Doral Classic Slim Menthol Gold 100 Box	
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) target: (b) (4) mg/cigarette) • Addition of white tipping paper (b) (4) target: (b) (4) mg/cigarette) • Deletion of filter tow (b) (4) target: (b) (4) mg/cigarette) • Addition of filter tow (b) (4) target: (b) (4) mg/cigarette) <p>Increasing/Decreasing the quantity of existing tobacco additives:</p> <ul style="list-style-type: none"> • Increase in the quantity of the filter sideseam adhesive (b) (4)
EX0000902: GPC Classic Menthol Soft Pack	
Length	83 mm
Diameter	7.8 mm
Ventilation	17%
Characterizing Flavor	Menthol
Product Modifications	<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> • Deletion of cork tipping paper (b) (4) target: (b) (4) mg/cigarette) • Addition of white tipping paper (b) (4) target: (b) (4) mg/cigarette) • Deletion of filter tow (b) (4) target: (b) (4) mg/cigarette) • Addition of filter tow (b) (4) target: (b) (4) mg/cigarette) • Deletion of box container closure system • Addition of soft pack container closure system

EX0000903: GPC Classic Menthol 100 Soft Pack	
Length	98 mm
Diameter	7.8 mm
Ventilation	17%
Characterizing Flavor	Menthol
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of cork tipping paper (b) (4) target: (b) (4) mg/cigarette) • Addition of white tipping paper (b) (4) target: (b) (4) mg/cigarette) • Deletion of filter tow (b) (4) target: (b) (4) mg/cigarette) • Addition of filter tow (b) (4) target: (b) (4) mg/cigarette) • Deletion of box container closure system • Addition of soft pack container closure system
EX0000904: GPC Classic Menthol Silver 100 Soft Pack	
Length	99 mm
Diameter	7.9 mm
Ventilation	52%
Characterizing Flavor	Menthol
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of white tipping paper (b) (4) target: (b) (4) mg/cigarette) • Addition of a white tipping paper (b) (4) target: (b) (4) mg/cigarette) • Deletion of filter tow (b) (4) target: (b) (4) mg/cigarette) • Addition of filter tow (b) (4) target: (b) (4) mg/cigarette)
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: EX0000901 Soft Pack: EX0000902 - EX0000904
Recommendation	
Issue Exempt order letters.	

Technical Project Lead (TPL):

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Date: 2020.02.04 16:28:45 -05'00'

Matthew J. Walters, Ph.D., MPH
CDR, U.S. Public Health Service
Deputy 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: 2020.02.05 11:07:36 -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

EX0000901: Doral Classic Slim Menthol Gold 100 Box	
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
EX0000902: GPC Classic Menthol Soft Pack	
Product Name	Doral Full Flavor Menthol Box
Package Type	Box
Package Quantity	20 Cigarettes
Length	83 mm
Diameter	7.8 mm
Ventilation	17%
Characterizing Flavor	Menthol
EX0000903: GPC Classic Menthol 100 Soft Pack	
Product Name	Doral Full Flavor Menthol 100s Box
Package Type	Box
Package Quantity	20 Cigarettes
Length	98 mm
Diameter	7.8 mm
Ventilation	17%
Characterizing Flavor	Menthol
EX0000904: GPC Classic Menthol Silver 100 Soft Pack	
Product Name	GPC Ultra Light Menthol 100s Soft Pack
Package Type	Soft Pack
Package Quantity	20 Cigarettes
Length	99 mm
Diameter	7.9 mm
Ventilation	52%
Characterizing Flavor	Menthol

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

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On December 11, 2019, FDA received Exemption Requests EX0000901-EX0000904 from RAI Services Company on behalf of R.J. Reynolds Tobacco Company. On December 18, 2019, FDA issued an Acceptance letter to the applicant.

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 white or cork tipping paper (b) (4)
- Addition of white tipping paper (b) (4)
- Deletion of filter tow (b) (4)
- Addition of filter tow (b) (4)
- Deletion of filter center line adhesive (b) (4) for EX0000901
- Addition of filter center line adhesive (b) (4) for EX0000901
- Deletion of tipping paper adhesive (b) (4) for EX0000901
- Addition of tipping paper adhesive (b) (4) for EX0000901
- Increase in the quantity of the filter sideseam adhesive (b) (4) for EX0000901
- Deletion of box container closure system for EX0000902 – EX0000903
- Addition of soft pack container closure system for EX0000902 – EX0000903

2. REGULATORY REVIEW

Regulatory reviews were completed by Antonio Thornton on December 18, 2019. The reviews conclude 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 January 14, 2020, conclude that the original tobacco products are grandfathered products. Therefore, the original products are eligible for modification under the Exemption Request pathway.¹

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.

4. SCIENTIFIC REVIEW

A scientific review was completed by Selvin Edwards on February 4, 2020.

The review states that the new tobacco products have been modified by adding or deleting tobacco additives and increasing tobacco additives. Tipping paper (white or cork), filter tow, filter center line adhesive,² tipping paper adhesive², and filter sideseam adhesive² are used in the manufacturing of the original tobacco products, 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 modifications of a tobacco product in accordance with section 905(j)(3)(A)(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). The review concludes that the deletion of white tipping paper and the addition of an alternate white or cork tipping paper is a minor modification. This change is not expected to have any significant effects on consumer perception as outlined in the May 16, 2017, social science memo. In addition, there was no change in the perforation during manufacturing for the tipping paper that could impact HPHC delivery between the original and new tobacco products. Furthermore, the review concludes that the deletion of filter tow and the addition of an alternate 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 tobacco products. The filter tow of the new products includes a 17% decrease in (b) (4) compared to the original product and possess the same amounts of (b) (4). Because the filter tows are not combusted, volatilized, or otherwise released during normal cigarette consumption, the modifications of ingredients in the filter tow are not expected to significantly alter the smoke chemistry and consumer exposure to chemical constituents from the filter tow while smoking. The filter tow can influence the ventilation and filter efficiency of a product; however, the ventilation remains the same when comparing the new and corresponding original tobacco products. In addition, for EX0000901, the review concludes, the deletion of filter center line adhesive in the original product and the addition of an alternate filter center line adhesive along with the increase in the quantity of filter sideseam adhesive in the new product is a minor modification. Because the filter centerline adhesive and filter sideseam 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. Finally, for EX0000901, the review also concludes that the deletion of tipping paper adhesive in the original product and the addition of an alternate tipping paper adhesive in the new product is a minor modification. Because the tipping paper adhesive is not combusted, volatilized, or otherwise released during normal cigarette consumption, therefore the ingredient differences and relatively small increase in content between the tipping paper 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.

5. ENVIRONMENTAL DECISION

Environmental reviews were completed by Bria Martin on January 10, 2020 for EX0000901 and on January 10, 2020 for EX0000902 – EX0000904.

² EX0000901 only

For EX0000901, a finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on January 16, 2020. The FONSI was supported by an environmental assessment prepared by FDA on January 16, 2020.

For EX0000902 – EX0000904, the final environmental review found that the applicant did not provide the overall market volumes from concurrent marketing of the new and original tobacco products. Therefore, additional information is needed to determine whether to prepare an Environmental Impact Statement (EIS) or Finding of No Significant Impact (FONSI).

6. CONCLUSION AND RECOMMENDATION

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

- Deletion of white or cork tipping paper (b) (4)
- Addition of white tipping paper (b) (4)
- Deletion of filter tow (b) (4)
- Addition of filter tow (b) (4)
- Deletion of filter center line adhesive (b) (4) for EX0000901
- Addition of filter center line adhesive (b) (4) for EX0000901
- Deletion of tipping paper adhesive (b) (4) for EX0000901
- Addition of tipping paper adhesive (b) (4) for EX0000901
- Increase in the quantity of the filter sideseam adhesive (b) (4) for EX0000901
- Deletion of box container closure system for EX0000902 – EX0000903
- Addition of soft pack container closure system for EX0000902 – EX0000903

I concur with the conclusion of the scientific review that these modifications are minor modifications of a tobacco product 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 concur with the scientific review that the changes represent the deletion of tobacco additives (tipping paper (white or cork), filter tow, filter center line adhesive,² tipping paper adhesive²) and the addition of tobacco additives (tipping paper (white), filter tow,⁴ filter center line adhesive,² and tipping paper adhesive²) and increasing the quantity of existing tobacco additives (filter sideseam adhesive²). 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 products to be marketed would be appropriate for protection of the public health. Based on the information submitted by the applicant, there is an additional modification for EX0000902 – EX0000903 of a change in container closure system, i.e., from box in the original product to soft pack in the new product. I, as TPL, find that the container closure systems in the original and new product meet the definition of ‘additive’ because they are substances used in the packaging of the tobacco products. In addition, I find that this modification is minor because this modification does not affect the characteristics of the consumable portion of the tobacco products.

The applicant proposes the deletion of white or cork tipping paper and the addition of an alternate white tipping paper, which is not expected to have any significant effects on product chemistry or consumer perception. In addition, there was no change in the perforation during manufacturing for the tipping paper that could impact HPHC delivery between the original and new tobacco products. The applicant also proposes to delete the filter tow and add an alternate filter tow which 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 tobacco products. The filter tow in the new products include a 17% decrease in ^{(b) (4)} compared to the original product and possess the same amounts of ^{(b) (4)}. Because the filter tows are not combusted, volatilized, or otherwise released during normal cigarette consumption, the modifications of ingredients in the filter tow are not expected to significantly alter the smoke chemistry and consumer exposure to chemical constituents from the filter tow while smoking. The filter tow can influence the ventilation and filter efficiency of a product; however, the ventilation of the new and corresponding original tobacco products remains the same. In addition, for EX0000901, the deletion of filter center line adhesive in the original product and the addition of an alternate filter center line adhesive along with the increase in the quantity of filter sideseam adhesive in the new product is a minor modification. Because the filter centerline adhesive and filter sideseam 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. Additionally, for EX0000901, the deletion of the tipping paper adhesive in the original product and the addition of an alternate tipping paper adhesive in the new product is a minor modification. Because the tipping paper adhesive is not combusted, volatilized, or otherwise released during normal cigarette consumption, therefore the ingredient differences and relatively small increase in content between the tipping paper 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. As TPL, I also find that the change in container closure system for EX0000902 – EX0000903 is not expected to materially affect any other characteristic (materials, ingredients, design, composition, heating source, or other features) of the products. Lastly, FDA finds, based on the information contained in the Exemption Requests and CTP's scientific understanding, that an exemption for these modifications are otherwise appropriate as required by section 905(j)(3)(a)(iii) of the FD&C Act. Therefore, the new tobacco products 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 are eligible for modifications through the Exemption Request pathway 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).

For EX0000901, FDA has examined the environmental effects of finding the new tobacco products exempt and made a finding of no significant impact.

An Exempt order letter should be issued for the new tobacco product in EX0000901, as identified on the cover page of this review.

For EX0000902 – EX0000904, FDA has examined the environmental effects of finding these new tobacco products exempt from substantial equivalence and found additional information is necessary to determine the impact of the action. Without this information, FDA is precluded from issuing EX orders.

An Environmental Information Request letter should be issued requesting the following information:

1. EX0000902 – EX0000904 indicate that the original tobacco products will continue to be manufactured and marketed upon receiving marketing orders for the new tobacco products. The current market volumes of the original tobacco products, and the projected market volumes in the first and fifth years for the new tobacco products are included in your EX Requests. However, there is conflicting information regarding the overall market volumes from concurrent marketing of the new and original tobacco products. Your EX Requests include statements indicating that “if the EX REQ for the new product is granted, the new product will replace current market volume” and “will replace some portion of the current in-market volume of the product.” For the original tobacco products, provide the projected market volumes in the first year and the fifth year of marketing the new tobacco products. Marketing information is used to assess the cumulative environmental impacts of concurrent manufacturing, use, and disposal of the new and original tobacco products. The information may be provided below in Table 1.

Table 1. Original Tobacco Product Market Volumes and Projections		
Original Tobacco Product	Projections	
	First Year (# of Cigarettes)	Fifth Year (# of Cigarettes)
EX0000902: Doral Full Flavor Menthol Box		
EX0000903: Doral Full Flavor Menthol 100s Box		
EX0000904: GPC Ultra Light Menthol 100s Soft Pack		

If the applicant adequately responds to the request and an EIS or FONSI is completed, EX order letters should be issued for the new tobacco products in EX0000902 – EX0000904, as identified on the cover page of this review.