

**Technical Project Lead (TPL) Review:
Exemption Request EX0000283 – EX0000288**

EX0000283: Winston Gold 100's Box	
Length	98 mm
Diameter	7.79 mm
Ventilation	28%
Characterizing Flavor	None
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Addition of filter center line adhesive (b) (4) • Deletion of filter center line adhesive (b) (4)
EX0000284: Winston Gold Box	
Length	83 mm
Diameter	7.79 mm
Ventilation	32%
Characterizing Flavor	None
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Addition of filter center line adhesive (b) (4) • Deletion of filter center line adhesive (b) (4)
EX0000285: Winston Red 100's Box	
Length	98 mm
Diameter	7.79 mm
Ventilation	17%
Characterizing Flavor	None
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Addition of filter center line adhesive (b) (4) • Deletion of filter center line adhesive (b) (4)
EX0000286: Winston Red Box	
Length	83 mm
Diameter	7.79 mm
Ventilation	17%
Characterizing Flavor	None
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Addition of filter center line adhesive (b) (4) • Deletion of filter center line adhesive (b) (4)
EX0000287: Winston White 100's Box	
Length	98 mm
Diameter	7.79 mm
Ventilation	60%
Characterizing Flavor	None
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Addition of filter center line adhesive (b) (4) • Deletion of filter center line adhesive (b) (4)

EX0000288: Winston White Box	
Length	83 mm
Diameter	7.79 mm
Ventilation	54%
Characterizing Flavor	None
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Addition of filter center line adhesive (b) (4) • Deletion of filter center line adhesive (b) (4)
Common Attributes of Exemption Requests	
Applicant	ITG Brands LLC
Product Category	Cigarette
Product Sub-Category	Combusted Filtered
Package Quantity	20 cigarettes
Package Type	Box
Recommendation	
Issue Exempt order letters.	

Technical Project Lead (TPL):

Matthew J. Walters -S
2018.11.29 13:12:16 -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)

Matthew R.
Holman -S
Digitally signed by Matthew R.
Holman -S
Date: 2018.11.29 13:27:26 -05'00'

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

TABLE OF CONTENTS

1. BACKGROUND4

 1.1. ORIGINAL TOBACCO PRODUCTS..... 4

 1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW..... 5

 1.3. SCOPE OF REVIEW..... 5

 1.4. TOBACCO ADDITIVE MODIFICATION..... 5

2. REGULATORY REVIEW6

3. COMPLIANCE REVIEW6

4. SCIENTIFIC REVIEW6

5. ENVIRONMENTAL DECISION.....6

6. CONCLUSION AND RECOMMENDATION6

1. BACKGROUND

1.1. ORIGINAL TOBACCO PRODUCTS

The applicant submitted the following original tobacco products:

Table 1. Original Tobacco Products

EX0000283: Winston Gold 100's Box	
Product Name	Winston Light 100s Box
Package Quantity	20 cigarettes
Package Type	Box
Length	98 mm
Diameter	7.79 mm
Ventilation	28%
Characterizing Flavor	None
EX0000284: Winston Gold Box	
Product Name	Winston Light Box
Package Quantity	20 cigarettes
Package Type	Box
Length	83 mm
Diameter	7.79 mm
Ventilation	32%
Characterizing Flavor	None
EX0000285: Winston Red 100's Box	
Product Name	Winston Full Flavor 100s Box
Package Quantity	20 cigarettes
Package Type	Box
Length	98 mm
Diameter	7.79 mm
Ventilation	17%
Characterizing Flavor	None
EX0000286: Winston Red Box	
Product Name	Winston Full Flavor Box
Package Quantity	20 cigarettes
Package Type	Box
Length	83 mm
Diameter	7.79 mm
Ventilation	17%
Characterizing Flavor	None

EX0000287: Winston White 100's Box	
Product Name	Winston Ultra Light 100s Box
Package Quantity	20 cigarettes
Package Type	Box
Length	98 mm
Diameter	7.79 mm
Ventilation	60%
Characterizing Flavor	None
EX0000288: Winston White Box	
Product Name	Winston Ultra Light Box
Package Quantity	20 cigarettes
Package Type	Box
Length	83 mm
Diameter	7.79 mm
Ventilation	54%
Characterizing Flavor	None

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

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

The applicant submitted the Exemption Requests EX0000283 – EX0000288 on October 15, 2018. FDA issued Acknowledgement letters for these Exemption Requests on October 18, 2018. On October 24, 2018, FDA requested additional information related to the unique identifying information of the new and original tobacco products. On October 29, 2018, the applicant provided the information under EX0000295.

1.3. SCOPE OF REVIEW

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

1.4. TOBACCO ADDITIVE MODIFICATION

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

- Addition of filter center line adhesive (b) (4) [REDACTED]
- Deletion of filter center line adhesive (b) (4) [REDACTED]

2. REGULATORY REVIEW

Regulatory reviews were completed by Megan Nguyen on October 18, 2018. The review concluded that these Exemption Requests are administratively complete.

3. COMPLIANCE REVIEW

The Office of Compliance and Enforcement (OCE) completed a review 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 review dated November 13, 2018 for EX0000283-EX0000287 and November 15, 2018 for EX0000288 concludes that the original tobacco products are grandfathered products.

4. SCIENTIFIC REVIEW

A scientific review was completed by Melis Corragio on November 29, 2018. The review states that the new tobacco products have been modified by adding and deleting a tobacco additive. Filter center line adhesive is used in the manufacturing of the original tobacco products and is an additive because its intended use may reasonably be expected to result, directly or indirectly, in it becoming a component or otherwise affecting the characteristics of the tobacco product. The review concludes that the modification is a minor modification of a tobacco product in accordance with section 905(j)(3)(A)(i) of the FD&C Act. The review determines that the deletion of filter center adhesive (b) (4) and the addition of an alternative center line adhesive (b) (4) due to a change from a customized adhesive to an adhesive that is purchased commercially by (b) (4), are not expected to materially affect any other characteristic (materials, ingredients, design, composition, heating source, or other features) of the product.

5. ENVIRONMENTAL DECISION

An environmental review was completed by Dilip Venugopal on November 27, 2018.

The final environmental review found that the applicant did not provide the first-year and fifth-year market projections for the new products and did not provide detailed measurements of the product components, which is used to assess the cigarette butt waste impact. 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:

- Addition of filter center line adhesive (b) (4)
- Deletion of filter center line adhesive (b) (4)

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 deletion of filter center adhesive (b) (4)) and addition of an alternative center line adhesive (b) (4) is an addition/deletion of a tobacco additive. 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. The review determines that the deletion of the filter center adhesive (b) (4) and the addition of an alternative center line adhesive (b) (4) due to a change from a customized adhesive to an adhesive that is purchased commercially by (b) (4) it is not expected to materially affect any other characteristic (materials, ingredients, design, composition, heating source, or other features) of the product. Specifically, this modification is made to the non-combusted component of the cigarette; the alternative center line adhesive is not combusted, volatilized or otherwise released during normal cigarette consumption and so consumer exposure to chemical constituents from the alternative center line adhesive is not expected. Thus, this change is considered a minor modification and meets the requirements set forth in section 905(j)(3)(A)(i) of the FD&C Act. Lastly, FDA finds, based on the information contained in the Exemption Requests 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 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 modification through the Exemption Request pathway because they can be 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 examined the environmental effects of finding these new tobacco products exempt from substantially equivalent and found additional information is necessary to determine the impact of the action. Without this information, FDA is precluded from issuing EX orders.

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

1. All of your EX Requests lack first-year and fifth-year market volume estimates for the new products. Marketing information is used to quantitatively assess the environmental impact of manufacturing, use, and disposal of the new products. If you deem any of this information confidential, mark it as such so that it can be placed in a confidential appendix to the public EA document.

Provide in Table 1 the market volume projections for the new products in the first and fifth year of marketing for each new product.

Table 1: Market Volume Estimates for the New Products			
STN	New Product	Market Projections (number of cigarettes)	
		First Year	Fifth Year
EX0000283	Winston Gold 100's Box		
EX0000284	Winston Gold Box		
EX0000285	Winston Red 100's Box		
EX0000286	Winston Red Box		
EX0000287	Winston White 100's Box		
EX0000288	Winston White Box		

2. All of your EX Requests do not provide detailed measurements of all product components. Product component details for combusted cigarettes are used to quantitatively assess the environmental impact of cigarette butt waste. For each new product, provide in Table 2 the total mass of one cigarette, the length of the tipping paper (filter overwrap), the length of the tobacco rod, and the mass of the tobacco rod (including tobacco filler, cigarette paper, and adhesive). Confirm the cigarette length data in Table 2 as provided in your October 29, 2018, submission.

Table 2: Product Component Measurements						
STN	New Product	Length of cigarette (mm)	Mass of one cigarette (g)	Length of tipping paper (filter overwrap) (mm)	Length of tobacco rod (mm)	Mass of tobacco rod including filler, paper, and adhesive (g)
EX0000283	Winston Gold 100's Box	98				
EX0000284	Winston Gold Box	83				
EX0000285	Winston Red 100's Box	98				
EX0000286	Winston Red Box	83				
EX0000287	Winston White 100's Box	98				
EX0000288	Winston White Box	83				

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 EX0000283 – EX0000288, as identified on the cover page of this review.