

**Technical Project Lead (TPL) Review:  
Exemption Requests EX0000736 – EX0000745**

EX0000736: Wave Full Flavor 100s	
Length	100 mm
Diameter	7.9 mm
Ventilation	33%
Characterizing Flavor <sup>1</sup>	None
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of two filter adhesives (b) (4)</li> <li>• Addition of two filter adhesives (b) (4)</li> </ul>
EX0000737: Wave Blue 100s	
Length	100 mm
Diameter	7.9 mm
Ventilation	48%
Characterizing Flavor <sup>1</sup>	None
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of two filter adhesives (b) (4)</li> <li>• Addition of two filter adhesives (b) (4)</li> </ul>
EX0000738: Wave Silver 100s	
Length	100 mm
Diameter	7.9 mm
Ventilation	63%
Characterizing Flavor <sup>1</sup>	None
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of two filter adhesives (b) (4)</li> <li>• Addition of two filter adhesives (b) (4)</li> </ul>

<sup>1</sup> The chemistry review identified the characterizing flavor as tobacco based on information provided by the applicant. However, since the finalization of the chemistry review, the Office of Science interprets the characterizing flavor of tobacco as none which has been reflected in this technical project lead (TPL) review.

EX0000739: Wave Full Flavor King Size	
Length	84 mm
Diameter	7.9 mm
Ventilation	18%
Characterizing Flavor <sup>1</sup>	None
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of two filter adhesives (b) (4)</li> <li>• Addition of two filter adhesives (b) (4)</li> </ul>
EX0000740: Wave Blue King Size	
Length	84 mm
Diameter	7.9 mm
Ventilation	40%
Characterizing Flavor <sup>1</sup>	None
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of two filter adhesives (b) (4)</li> <li>• Addition of two filter adhesives (b) (4)</li> </ul>
EX0000741: Wave Menthol King Size	
Length	84 mm
Diameter	7.9 mm
Ventilation	22%
Characterizing Flavor	Menthol
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of two filter adhesives (b) (4)</li> <li>• Addition of two filter adhesives (b) (4)</li> </ul>
EX0000742: Wave Menthol Green King Size	
Length	84 mm
Diameter	7.9 mm
Ventilation	40%
Characterizing Flavor	Menthol
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of two filter adhesives (b) (4)</li> <li>• Addition of two filter adhesives (b) (4)</li> </ul>

EX0000743: Wave Silver King Size	
Length	84 mm
Diameter	7.9 mm
Ventilation	56%
Characterizing Flavor <sup>1</sup>	None
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of two filter adhesives (b) (4)</li> <li>• Addition of two filter adhesives (b) (4)</li> </ul>
EX0000744: Wave Menthol 100s	
Length	100 mm
Diameter	7.9 mm
Ventilation	33%
Characterizing Flavor	Menthol
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of two filter adhesives (b) (4)</li> <li>• Addition of two filter adhesives (b) (4)</li> </ul>
EX0000745: Wave Menthol Green 100s	
Length	100 mm
Diameter	7.9 mm
Ventilation	48%
Characterizing Flavor	Menthol
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of two filter adhesives (b) (4)</li> <li>• Addition of two filter adhesives (b) (4)</li> </ul>
Common Attributes of Exemption Requests	
Applicant	Japan Tobacco International USA, Inc.
Product Category	Cigarette
Product Sub-Category	Combusted Filtered
Package Quantity	20 Cigarettes
Package Type	Hard Pack
Recommendation	
Issue Exempt order letters.	

**Technical Project Lead (TPL):**

Digitally signed by Matthew J. Walters -S  
Date: 2019.11.07 16:06:39 -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: 2019.11.08 07:04:34 -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**

<b>EX0000736: Wave Full Flavor 100s</b>	
<b>Product Name</b>	Wave Full Flavor 100 Hard Pack
<b>Package Quantity</b>	20 Cigarettes
<b>Package Type</b>	Hard Pack
<b>Length</b>	100 mm
<b>Diameter</b>	7.9 mm
<b>Ventilation</b>	33%
<b>Characterizing Flavor</b>	None
<b>EX0000737: Wave Blue 100s</b>	
<b>Product Name</b>	Wave Light 100 Hard Pack
<b>Package Quantity</b>	20 Cigarettes
<b>Package Type</b>	Hard Pack
<b>Length</b>	100 mm
<b>Diameter</b>	7.9 mm
<b>Ventilation</b>	48%
<b>Characterizing Flavor</b>	None
<b>EX0000738: Wave Silver 100s</b>	
<b>Product Name</b>	Wave Ultra Light 100 Hard Pack
<b>Package Quantity</b>	20 Cigarettes
<b>Package Type</b>	Hard Pack
<b>Length</b>	100 mm
<b>Diameter</b>	7.9 mm
<b>Ventilation</b>	63%
<b>Characterizing Flavor</b>	None
<b>EX0000739: Wave Full Flavor King Size</b>	
<b>Product Name</b>	Wave Full Flavor King Size
<b>Package Quantity</b>	20 Cigarettes
<b>Package Type</b>	Hard Pack
<b>Length</b>	84 mm
<b>Diameter</b>	7.9 mm
<b>Ventilation</b>	18%
<b>Characterizing Flavor</b>	None

<b>EX0000740: Wave Blue King Size</b>	
<b>Product Name</b>	Wave Light King Size
<b>Package Quantity</b>	20 Cigarettes
<b>Package Type</b>	Hard Pack
<b>Length</b>	84 mm
<b>Diameter</b>	7.9 mm
<b>Ventilation</b>	40%
<b>Characterizing Flavor</b>	None
<b>EX0000741: Wave Menthol King Size</b>	
<b>Product Name</b>	Wave Menthol King Size
<b>Package Quantity</b>	20 Cigarettes
<b>Package Type</b>	Hard Pack
<b>Length</b>	84 mm
<b>Diameter</b>	7.9 mm
<b>Ventilation</b>	22%
<b>Characterizing Flavor</b>	Menthol
<b>EX0000742: Wave Menthol Green King Size</b>	
<b>Product Name</b>	Wave Menthol Light King Size Hard Pack
<b>Package Quantity</b>	20 Cigarettes
<b>Package Type</b>	Hard Pack
<b>Length</b>	84 mm
<b>Diameter</b>	7.9 mm
<b>Ventilation</b>	40%
<b>Characterizing Flavor</b>	Menthol
<b>EX0000743: Wave Silver King Size</b>	
<b>Product Name</b>	Wave Ultra Light King Size Hard Pack
<b>Package Quantity</b>	20 Cigarettes
<b>Package Type</b>	Hard Pack
<b>Length</b>	84 mm
<b>Diameter</b>	7.9 mm
<b>Ventilation</b>	56%
<b>Characterizing Flavor</b>	None
<b>EX0000744: Wave Menthol 100s</b>	
<b>Product Name</b>	Wave Menthol 100
<b>Package Quantity</b>	20 Cigarettes
<b>Package Type</b>	Hard Pack
<b>Length</b>	100 mm
<b>Diameter</b>	7.9 mm
<b>Ventilation</b>	33%
<b>Characterizing Flavor</b>	Menthol

EX0000745: Wave Menthol Green 100s	
Product Name	Wave Menthol Light 100 Hard Pack
Package Quantity	20 Cigarettes
Package Type	Hard Pack
Length	100 mm
Diameter	7.9 mm
Ventilation	48%
Characterizing Flavor	Menthol

The applicant manufactures the original tobacco products and claims that they are either grandfathered (EX0000736 – EX0000738, EX0000740, and EX0000742 – EX0000745) or were previously found substantially equivalent (EX0000739 and EX0000741).

## 1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On August 9, 2019, FDA received Exemption Requests (EX0000736-EX0000745) from Japan Tobacco International USA, Inc. On August 29, 2019, FDA issued an Acknowledgement letter to the applicant. FDA requested additional product identification information from the applicant on August 28, 2019, September 5, 2019, September 10, 2019, September 26, 2019, and October 25, 2019. In response, the applicant submitted amendments, respectively, on September 6, 2019 (EX0000770); on September 10, 2019 (EX0000774); on September 11, 2019 (EX0000776); on September 30, 2019 (EX0000790); and on November 5, 2019 (EX0000828).

## 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:

- Deletion of two filter adhesives (b) (4)
- Addition of two filter adhesives (b) (4)

## 2. REGULATORY REVIEW

Regulatory reviews were completed by Camille Hayslett on August 29, 2019. The reviews conclude 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 September 20, 2019, concludes that the original tobacco products for EX0000736 – EX0000738, EX0000740, and EX0000742 – EX0000745 are grandfathered products.

The original tobacco products in EX0000739 and EX0000741 were previously determined to be substantially equivalent and in compliance with the Federal Food, Drug, and Cosmetic Act (FD&C Act) by FDA.

The original tobacco products referenced for these Exemption Requests are outlined in the table below.

EX Requests	Original Tobacco Product	Original Tobacco Product Found GF/SE Under:	Date
EX0000736	Wave Full Flavor 100 Hard Pack	GF1200112	September 20, 2019
EX0000737	Wave Light 100 Hard Pack	GF1200113	September 20, 2019
EX0000738	Wave Ultra Light 100 Hard Pack	GF1200116	September 20, 2019
EX0000739	Wave Full Flavor King Size	SE0013537	August 25, 2017
EX0000740	Wave Light King Size	GF1200105	September 20, 2019
EX0000741	Wave Menthol King Size	SE0013536	August 25, 2017
EX0000742	Wave Menthol Light King Size Hard Pack	GF1200107	September 20, 2019
EX0000743	Wave Ultra Light King Size Hard Pack	GF1200108	September 20, 2019
EX0000744	Wave Menthol 100	GF1200114	September 20, 2019
EX0000745	Wave Menthol Light 100 Hard Pack	GF1200115	September 20, 2019

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

#### 4. SCIENTIFIC REVIEW

A scientific review was completed by Mimy Young on November 7, 2019.

The review states that the new tobacco products have been modified by adding and deleting tobacco additives. Filter adhesives 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 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 FD&C Act. The review determines that the deletion of two filter adhesives (both from (b) (4) ) and the addition of two alternative filter adhesives (b) (4) ) due to a change in supplier, is not expected to materially affect any

<sup>2</sup> 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.

other characteristic (materials, ingredients, design, composition, heating source, or other features) of the tobacco products. The filter adhesives are not present in the tobacco column and are therefore not intended to be part of the combustion product.

## 5. ENVIRONMENTAL DECISION

An environmental review was completed by William Brenner on September 13, 2019.

The final environmental review found that the applicant did not provide an individual environmental assessment for each EX Request. 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 two filter adhesives (b) (4)
- Addition of two filter adhesives (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 two adhesives (both supplied by (b) (4) ) and the addition of two alternative filter adhesives (supplied by (b) (4) ) is an addition/deletion of tobacco additives. 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 two filter adhesives (b) (4) ) and the addition of two alternative filter adhesives (b) (4) ) due to a change in suppliers, is not expected to materially affect any other characteristic (materials, ingredients, design, composition, heating source, or other features) of the tobacco products. Specifically, these modifications are made to the non-combusted component of the cigarettes; the alternative adhesives are not combusted, volatilized or otherwise released during normal cigarette consumption and so consumer exposure to chemical constituents from the alternative adhesives is not expected. Thus, these changes are considered minor modifications and meet 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 these modifications 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. For EX0000736 – EX0000738, EX0000740, and EX0000742 – EX0000745, 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). Additionally, for EX0000739 and EX0000741 the original products were previously found SE and in compliance with the FD&C Act] by FDA under SE0013537 and SE0013536, respectively.

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. All of your EX Requests lack individual environmental assessments (EA); that is, one EA for each EX Request. FDA's regulations implementing the National Environmental Policy Act (NEPA) of 1969 (21 CFR 25.15(a)), requires that "[a]ll applications or petitions requesting agency action require the submission of an [environmental assessment] or a claim of categorical exclusion." In addition, 21 CFR 1107.1(b)(9) requires that EX Requests include an EA that is prepared in accordance with the requirements of 21 CFR 25.40(a). An EA shall include, at a minimum, brief discussions of the need for the proposed action, of alternatives as required by section 102(2)(E) of NEPA, of the environmental impacts of the proposed action and alternatives, a listing of the agencies and persons consulted, and the relevant environmental issues relating to the use and disposal of each new tobacco product. The environmental issues may be different for each product depending on product-specific information, manufacturing, and projected sales. Therefore, the environmental impact of each proposed action is evaluated for each product in an accompanying EA. Submit an EA for each EX Request, as provided in 21 CFR 25.40(a).

If the applicant adequately responds to the request and an EIS or FONSI is completed, an EX order letter should be issued for the new tobacco products in EX0000736 – EX0000745, as identified on the cover page of this review.