

**Technical Project Lead (TPL) Review of Exemption Requests:
EX0001032 – EX0001033**

Common Attributes of EX Requests		
Applicant	R.J. Reynolds Tobacco Company	
Product category	Cigarettes	
Product subcategory	Combusted, Filtered	
EX Requests Included in this Review		
Tobacco Product	New	Original
Submission tracking number	EX0001032	EX0000858
Product name	Newport Non-Menthol Gold Box 100s	Newport Non-Menthol Gold Box 100s
Eligibility status	Not applicable	Previously found EX
Marketing order date	Not applicable	January 17, 2020
Abbreviated report date	Not applicable	February 28, 2020
Package type	Box	Box
Package quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	None	None
Length	99 mm	99 mm
Diameter	7.9 mm	7.9 mm
Ventilation	33%	33%
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of filter tow (b) (4) [redacted]; target: (b) (4) mg/cigarette) • Addition of filter tow (b) (4) [redacted]; target: (b) (4) mg/cigarette) 	

Tobacco Product	New	Original
Submission tracking number	EX0001033	EX0000857
Product name	Newport Non-Menthol Gold Box	Newport Non-Menthol Gold Box
Eligibility status	Not applicable	Previously found EX
Marketing order date	Not applicable	January 17, 2020
Abbreviated report date	Not applicable	February 28, 2020
Package Type	Box	Box
Package Quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	None	None
Length	80 mm	80 mm
Diameter	7.9 mm	7.9 mm
Ventilation	38%	38%
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none">• Deletion of filter tow (b) (4)]; target: (b) (4) mg/cigarette)• Addition of filter tow (b) (4)]; target: (b) (4) mg/cigarette)	
Recommendation		
Issue Exempt (EX) order.		

Technical Project Lead (TPL):

Digitally signed by Charles Feng -S
Date: 2020.05.21 08:11:43 -04'00'

Charles Feng, Ph.D.
Chemistry Branch Chief
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: 2020.05.21 08:43:01 -04'00'

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

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1. BACKGROUND

1.1. ORIGINAL TOBACCO PRODUCTS

The original tobacco products are combusted, filtered cigarettes manufactured by the applicant as indicated on the cover page of this review.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On April 2, 2020, FDA received Exemption Requests (EX0001032-EX0001033) from RAI Services Company on behalf of R.J. Reynolds Tobacco Company. FDA issued an Acceptance letter for these EX Requests on April 8, 2020.

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 modification compared to the corresponding original tobacco products:

- deleting an additive (filter tow) in all EX Requests
- adding an additive (alternate filter tow) in all EX Requests

2. REGULATORY REVIEW

A regulatory review was completed by Crystal Caesar on April 8, 2020. The review concludes that the Exemption Requests are administratively complete.

3. COMPLIANCE REVIEW

The original tobacco products in EX0001032 and EX0001033 were determined by FDA under EX0000858 and EX0000857 to be exempt from the requirements of section 905(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) relating to the demonstration of substantial equivalence; and Reports under section 905(j)(1)(A)(ii) (Abbreviated Reports) were received on February 28, 2020. Therefore, the original tobacco products are eligible for modification under the Exemption Request pathway¹ on May 28, 2020, the date when 90 days will elapse since FDA receipt of the Abbreviated Reports.

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 chemistry review was completed by Abdurrafay Shareef on May 1, 2020.

The review states that the new tobacco products have been modified by adding or deleting a tobacco additive. Filter tow 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 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 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 tows of the new tobacco products include a (b) (4) higher (b) (4) and (b) (4) increases in (b) (4) compared to the corresponding original products. In addition, (b) (4) mg/cigarette) and (b) (4) mg/cigarette) were added to the filter tows of the new tobacco products. 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. The review indicates that there were (b) (4) decreases in target denier per filament (DPF) and a (b) (4) decrease in total denier (TD) in the filter tow. However, the review concludes that the combined effects of the modifications in DPF and TD on filter efficiency are likely to be minimal based on the data submitted.

5. ENVIRONMENTAL DECISION

An environmental review was completed by Ronald Edwards on May 15, 2020.

A finding of no significant impact (FONSI) was signed by Luis Valerio, Ph.D. on May 15, 2020. The FONSI was supported by an environmental assessment prepared by FDA on May 15, 2020.

6. CONCLUSION AND RECOMMENDATION

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

- deleting an additive (filter tow) in all EX Requests
- adding an additive (alternate filter tow) in all EX Requests

I concur with the conclusion of the scientific review that this modification is a minor modification 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 it 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 filter tow 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 the protection of the public health. The applicant 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 (b) (4) higher (b) (4) and (b) (4) increases in (b) (4) compared to the corresponding original products. In addition, (b) (4) mg/cigarette) and (b) (4) mg/cigarette) are added to the filter tows of the new tobacco products. 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. Furthermore, there were (b) (4) decreases in target denier per filament (DPF) and a (b) (4) decrease in total denier (TD) in the filter tow. However, in this case, the combined effects of the modifications in DPF and TD on filter efficiency are likely to be minimal based on the data submitted. 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 products in EX0001032 and EX0001033 were previously found Exempt by FDA under EX0000858 and EX0000857, and Abbreviated Reports were received on February 28, 2020. Therefore, the original tobacco products are eligible for modification under the Exemption Request pathway on May 28, 2020, the date when 90 days will elapse since FDA receipt of the Abbreviated Reports.

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

An exempt order should be issued for the new tobacco products in EX0001032 – EX0001033, as identified on the cover page of this review.