

**Technical Project Lead (TPL) Review of Exemption Requests:
EX0000975 – EX0000977**

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	EX0000975	EX0000631
Product name	True Blue 100 Box	True Blue 100 Soft Pack
Eligibility status	Not applicable	Previously found EX
Marketing order date	Not applicable	November 15, 2019
Abbreviated report date	Not applicable	January 10, 2020
Package type	Box	Soft Pack
Package quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	None	None
Length	99 mm	99 mm
Diameter	7.9 mm	7.9 mm
Ventilation	54%	54%
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) • Deletion of soft pack container closure system • Addition of box container closure system 	

Tobacco Product	New	Original
Submission tracking number	EX0000976	EX0000631
Product name	True Blue 100 Soft Pack	True Blue 100 Soft Pack
Eligibility status	Not applicable	Previously found EX
Marketing order date	Not applicable	November 15, 2019
Abbreviated report date	Not applicable	January 10, 2020
Package Type	Soft Pack	Soft Pack
Package Quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	None	None
Length	99 mm	99 mm
Diameter	7.9 mm	7.9 mm
Ventilation	54%	54%
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) 	
Tobacco Product	New	Original
Submission tracking number	EX0000977	EX0000749
Product name	Pall Mall Red Filter 100 Box	Pall Mall Red Filter 100
Eligibility status	Not applicable	Previously found EX
Marketing order date	Not applicable	October 2, 2019
Abbreviated report date	Not applicable	November 8, 2019
Package Type	Box	Box
Package Quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	None	None
Length	97 mm	97 mm
Diameter	7.9 mm	7.9 mm
Ventilation	32%	32%
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of tipping paper adhesive (b) (4) • Addition of tipping paper adhesive (b) (4) 	
Recommendation		
Issue Exempt (EX) order.		

Technical Project Lead (TPL):

Digitally signed by Matthew J. Walters -S
Date: 2020.03.12 16:40:46 -04'00'

Matthew J. Walters, Ph.D., MPH
CDR, US 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: 2020.03.13 07:05:44 -04'00'

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

TABLE OF CONTENTS

1. BACKGROUND.....5
 1.1. ORIGINAL TOBACCO PRODUCTS..... 5
 1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW 5
 1.3. SCOPE OF REVIEW 5
 1.4. TOBACCO ADDITIVE MODIFICATION 5

2. REGULATORY REVIEW5

3. COMPLIANCE REVIEW.....5

4. SCIENTIFIC REVIEW.....6

5. ENVIRONMENTAL DECISION6

6. CONCLUSION AND RECOMMENDATION7

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 February 3, 2020, FDA received Exemption Requests EX0000975-EX0000977 from RAI Services Company on behalf of R.J. Reynolds Tobacco Company. FDA issued an Acceptance letter on February 6, 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 EX0000975 and EX0000976
- adding an additive (filter tow) in EX0000975 and EX0000976
- deleting an additive (soft pack container closure system) in EX0000975
- adding an additive (box container closure system) in EX0000975
- deleting an additive (tipping paper adhesive) in EX0000977
- adding an additive (tipping paper adhesive) in EX0000977

2. REGULATORY REVIEW

Regulatory reviews were completed by Camille Hayslett on February 6, 2020. The reviews conclude that the Exemption Requests are administratively complete.

3. COMPLIANCE REVIEW

The original tobacco products in EX0000975 – EX0000977 were determined 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 under EX0000631 (for EX0000975 and EX0000976) and EX0000749 (for EX0000977) by FDA. Reports under section 905(j)(1)(A)(ii) (Abbreviated Reports) were received on November 8, 2019 for EX0000749 and January 10, 2020 for EX0000631. Therefore, the original tobacco products are eligible for modification under the Exemption Request pathway¹ on February 6, 2020 and April 9, 2020 respectively, 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 Jiu Aiu on March 12, 2020.

The review states that the new tobacco products have been modified by adding or deleting tobacco additives. Filter tow² and tipping paper adhesive³ 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 modification for EX0000975 and EX0000976 is not a minor modification of a tobacco product in accordance with section 905(j)(3)(A)(i) of the FD&C Act. The review concludes for EX0000975 and EX0000976 only, that the deletion of filter tow and the addition of an alternate filter tow is not a minor modification and is expected to materially affect any other characteristic (materials, ingredients, design, composition, heating source, or other features) of the tobacco products. The review indicates that there were decreases (5%) in denier per filament (DPF) and increases (7%) in total denier (TD) in the filter tow which resulted in a larger total number of filaments in the filter tow. While the review recognizes that the combined effect of these modifications of the filter tow of the new tobacco product may increase the filtration efficiency and reduce the mainstream smoke yields, the review indicates that the impact on pressure drop of increasing TD at lower DPF, is more significant than the impact of increasing TD at a higher DPF, and pressure drop is strongly correlated to filter efficiency. Therefore, the review concludes that the quantitative scale of the impact of these modifications towards the cigarette smoke yields is not known even though they are likely to reduce mainstream smoke yields and additional information is needed to determine if this modification is minor. The review also concludes for EX0000977 that the modification is a minor modification of a tobacco product in accordance with section 905(j)(3)(A)(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). For EX0000977 only, the review 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

An environmental review was completed by Rudaina Alrefai-Kirkpatrick on February 26, 2020.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on February 27, 2020. The FONSI was supported by an environmental assessment prepared by FDA on February 27, 2020.

² EX0000975 and EX0000976 only

³ EX0000977 only

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 EX0000975 and EX0000976
- adding an additive (filter tow) in EX0000975 and EX0000976
- deleting an additive (soft pack container closure system) in EX0000975
- adding an additive (box container closure system) in EX0000975
- deleting an additive (tipping paper adhesive) in EX0000977
- adding an additive (tipping paper adhesive) in EX0000977

I concur partly with the conclusions of the scientific review. I agree with the scientific review that the tipping paper adhesive in EX0000977 is a minor modification, but disagree with the conclusion of the scientific review that the filter tow is not a minor modification in EX0000975 and EX0000976. As TPL, I have concluded 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 (filter tow² and tipping paper adhesive³) and the addition of tobacco additives (filter tow² and tipping paper adhesive³). 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 EX0000975 of a change in container closure system, i.e., from soft pack in the original product to box 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 to delete the filter tow and add an alternate filter tow for EX0000975 and EX0000976 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 scientific review concludes for EX0000975 and EX0000976, the deletion of filter tow and the addition of an alternate filter tow is not a minor modification and is expected to materially affect any other characteristic (materials, ingredients, design, composition, heating source, or other features) of the tobacco products. The review indicates that there were decreases (5%) in denier per filament (DPF) and increases (7%) in total denier (TD) in the filter tow which resulted in a larger total number of filaments in the filter tow. While the review recognizes that the combined effect of these modifications of the filter tow of the new tobacco product may increase the filtration efficiency and reduce the mainstream smoke yields, the review indicates that the impact on pressure drop of increasing TD at lower DPF, is more significant than the impact of increasing TD at a higher DPF, and pressure drop is strongly correlated to filter efficiency. Therefore, the review concludes that the quantitative scale of the impact of these modifications towards the cigarette smoke yields is not known even though they are likely to reduce mainstream smoke yields

and additional information is needed to determine if this modification is minor. However, as TPL, I disagree with this conclusion as the relatively small change in DPF and TD are unlikely to have an impact that would result in increases in HPHCs that would raise a public health concern. As concluded by the scientific review, these changes in filter tow properties are likely to result in better filtration and decreases in HPHC yields. Therefore, as TPL, I have concluded that the difference in the filter tow is a minor modification as discussed above along with the fact that 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 EX0000977, 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 EX0000975 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 previously found Exempt by FDA under EX0000631 and EX0000749, Abbreviated Reports were received on November 8, 2019 for EX0000749 and January 10, 2020 for EX0000631. Therefore, the original tobacco products are eligible for modification under the Exemption Request pathway on February 6, 2020 and April 9, 2020 respectively, 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 EX0000975 – EX0000977, as identified on the cover page of this review.