

Technical Project Lead (TPL) Review of Exemption Requests: EX0000962 – EX0000969

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	EX0000962	GF1200347
Product Name	True Blue Soft Pack	True Kings
Eligibility Status	N/A	Grandfathered
Marketing Order Date	N/A	N/A
Abbreviated Report Date	N/A	N/A
Package Type	Soft Pack	Soft Pack
Package Quantity	20 Cigarettes	20 Cigarettes
Characterizing Flavor	None	None
Length	84 mm	84 mm
Diameter	7.9 mm	7.9 mm
Ventilation	61%	61%
Product Modifications	<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> • Deletion of non-Fire Standards Compliant (FSC) cigarette paper (b) (4)]; target: (b) (4) mg/cigarette) • Addition of FSC cigarette paper (b) (4) target: (b) (4) mg/cigarette) • 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) • Deletion of complex flavor ingredients (b) (4) and (b) (4) in the tobacco casing • Deletion of printed monogram (black) ink on cigarette barrel <p>Increasing/Decreasing the quantity of existing tobacco additives:</p> <ul style="list-style-type: none"> • Increasing the quantity of (b) (4) in the tobacco casing • Increasing the quantity of (b) (4) in the tobacco casing 	

Tobacco Product	New	Original
Submission Tracking Number	EX0000963	GF1501407
Product Name	Doral Classic Menthol Gold 100 Box	Highway Menthol Lights 100
Eligibility Status	N/A	Grandfathered
Marketing Order Date	N/A	N/A
Abbreviated Report Date	N/A	N/A
Package Type	Box	Box
Package Quantity	20 Cigarettes	20 Cigarettes
Characterizing Flavor	Menthol	Menthol
Length	98 mm	98 mm
Diameter	7.8 mm	7.8 mm
Ventilation	34%	34%
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 cork 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) 	
Tobacco Product	New	Original
Submission Tracking Number	EX0000964	EX0000633
Product Name	True Menthol Green 100 Soft Pack	True Menthol Green 100 Soft Pack
Eligibility Status	N/A	Previously found EX
Marketing Order Date	N/A	November 15, 2019
Abbreviated Report Date	N/A	January 10, 2020
Package Type	Soft Pack	Soft Pack
Package Quantity	20 Cigarettes	20 Cigarettes
Characterizing Flavor	Menthol	Menthol
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	EX0000965	GF1200346
Product Name	True Blue Box	True Box
Eligibility Status	N/A	Grandfathered
Marketing Order Date	N/A	N/A
Abbreviated Report Date	N/A	N/A
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	61%	61%
Product Modifications	<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> • Deletion of non-FSC cigarette paper (b) (4) target: (b) (4) mg/cigarette) • Addition of FSC cigarette paper (b) (4) target: (b) (4) mg/cigarette) • 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) • Deletion of complex purchased flavor ingredients (b) (4) and (b) (4) in the tobacco casing • Deletion of printed monogram (black) ink on cigarette barrel <p>Increasing/Decreasing the quantity of existing tobacco additives:</p> <ul style="list-style-type: none"> • Increasing the quantity of (b) (4) in the tobacco casing • Increasing the quantity of (b) (4) in the tobacco casing 	

Tobacco Product	New	Original
Submission Tracking Number	EX0000966	GF1200346
Product Name	True Blue Box	True Box
Eligibility Status	N/A	Grandfathered
Marketing Order Date	N/A	N/A
Abbreviated Report Date	N/A	N/A
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	61%	61%
Product Modifications	<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> • Deletion of non-FSC cigarette paper (b) (4) target: (b) (4) mg/cigarette) • Addition of FSC cigarette paper (b) (4) target: (b) (4) mg/cigarette) • 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 complex purchased flavor ingredients (b) (4) and (b) (4) in the tobacco casing • Deletion of printed monogram (black) ink on cigarette barrel <p>Increasing/Decreasing the quantity of existing tobacco additives:</p> <ul style="list-style-type: none"> • Increasing the quantity of (b) (4) in the tobacco casing • Increasing the quantity of (b) (4) in the tobacco casing 	

Tobacco Product	New	Original
Submission Tracking Number	EX0000967	GF1200347
Product Name	True Blue Soft Pack	True Kings
Eligibility Status	N/A	Grandfathered
Marketing Order Date	N/A	N/A
Abbreviated Report Date	N/A	N/A
Package Type	Soft Pack	Soft Pack
Package Quantity	20 Cigarettes	20 Cigarettes
Characterizing Flavor	None	None
Length	84 mm	84 mm
Diameter	7.9 mm	7.9 mm
Ventilation	61%	61%
Product Modifications	<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> • Deletion of non-FSC cigarette paper (b) (4) target: (b) (4) mg/cigarette) • Addition of FSC cigarette paper (b) (4) target: (b) (4) mg/cigarette) • 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 complex purchased flavor ingredients (b) (4) and (b) (4) in the tobacco casing • Deletion of printed monogram (black) ink on cigarette barrel <p>Increasing/Decreasing the quantity of existing tobacco additives:</p> <ul style="list-style-type: none"> • Increasing the quantity of (b) (4) in the tobacco casing • Increasing the quantity of (b) (4) in the tobacco casing 	

Tobacco Product	New	Original
Submission Tracking Number	EX0000968	GF1200344
Product Name	True Menthol Green Soft Pack	True Menthol Kings
Eligibility Status	N/A	Grandfathered
Marketing Order Date	N/A	N/A
Abbreviated Report Date	N/A	N/A
Package Type	Soft Pack	Soft Pack
Package Quantity	20 Cigarettes	20 Cigarettes
Characterizing Flavor	Menthol	Menthol
Length	84 mm	84 mm
Diameter	7.9 mm	7.9 mm
Ventilation	61%	61%
Product Modifications	<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> • Deletion of non-FSC cigarette paper (b) (4) target: (b) (4) mg/cigarette) • Addition of FSC cigarette paper (b) (4) target: (b) (4) mg/cigarette) • 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) • Deletion of complex purchased flavor ingredients (b) (4) and (b) (4) in the tobacco casing • Deletion of printed monogram ink (black) on cigarette barrel <p>Increasing/Decreasing the quantity of existing tobacco additives:</p> <ul style="list-style-type: none"> • Increasing the quantity of (b) (4) in the tobacco casing • Increasing the quantity of (b) (4) in the tobacco casing 	

Tobacco Product	New	Original
Submission Tracking Number	EX0000969	GF1200344
Product Name	True Menthol Green Soft Pack	True Menthol Kings
Eligibility Status	N/A	Grandfathered
Marketing Order Date	N/A	N/A
Abbreviated Report Date	N/A	N/A
Package Type	Soft Pack	Soft Pack
Package Quantity	20 Cigarettes	20 Cigarettes
Characterizing Flavor	Menthol	Menthol
Length	84 mm	84 mm
Diameter	7.9 mm	7.9 mm
Ventilation	61%	61%
Product Modifications	<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> • Deletion of non-FSC cigarette paper (b) (4) target: (b) (4) mg/cigarette) • Addition of FSC cigarette paper (b) (4) target: (b) (4) mg/cigarette) • 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 complex purchased flavor ingredients (b) (4) and (b) (4) in the tobacco casing • Deletion of printed monogram ink (black) on cigarette barrel <p>Increasing/Decreasing the quantity of existing tobacco additives:</p> <ul style="list-style-type: none"> • Increasing the quantity of (b) (4) in the tobacco casing • Increasing the quantity of (b) (4) in the tobacco casing 	
Recommendation		
Issue Exempt (EX) order.		

Technical Project Lead (TPL):

Digitally signed by Matthew J. Walters -S
Date: 2020.03.03 09:14:54 -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: 2020.03.03 10:32:37 -05'00'

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 January 23, 2020, FDA received Exemption Requests EX0000962-EX0000969 from RAI Services on behalf of R.J. Reynolds Tobacco Company. FDA issued an Acceptance letter to the applicant on January 31, 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 modifications compared to the corresponding original tobacco products:

- deleting additives (b) (4) in EX0000962, and EX0000965 – EX0000969
- increasing the quantities of existing additives (b) (4) in EX0000962, and EX0000965 – EX0000969
- deleting an additive (black monogram ink) in EX0000962, and EX0000965 – EX0000969
- deleting an additive (non-FSC cigarette paper) in EX0000962, and EX0000965 – EX0000969
- adding an additive (FSC cigarette paper) in EX0000962, and EX0000965 – EX0000969
- deleting an additive (white tipping paper) in EX0000962, EX0000963, and EX0000965 – EX0000969
- adding an additive (white or cork tipping paper) in EX0000962, EX0000963, and EX0000965 – EX0000969
- deleting an additive (filter tow) in EX0000962 – EX0000965, and EX0000968
- adding an additive (filter tow) in EX0000962 – EX0000965, and EX0000968

2. REGULATORY REVIEW

Regulatory reviews were completed by Crystal Caesar on January 31, 2020. The reviews conclude that the Exemption Requests are administratively complete.

3. COMPLIANCE REVIEW

For EX0000962, EX0000963, and EX0000965 – EX0000969, 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 February 17, 2020 for EX0000962, EX0000963, EX0000965-EX0000967, and EX0000969, and February 24, 2020, for EX0000968, conclude that the original tobacco products are grandfathered products.

The original tobacco product in EX0000964 was determined by FDA under EX0000633 to be exempt from the requirements of section 905(j) of the FD&C Act relating to the demonstration of substantial equivalence, and a report under section 905(j)(1)(A)(ii) (Abbreviated Report) was received on January 10, 2020.

Therefore, the original products of EX0000962, EX0000963, and EX0000965 – EX0000969 are eligible for modification under the Exemption Request Pathway while the original product subject of EX0000964 is eligible for modification under the Exemption Request pathway¹ once found exempt and 90 days after FDA receipt of the Abbreviated Report, i.e., April 9, 2020.

4. SCIENTIFIC REVIEW

A scientific review was completed by Salome Bhagan on February 21, 2020.

The review states that the new tobacco products have been modified by adding or deleting tobacco additives and increasing tobacco additives. Cigarette paper,² tipping paper (white),³ filter tow,⁴ complex flavor ingredients ^{(b) (4)} in the tobacco casing,⁵ ^{(b) (4)} and black monogram ink⁵ 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 there 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. For EX0000962, and EX0000965 – EX0000969, the review concludes that the deletion of non-FSC cigarette paper and addition of FSC cigarette paper in the new product is a minor modification. The change from non-FSC to FSC cigarette paper may result in increased harmful and potentially harmful constituents (HPHC) yields; however, the reduction in household fires is anticipated to outweigh any potential increased health risks from the small increases in HPHC exposures that may occur from the use of the FSC cigarette paper, as outlined in the July 17, 2017, toxicology memo. The review also concludes, for EX0000962, EX0000963, and EX0000965 – EX0000969, 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. Additionally, there were no changes in the perforation in the tipping paper between the new and original tobacco products. Furthermore, for EX0000962 – EX0000965, and EX0000968, 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 can influence the ventilation of a product; however, the ventilation

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

² EX0000962, and EX0000965 – EX0000969 only

³ EX0000962, EX0000963, and EX0000965 – EX0000969 only

⁴ EX0000962 – EX0000965, and EX0000968 only

⁵ EX0000962, and EX0000965– EX0000969 only

remains the same when comparing the new and corresponding original tobacco products. In addition, for EX0000962, and EX0000965 – EX0000969, the deletion of the complex flavor ingredients of (b) (4) along with an increase of existing additives of (b) (4) in the tobacco casing are minor modifications and are not expected to materially affect any other characteristic (materials, ingredients, design, composition, heating source, or other features) of the tobacco products. Finally, for EX0000962, and EX0000965 – EX0000969, the review concludes that the deletion of monogram ink (black) on the cigarette barrel is a minor modification and this removal of the monogram ink is not expected to materially affect any other characteristic (materials, ingredients, design, composition, heating source, or other features) of the tobacco products and may potentially decrease HPHC yields.

5. ENVIRONMENTAL DECISION

An environmental review was completed by Bria J. Martin on February 24, 2020.

For EX0000962, EX0000963, and EX0000965 – EX0000969, the environmental review found that the applicant provided conflicting statements regarding final marketing intentions. Therefore, additional information is needed to determine whether to prepare an environmental impact statement (EIS) or finding of no significant impact (FONSI).

For EX0000964, 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.

6. CONCLUSION AND RECOMMENDATION

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

- deleting additives (b) (4) in EX0000962, and EX0000965–EX0000969
- increasing the quantities of existing additives (b) (4) in EX0000962, and EX0000965 – EX0000969
- deleting an additive (black monogram ink) in EX0000962, and EX0000965 – EX0000969
- deleting an additive (non-FSC cigarette paper) in EX0000962, and EX0000965 – EX0000969
- adding an additive (FSC cigarette paper) in EX0000962, and EX0000965 – EX0000969
- deleting an additive (white tipping paper) in EX0000962, EX0000963, and EX0000965 – EX0000969
- adding an additive (white or cork tipping paper) in EX0000962, EX0000963, and EX0000965 – EX0000969
- deleting an additive (filter tow) in EX0000962 – EX0000965, and EX0000968
- adding an additive (filter tow) in EX0000962 – EX0000965, and EX0000968

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 (FSC cigarette paper,² tipping paper (white),³ filter tow,⁴ complex flavor ingredients (b) (4) in the tobacco casing,⁵ and monogram ink on cigarette barrel⁵), and the addition of tobacco additives (FSC cigarette paper,² alternate tipping paper (white or cork),³ and alternate filter tow⁴), and increasing existing tobacco additives (b) (4). 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. For EX0000962, and EX0000965 – EX0000969, at this time, based on the information available and CTP’s scientific understanding and experience with non-FSC to FSC cigarette paper modifications that are limited to changes in tobacco additives and do not result in other changes to the product (e.g., no changes to tobacco blend, design parameters such as ventilation), the benefit of using FSC paper in cigarettes to reduce household fires is anticipated to outweigh any potential increased health risks from the small increases in HPHC exposures that may occur from the use of FSC paper. Additionally, for EX0000962, EX0000963, and EX0000965 – EX0000969, the applicant also proposes the deletion of white tipping paper and the addition of an alternate white or cork tipping paper, which is not expected to have any significant effects on product chemistry or consumer perception. There were no changes in the perforation of the tipping paper between the new and original tobacco products. For EX0000962 – EX0000965, and EX0000968, 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 can influence the ventilation of a product; however, the ventilation of the new and corresponding original tobacco products remains the same. In addition, for EX0000962, and EX0000965 – EX0000969, the deletion of the complex flavor ingredients of (b) (4) and (b) (4) along with an increase of existing additives of (b) (4) in the tobacco casing are minor modifications that are not expected to materially affect any other characteristic (materials, ingredients, design, composition, heating source, or other features) of the tobacco products. Additionally, for EX0000962, and EX0000965 – EX0000969, the deletion of monogram ink (black) on the cigarette barrel is a minor modification that is not expected to materially affect any other characteristic (materials, ingredients, design, composition, heating source, or other features) of the tobacco products and may potentially decrease HPHC yields. 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 modification through the Exemption Request pathway because they can be legally marketed in the United States. For EX0000962, EX0000963, and EX0000965 – EX0000969, 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. Additionally, for EX0000964, the original tobacco product was previously found Exempt by FDA under EX0000633, and an Abbreviated Report was received on January 10, 2020. Therefore, the original tobacco product eligible is for modification under the Exemption Request pathway on April 9, 2020, the date when 90 days will elapse since FDA receipt of the Abbreviated Report.

For EX0000964, FDA has examined the environmental effects of finding the new tobacco product exempt and made a finding of no significant impact.

An exempt order should be issued for the new tobacco product in EX0000964, as identified on the cover page of this review.

For EX0000962, EX0000963, and EX0000965 – EX0000969, FDA has examined the environmental effects of finding these new tobacco products exempt from substantial equivalence and found that additional information is necessary to determine the impact of the action. Without this information, FDA is precluded from issuing an EX order.

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

1. EX0000962, EX0000963 and EX0000965-EX0000969 indicate that the original tobacco products will not 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, your EX Requests include conflicting statements regarding final marketing intention. On page 21 of the EA, you state that you “will not simultaneously commercially market the original product and new product” and in the Confidential Appendix of the EA you state that “the new product will replace some portion of the current in-market volume.” Clarify if the original products will continue to be marketed upon receiving marketing orders for the new products and state whether the new products will replace current market volume of the corresponding original products. This information will be used to determine impacts from manufacturing and use of the products.

If the applicant adequately responds to the request and an EIS or FONSI is completed, an EX order should be issued for the new tobacco products in EX0000962, EX0000963, and EX0000965 – EX0000969, as identified on the cover page of this review.