

**Technical Project Lead (TPL) Review:
Exemption Requests EX0000631 and EX0000633**

EX0000631: True Blue 100 Soft Pack	
Length	99 mm
Diameter	7.9 mm
Ventilation	54%
Characterizing Flavor	None
Product Modifications	<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> • Deletion of non-FSC¹ cigarette paper (b)(4) (b)(4) target: (b)(4) mg/cig • Addition of FSC cigarette paper (b)(4) (b)(4) ; target: (b)(4) mg/cig • Deletion of white tipping paper (b)(4) (b)(4) target: (b)(4) mg/cig • Addition of white tipping paper (b)(4) (b)(4) target: (b)(4) mg/cig • Deletion of non-porous plug wrap ((b)(4) (b)(4)); target: (b)(4) mg/cig • Addition of non-porous plug wrap ((b)(4) (b)(4)); target: (b)(4) mg/cig • Deletion of complex purchased flavor ingredient (b)(4) • Deletion of complex purchased flavor ingredient (b)(4) • Deletion of printed monogram ink (blue) on cigarette barrel <p>Increasing/Decreasing the quantity of existing tobacco additives:</p> <ul style="list-style-type: none"> • Increase in quantity of (b)(4) in tobacco casing • Increase in quantity of (b)(4) in tobacco casing

¹ FSC: Fire Standards Compliant

EX0000633: True Menthol Green 100 Soft Pack	
Length	99 mm
Diameter	7.9 mm
Ventilation	54%
Characterizing Flavor	Menthol
Product Modifications	<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> • Deletion of non-FSC cigarette paper (b)(4) (b)(4)]; target: (b)(4) mg/cig • Addition of FSC cigarette paper (b)(4) (b)(4) ; target (b)(4) mg/cig • Deletion of white tipping paper (b)(4) (b)(4)]; target (b)(4) mg/cig • Addition of white tipping paper (b)(4) (b)(4)]; target: (b)(4) mg/cig • Deletion of non-porous plug wrap (b)(4) (b)(4)]; target: (b)(4) mg/cig • Addition of non-porous plug wrap (b)(4) (b)(4) target: (b)(4) mg/cig • Deletion of complex purchased flavor ingredient (b)(4) • Deletion of complex purchased flavor ingredient (b)(4) • Deletion of printed monogram ink (blue) on cigarette barrel <p>Increasing/Decreasing the quantity of existing tobacco additives:</p> <ul style="list-style-type: none"> • Increase in quantity of (b)(4) in tobacco casing • Increase in quantity of (b)(4) in tobacco casing
Attributes of Exemption Requests	
Applicant	R.J. Reynolds Tobacco Company
Product Category	Cigarette
Product Sub-Category	Combusted Filtered
Package Quantity	20 Cigarettes
Package Type	Soft Pack
Recommendation	
Issue an Exempt order letter.	

Technical Project Lead (TPL):

Digitally signed by Matthew J. Walters -S
Date: 2019.11.14 14:28:00 -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: 2019.11.15 10:50:08 -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

EX0000631: True Blue 100 Soft Pack	
Product Name	True 100s
Package Type	Soft Pack
Package Quantity	20 Cigarettes
Length	99 mm
Diameter	7.9 mm
Ventilation	54%
Characterizing Flavor	None
EX0000633: True Menthol Green 100 Soft Pack	
Product Name	True Menthol 100s
Package Type	Soft Pack
Package Quantity	20 Cigarettes
Length	99 mm
Diameter	7.89 mm
Ventilation	54%
Characterizing Flavor	Menthol

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

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On June 14, 2019, FDA received Exemption Requests (EX0000631 and EX0000633) from RAI Services Company on behalf of R.J. Reynolds Tobacco Company. On June 18, 2019, FDA issued an Acknowledgement letter to the applicant.

1.3. SCOPE OF REVIEW

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

1.4. TOBACCO ADDITIVE MODIFICATIONS

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

- Deletion of non-FSC cigarette paper (b) (4)
- Addition of FSC cigarette paper (b) (4)
- Deletion of white tipping paper ((b)(4)
- Addition of white tipping paper ((b)(4)
- Deletion of non-porous plug wrap (b)(4)
- Addition of non-porous plug wrap (b)(4)
- Deletion of complex purchased flavor ingredients of (b) (4)
- Increase in the quantities of (b) (4) in the tobacco casing
- Deletion of printed monogram ink (blue) on cigarette barrel

2. REGULATORY REVIEW

Regulatory reviews were completed by Nia White on June 18, 2019. The reviews conclude that the Exemption Requests are administratively complete.

3. COMPLIANCE REVIEW

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 July 3, 2019, conclude that the original tobacco products are grandfathered products. Therefore, the original products are eligible for modification under the Exemption Request pathway.²

4. SCIENTIFIC REVIEW

A scientific review was completed by Samantha Reilly on November 8, 2019.

The review states that the new tobacco products have been modified by adding or deleting tobacco additives and increasing or decreasing tobacco additives. FSC cigarette paper, tipping paper (white), plug wrap, complex flavor ingredients (b) (4) in the (b)(4), and monogram ink 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 modifications are minor modifications of a tobacco product in accordance with section 905(j)(3)(A)(i) of the Federal Food, Drug, and Cosmetics Act (FD&C Act). For all EX Requests, the review concludes that the deletion of non-FSC cigarette paper and addition of FSC cigarette paper in the new product is a minor

² 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.

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 small increases in HPHC exposures that may occur from the use of the FSC cigarette paper, as outlined in the July 14, 2017, toxicology memo. The review also concludes that the deletion of white tipping paper and the addition of an alternate white 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. The review concludes that the deletion of plug wrap and the addition of an alternate plug wrap is a minor modification. The plug wraps between the new and original products contain minimal differences in the additives that compose the plug wraps. In addition, there was no change in the perforation during manufacturing, meaning the plug wraps are non-porous in the original and new tobacco products. Along with limited other additional additive changes that could impact product performance and HPHCs, (e.g., tipping paper), in this case, the review concludes that the change in plug wrap is a minor modification of a tobacco product. Additionally, 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 and are not expected to materially affect any other characteristic (materials, ingredients, design, composition, heating source, or other features) of the tobacco products. Finally, the review concludes that the deletion of monogram ink (blue) 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 Dilip Venugopal on July 10, 2019.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on November 6, 2019. The FONSI was supported by an environmental assessment prepared by FDA on November 6, 2019.

6. CONCLUSION AND RECOMMENDATION

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

- Deletion of non-FSC cigarette paper (b) (4)
- Addition of FSC cigarette paper (b) (4)
- Deletion of white tipping paper ((b)(4)
- Addition of white tipping paper ((b)(4)
- Deletion of non-porous plug wrap ((b)(4)
- Addition of non-porous plug wrap ((b)(4)
- Deletion of complex purchased flavor ingredients of (b) (4)
(b) (4)
- Increase in the quantities of (b) (4) in the tobacco casing
- Deletion of printed monogram ink (blue) on cigarette barrel

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 (non-FSC cigarette paper, tipping paper (white), plug wrap, complex flavor ingredients (b) (4) (b) (4) in the tobacco casing, and monogram ink on cigarette barrel), and the addition of tobacco additives (FSC cigarette paper, alternate tipping paper (white), and alternate plug wrap), 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. At this time, for these EX Requests, 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 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. The applicant also proposes the deletion of white tipping paper and the addition of an alternate white tipping paper, which is not expected to have any significant effects on product chemistry or consumer perception. The applicant also proposes the deletion of plug wrap and the addition of an alternate plug wrap. The plug wraps between the new and original products contain minimal differences in the additives that compose the plug wraps. In addition, there is no change in the perforation during manufacturing, meaning the plug wraps are non-porous in the original and new tobacco products; These minor differences are not expected to have a significant impact on product performance or HPHCs (e.g., tipping paper), and is considered a minor modification. In addition, 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, the deletion

of monogram ink (blue) 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 modifications through the Exemption Request pathway because they are 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 has examined the environmental effects of finding the new tobacco products exempt and made a finding of no significant impact.

An Exempt order letter should be issued for the new tobacco products in EX0000631 and EX0000633 as identified on the cover page of this review.