

**Technical Project Lead (TPL) Review:
Exemption Requests EX0000856-EX0000861**

EX0000856: Lucky Strike Red Box	
Length	80 mm
Diameter	7.9 mm
Ventilation	0%
Characterizing Flavor	None
Product Modifications	<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> • Deletion of cork-on white tipping paper (b)(4) (b)(4)]; target: (b)(4) mg/cigarette) • Addition of cork-on white tipping paper (b)(4) (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)
EX0000857: Newport Non-Menthol Gold Box	
Length	80 mm
Diameter	7.9 mm
Ventilation	0%
Characterizing Flavor	None
Product Modifications	<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> • Deletion of FSC¹ cigarette paper (b)(4) target: (b)(4) mg/cigarette) • Addition of FSC cigarette paper (b)(4) target: (b)(4) mg/cigarette) • Deletion of printed monogram ink (black) on cigarette barrel
EX0000858: Newport Non-Menthol Gold Box 100s	
Length	99 mm
Diameter	7.9 mm
Ventilation	33%
Characterizing Flavor	None
Product Modifications	<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> • Deletion of FSC cigarette paper (b)(4) (b)(4)]; target: (b)(4) mg/cigarette) • Addition of FSC cigarette paper (b)(4) target: (b)(4) mg/cigarette) • Deletion of printed monogram ink (blue) on cigarette barrel
EX0000859: Lucky Strike Red 100 Box	
Length	99 mm
Diameter	7.9 mm
Ventilation	0%
Characterizing Flavor	None

¹ FSC: Fire standards compliant

<p>Product Modifications</p>	<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> • Deletion of cork-on white tipping paper (b)(4) mg/cigarette • Addition of cork-on white tipping paper (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
<p>EX0000860: Lucky Strike Gold Box</p>	
<p>Length</p>	<p>80 mm</p>
<p>Diameter</p>	<p>7.9 mm</p>
<p>Ventilation</p>	<p>38%</p>
<p>Characterizing Flavor</p>	<p>None</p>
<p>Product Modifications</p>	<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> • Deletion of FSC cigarette paper (b)(4) mg/cigarette • Addition of FSC cigarette paper (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 printed monogram ink (black) on cigarette barrel
<p>EX0000861: Lucky Strike Gold 100 Box</p>	
<p>Length</p>	<p>99 mm</p>
<p>Diameter</p>	<p>7.9 mm</p>
<p>Ventilation</p>	<p>33%</p>
<p>Characterizing Flavor</p>	<p>None</p>
<p>Product Modifications</p>	<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> • Deletion of FSC cigarette paper (b)(4) mg/cigarette • Addition of FSC cigarette paper (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 printed monogram ink (blue) on cigarette barrel
<p>Common Attributes of Exemption Requests</p>	
<p>Applicant</p>	<p>R.J. Reynolds Tobacco Company</p>
<p>Product Category</p>	<p>Cigarette</p>
<p>Product Sub-Category</p>	<p>Combusted, Filtered</p>
<p>Package Quantity</p>	<p>20 -Cigarettes</p>
<p>Package Type</p>	<p>Box</p>
<p>Conclusion</p>	
<p>Issue Exempt order letter.</p>	

Technical Project Lead (TPL):

Todd L. Cecil -S Digitally signed by Todd L. Cecil -
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Date: 2020.01.17 15:14:12 -05'00'

Todd L. Cecil, Ph.D.
Associate 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: 2020.01.17 15:34:10 -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

EX0000856: Lucky Strike Red Box	
Product Name	Newport Non-Menthol Box
Package Type	Box
Package Quantity	20 Cigarettes
Length	80 mm
Diameter	7.9 mm
Ventilation	0%
Characterizing Flavor	None
EX0000857: Newport Non-Menthol Gold Box EX0000860: Lucky Strike Gold Box	
Product Name	Newport Non-Menthol Gold Box
Package Type	Box
Package Quantity	20 Cigarettes
Length	80 mm
Diameter	7.9 mm
Ventilation	38%
Characterizing Flavor	None
EX0000858: Newport Non-Menthol Gold Box 100s EX0000861: Lucky Strike Gold 100 Box	
Product Name	Newport Non-Menthol Gold Box 100s
Package Type	Box
Package Quantity	20 Cigarettes
Length	99 mm
Diameter	7.9 mm
Ventilation	33%
Characterizing Flavor	None
EX0000859: Lucky Strike Red 100 Box	
Product Name	Newport Non-Menthol Box 100s
Package Type	Box
Package Quantity	20 Cigarettes
Length	99 mm
Diameter	7.9 mm
Ventilation	0%
Characterizing Flavor	None

The applicant manufactures the original tobacco products and claims that they are previously found substantially equivalent (EX0000857, EX0000858, EX0000860, EX0000861) or previously found exempt (EX0000856, EX0000859).

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On November 18, 2019, FDA received Exemption Requests (EX0000856-EX0000861) from RAI Services Company on behalf of R.J. Reynolds Tobacco Company. On November 27, 2019, FDA held a teleconference with the applicant to request clarifying information regarding the submission of Abbreviated Reports for the original products in EX0000856 and EX0000859. On December 3, 2019, FDA received an amendment from the applicant with a statement that Abbreviated Reports had not yet been submitted and their intent to provide Abbreviated Reports no later than December 31, 2019 (EX0000900). On December 6, 2019, FDA issued an Acceptance Letter to the applicant for EX0000857-EX0000858 and EX0000860-EX0000861. On December 30, 2019, FDA issued an Acceptance Letter to the applicant for EX0000856 and EX0000859.

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 FSC cigarette paper (b) (4) (EX0000857, EX0000858, EX0000860, EX0000861)
- Addition of FSC cigarette paper (b) (4) (EX0000857, EX0000858, EX0000860, EX0000861)
- Deletion of printed monogram ink (black) on cigarette barrel (EX0000857, EX0000860)
- Deletion of printed monogram ink (blue) on cigarette barrel (EX0000858, EX0000861)
- Deletion of white tipping paper (b) (4) (EX0000860, EX0000861)
- Addition of white tipping paper (b) (4) (EX0000860, EX0000861)
- Deletion of cork-on white tipping paper (b) (4) (EX0000856, EX0000859)
- Addition of cork-on white tipping paper (b) (4) (EX0000856, EX0000859)
- Deletion of filter tow (b) (4) (EX0000856, EX0000859)
- Addition of filter tow (b) (4) (EX0000856, EX0000859)

2. ADMINISTRATIVE REVIEW

Regulatory reviews were completed by Nia White on December 6, 2019 for EX0000857-EX0000858 and EX0000860-EX0000861, and by Camille Hayslett on December 30, 2019 for EX0000856 and EX0000859. The reviews conclude that these Exemption Requests are administratively complete.

3. COMPLIANCE REVIEW

The original tobacco products in EX0000857 and EX0000860 were determined to be substantially equivalent and in compliance with the Federal Food, Drug, and Cosmetic Act (FD&C Act) by FDA under SE0003731. The original tobacco products in EX0000858 and EX0000861 were determined to be substantially equivalent and in compliance with the FD&C Act by FDA under SE0003730.

The original tobacco products in EX0000856 and EX0000859 were determined by FDA under EX0000251 and EX0000230 to be exempt from the requirements of section 905(j) of the FFD&C Act relating to the demonstration of substantial equivalence; Reports under section 905(j)(1)(A)(ii) (Abbreviated Reports) were received on December 10, 2019.

We completed review of your EX REQs² and determined that the new tobacco products listed in EX0000857, EX0000858, EX0000860, and EX0000861 are exempt from the requirements of Substantial Equivalence as of the date of this letter and the new tobacco products listed in EX0000856 and EX0000859, are exempt from the requirements of Substantial Equivalence effective on March 9, 2020.³

An Exemption Request may be made only by the manufacturer of a legally marketed tobacco product for a minor modification to that tobacco product. A legally marketed product appropriate for modification can be a tobacco product FDA has previously found exempt from substantial equivalence and for which an Abbreviated Report was submitted at least 90 days prior to making such introduction or delivery for introduction into interstate commerce for commercial distribution. Although the tobacco products in EX0000856 and EX0000859 that you propose to modify are tobacco products FDA has previously found exempt from SE, FDA received your Abbreviated Reports for these products on December 10, 2019. These tobacco products cannot be legally marketed tobacco products until 90 days after submission of the Abbreviated Reports, i.e., March 9, 2020. Therefore, the new tobacco products listed in EX0000856 and EX0000859 are exempt from the requirements of Substantial Equivalence effective on March 9, 2020.

4. SCIENTIFIC REVIEW

A scientific review was completed by DeLauren McCauley on January 13, 2020.

The scientific review concludes that the new tobacco products have been modified by adding or deleting tobacco additives and increasing or decreasing tobacco additives. These tipping paper⁴, FSC cigarette paper⁵, monogram ink², filter tow⁶, used in the manufacturing of the original tobacco products, 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 a minor modification of a tobacco product in accordance with section 905(j)(3)(A)(i) of the FD&C Act. The review concludes that in EX0000857, EX0000858, EX0000860 and EX0000861, the deletion of an original FSC cigarette paper with the addition of an FSC cigarette paper is a minor modification. The differences between the original FSC cigarette paper and the FSC cigarette paper showed very minor differences in the (b) (4) and (b) (4) between the two cigarette papers. These differences are not expected to have a significant impact on the product performance or HPHC yields. The review also finds that the deletion of the printed monogram ink on the cigarette barrel would decrease the total number of materials combusted and result in lower yields of HPHCs. Additionally, the proposed

² Requests for Exemption from Substantial Equivalence (EX REQs) submitted under section 905(j)(3) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)

³ See section 910(a)(3)(a) of the FD&C Act

⁴ EX0000856 and EX0000859-EX0000861

⁵ EX0000857, EX0000858, EX0000860, EX0000861

⁶ EX0000856 and EX0000859

change is not intended or expected to materially affect any other characteristic (e.g., materials, ingredients, design, composition, heating source, or other features) of the tobacco products. Thus, the deletion of the printed monogram ink on the cigarette barrel in the new tobacco products alone is a minor modification as defined under the requirements in section 905(j)(3)(A) of the FD&C Act. The review also concludes that the deletion of cork-on-white tipping paper and the addition of cork-on-white tipping paper in EX0000856 and EX0000859 and the deletion of white tipping paper and the addition of white tipping paper in EX0000860 and EX0000861 is a minor modification. These changes are not expected to have any significant effects on consumer perception as outlined in the May 16, 2017, social science memo and because the tipping paper is not combusted, volatilized, or otherwise released during normal cigarette consumption, the modifications of these ingredients in the tipping paper are not expected to significantly alter the smoke chemistry or consumer exposure to chemical constituents while smoking. The review also concludes that the deletion of a lip release agent, the addition of another lip release agent and the decreased amount of lip release agent in EX0000860 and EX0000861 is a minor modification as defined under the requirements in section 905(j)(3)(A) of the FD&C Act. The lip release agents are applied to the tipping paper which is in a not combusted or volatilized, portion of the cigarette, the modifications of these ingredients in the lip release agents are not expected to significantly alter the smoke chemistry or consumer exposure to chemical constituents while smoking. Furthermore, the review concludes that for EX0000856 and EX0000859, 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 differences in the filter tow in the original and new tobacco products is the quantity of (b) (4) used in the new products is lower than the amount used in the original products. The difference in the relative quantities of (b) (4) are not expected to have a meaningful impact on the relative performance of the new and original product filters. As a result, the ingredient differences between the filter tow 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 tobacco product.

5. ENVIRONMENTAL DECISION

An environmental review was completed by Dilip Venugopal on December 6, 2019.

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

6. CONCLUSION AND RECOMMENDATION

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

- Deletion of FSC cigarette paper (EX0000857, EX0000858, EX0000860, EX0000861)
- Addition of FSC cigarette paper (EX0000857, EX0000858, EX0000860, EX0000861)
- Deletion of printed monogram ink (black) on cigarette barrel (EX0000857, EX0000860)
- Deletion of printed monogram ink (blue) on cigarette barrel (EX0000858, EX0000861)
- Deletion of white tipping paper (EX0000860, EX0000861)
- Addition of white tipping paper (EX0000860, EX0000861)
- Deletion of cork-on white tipping paper (EX0000856, EX0000859)
- Addition of cork-on white tipping paper (EX0000856, EX0000859)
- Deletion of filter tow (EX0000856, EX0000859)
- Addition of filter tow (EX0000856, EX0000859)

I concur with the conclusion of the scientific review that these modifications are a minor modification involving tobacco additives 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 agree with the scientific review that the new tobacco products have been modified by adding or deleting tobacco additives and increasing or decreasing tobacco additives. The tipping paper, FSC cigarette paper, monogram ink, filter tow, and lip release agents, used in the manufacturing of the original tobacco product(s), 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. I concur with the conclusion in the review that the modifications are minor modification of tobacco additives in accordance with section 905(j)(3)(A)(i) of the FD&C Act. 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.

I also agree with the conclusion that in EX0000857, EX0000858, EX0000860 and EX0000861, the deletion of an original FSC cigarette paper with the addition of an FSC cigarette paper is a minor modification. The differences between the original FSC cigarette paper and the FSC cigarette paper showed very minor differences in the (b) (4) and (b) (4) between the two cigarette papers. These differences are not expected to have a significant impact on the product performance or HPHC yields. I agree with the scientific review that the deletion of the printed monogram ink on the cigarette barrel would decrease the total number of materials combusted and result in lower yields of HPHCs. Additionally, the proposed change is not intended or expected to materially affect any other characteristic (e.g., materials, ingredients, design, composition, heating source, or other features) of the products. Thus, the deletion of the printed monogram ink on the cigarette barrel in the new tobacco products alone is a minor modification as defined under the requirements in section 905(j)(3)(A) of the FD&C Act. I agree with the conclusion that the deletion of cork-on-white tipping paper and the addition of cork-on-white tipping paper in EX0000856 and EX0000859 and the deletion of white tipping paper and the addition of white tipping paper in

EX0000860 and EX0000861 is a minor modification. These changes are not expected to have any significant effects on consumer perception as outlined in the May 16, 2017, social science memo and because the tipping paper is not combusted, volatilized, or otherwise released during normal cigarette consumption, the modifications of these ingredients in the tipping paper are not expected to significantly alter the smoke chemistry or consumer exposure to chemical constituents while smoking. I also agree that the deletion of a lip release agent, the addition of another lip release agent and the decreased amount of lip release agent in EX0000860 and EX0000861 is a minor modification as defined under the requirements in section 905(j)(3)(A) of the FD&C Act. The lip release agents are applied to the tipping paper which is in a not combusted or volatilized, portion of the cigarette, the modifications of these ingredients in the lip release agents are not expected to significantly alter the smoke chemistry or consumer exposure to chemical constituents while smoking. I also agree with the conclusion that for EX0000856 and EX0000859, 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 characteristics (materials, ingredients, design, composition, heating source, or other features) of the tobacco products. The differences in the filter tow in the original and new tobacco products is the quantity of (b) (4) used in the new products is lower than the amount used in the original products. The difference in the relative quantities of (b) (4) are not expected to have a meaningful impact on the relative performance of the new and original product filters. As a result, the ingredient differences between the filter tow 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 tobacco product. Lastly, FDA finds, based on the information contained in the Exemption Request 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 product 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 EX0000857, EX0000858, EX0000860, and EX0000861 are grandfathered products (i.e., were commercially marketed in the United States, other than exclusively in test markets, as of February 15, 2007) and are therefore eligible for modification through the exemption request pathway because they can be legally marketed in the United States. The original products in EX0000856 and EX0000859 are previously found exempt by FDA under EX0000251 and EX0000230 and reports under section 905(j)(1)(A)(ii) (Abbreviated Reports) were submitted under AS0000297 and AS0000300, respectively. Therefore, the original products in EX0000856 and EX0000859 are eligible for modification under the Exemption Request pathway on March 9, 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 letter should be issued for the new tobacco products in EX0000856-EX0000861 as identified on the cover page of this review.