

**Technical Project Lead (TPL) Review:
Exemption Requests EX0000366 and EX0000367**

EX0000366: Cougar Long Cut Natural	
Tobacco Cut Size	(b) (4) ¹
Characterizing Flavor	None
Product Modifications	<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> Deletion of (b) (4)(b) (4) <p>Increasing/Decreasing the quantity of existing tobacco additives:</p> <ul style="list-style-type: none"> Increase in quantity of (b) (4)(b) (4)(b) (4)
EX0000367: Cougar Snuff	
Tobacco Cut Size	(b) (4) ¹
Characterizing Flavor	None
Product Modifications	<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> Deletion of PM civet absolute <p>Increasing/Decreasing the quantity of existing tobacco additives:</p> <ul style="list-style-type: none"> Increase in quantity of (b) (4)(b) (4)(b) (4)
Common Attributes of Exemption Requests	
Applicant	American Snuff Company, LLC
Product Category	Smokeless Tobacco
Product Sub-Category	Loose Moist Snuff
Package Quantity	1.2 oz (34.02 grams)
Package Type	Plastic Can with Plastic Lid
Recommendation	
Issue an Exempt order letter.	

¹ For purposes of an EX REQ, a numerical value is not necessary as the tobacco itself cannot be modified

Technical Project Lead (TPL):

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2019.02.12 11:13:29 -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: 2019.02.12 11:32:23 -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

EX0000366: Cougar Long Cut Natural	
Product Name	Cougar Long Cut Natural
Package Type	Plastic Can with Plastic Lid
Package Quantity	1.2 oz (34.02 grams)
Tobacco Cut Size	(b) (4) ¹
Characterizing Flavor	None
EX0000367: Cougar Snuff	
Product Name	Cougar Snuff
Package Type	Plastic Can with Plastic Lid
Package Quantity	1.2 oz (34.02 grams)
Tobacco Cut Size	(b) (4) ¹
Characterizing Flavor	None

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

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On December 20, 2018, FDA received Exemption Requests (EX0000366-EX0000367) from RAI Services Company on behalf of American Snuff Company LLC. FDA issued Acknowledgement letters to the applicant on December 27, 2018.

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:

- Deletion of (b) (4)
- Increase of (b) (4)

2. REGULATORY REVIEW

Regulatory reviews were completed by Shontelle Dixon on December 27, 2018. The reviews conclude that these 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 January 25, 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 Megan Mekoli on February 12, 2018. The review states that the new tobacco products have been modified by deleting a tobacco additive (b) (4)(b) (4) and increasing the quantity of an existing additive (b) (4)(b) (4)(b) (4). These substances, 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 minor modifications of a tobacco product in accordance with section 905(j)(3)(A)(i) of the FD&C Act. This change resulted in the removal of (b) (4)(b) (4)(b) (4)(b) (4) and increasing (b) (4) (b) (4)(b) (4)(b) (4)(b) (4) in the new tobacco products. This modification was due to a supply chain issue in (b) (4), which is used in the new and original products. These modifications were made to the sub-components of (b) (4) and results in a minimal quantity change between these two additives. Additionally, the change in these additives is not expected to materially affect any other characteristic (materials, ingredients, design, composition, heating source, or other features) of the products.

5. ENVIRONMENTAL DECISION

An environmental review was completed by Susana Addo Ntim on January 11, 2019.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on February 8, 2019. The FONSI was supported by an environmental assessment prepared by FDA on February 8, 2019.

6. CONCLUSION AND RECOMMENDATION

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

- Deletion of (b) (4)
- Increase of (b) (4)

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.

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 (b) (4) (b) (4) is a deletion of a tobacco additive and (b) (4)(b) (4)(b) (4) is an increase in the quantity of an existing 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 protection of the public health. This change is the result of the removal of (b) (4)(b) (4)(b) (4)(b) (4) and increase of (b) (4) of (b) (4)(b) (4)(b) (4) in the new tobacco products. This modification was due to a supply chain issue in (b) (4)(b) (4) which is used in the new and original products. These modifications were made to the sub-components of (b) (4) and results in a minimal quantity change between these two additives. Additionally, the change in these additives 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 Request and CTP's scientific understanding, that an exemption for these modifications 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 tobacco products are eligible for modification through the Exemption Request pathway because they can be 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.

Exempt order letters should be issued for the new tobacco products in EX0000366 and EX0000367 as identified on the cover page of this review.