

Technical Project Lead (TPL) Review of Exemption Request: EX0000892

Common Attributes of EX Request		
Applicant	Vandenberg Special Products, B.V.	
Product category	Roll-Your-Own Tobacco Products	
Product subcategory	Non-Filtered Cigarette Tubes ¹	
EX Request Included in this Review		
Tobacco Product	New	Original
Submission tracking number	EX0000892	GF1804839
Product name	Cones Unbleached 1 ¼ 6 Piece	Cones 6 Piece 83 mm
Eligibility status	Not applicable	Grandfathered
Marketing order date	Not applicable	Not applicable
Abbreviated report date	Not applicable	Not applicable
Package type	Blister Pack	Blister Pack
Package quantity	6 Tubes	6 Tubes
Characterizing flavor	None	None
Length	83 mm	83 mm
Diameter	11.05–11.10 mm (top); 5.40–5.45 mm (bottom)	11.05–11.10 mm (top); 5.40–5.45 mm (bottom)
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of (b) (4) [REDACTED] and other bleaching agents (b) (4) [REDACTED] 	
Recommendation		
Issue an Exempt (EX) order.		

¹ Manufacturer identifies the subcategory of the new and original tobacco products as paper cones.

Technical Project Lead (TPL):

Digitally signed by Matthew J. Walters -S
Date: 2020.04.07 11:40:55 -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: 2020.04.07 13:11:27 -04'00'

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

TABLE OF CONTENTS

1. BACKGROUND.....4
 1.1. ORIGINAL TOBACCO PRODUCT 4
 1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW 4
 1.3. SCOPE OF REVIEW 4
 1.4. TOBACCO ADDITIVE MODIFICATION 4

2. REGULATORY REVIEW4

3. COMPLIANCE REVIEW.....4

4. SCIENTIFIC REVIEW.....5

5. ENVIRONMENTAL DECISION5

6. CONCLUSION AND RECOMMENDATION5

1. BACKGROUND

1.1. ORIGINAL TOBACCO PRODUCT

The original tobacco product is a roll-your own tobacco product, non-filtered cigarette tube manufactured by the applicant as indicated on the cover page of this review.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On December 5, 2019, FDA received an Exemption Request (EX0000892) from Vandenberg Special Products, B.V. FDA issued an Acceptance letter to the applicant on December 12, 2019. On January 23, 2020, FDA issued a Deficiency letter for EX0000892. In response, the applicant submitted an amendment (EX0000992) to the Exemption Request, received by FDA on February 21, 2020.

1.3. SCOPE OF REVIEW

This review captures all regulatory, compliance, and scientific reviews completed for this Exemption Request.

1.4. TOBACCO ADDITIVE MODIFICATION

The new tobacco product contains the following modification compared to the original tobacco product:

- deleting additives (b) (4) and other bleaching agents (b) (4)

2. REGULATORY REVIEW

A regulatory review was completed by Cynthia Colon on December 12, 2019. The review concludes that the Exemption Request is administratively complete.

3. COMPLIANCE REVIEW

The Office of Compliance and Enforcement (OCE) completed a review to determine whether the applicant established that the original tobacco product is a grandfathered product; i.e., was commercially marketed in the United States other than exclusively in test markets as of February 15, 2007. The OCE review dated January 14, 2020 concludes that the original tobacco product is a grandfathered product. Therefore, the original tobacco product is eligible for modification under the Exemption Request pathway.²

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.

4. SCIENTIFIC REVIEW

Scientific reviews were completed by Scott Wasdo on January 13, 2020 and April 6, 2020.

The final review states that the new tobacco product has been modified by deleting tobacco additives. (b) (4) and bleaching agents are used in the manufacturing of the original tobacco product 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 product. 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. The review concludes that the modification of the original product by deletion of (b) (4) and other bleaching agents (b) (4) from the manufacturing process are collectively minor modifications. The deletion of (b) (4) and other bleaching agents (b) (4) in the manufacturing process for the new tobacco product does not result in a new tobacco product with characteristics that materially differ from those of the original tobacco product. The removal of these additives prevents the breakdown of (b) (4) and other (b) (4) compounds in the paper. However, the process of producing unbleached (b) (4) removes most of the (b) (4) and (b) (4) materials from the source wood, so the quantity of these compounds remaining in new tobacco product is expected to be low. In addition, these changes are not expected to result in any change in product performance or other characteristics that could impact consumer use with a slightly higher amount of (b) (4) in the new tobacco product compared to the original tobacco product.

5. ENVIRONMENTAL DECISION

Environmental reviews were completed by Susana Addo Ntim on January 7, 2020 and Rudaina Alrefai-Kirkpatrick on March 13, 2020.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on March 19, 2020. The FONSI was supported by an environmental assessment prepared by FDA on March 18, 2020.

6. CONCLUSION AND RECOMMENDATION

The new tobacco product contains the following modification compared to the original tobacco product:

- deleting additives (b) (4) and other bleaching agents (b) (4)

I concur with the conclusion of the scientific reviews 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 (b) (4) and bleaching agents are deletions of tobacco additives. 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 product to be marketed would be appropriate for the protection of the public health. The applicant intends to delete (b) (4) and other bleaching agents (b) (4) from the manufacturing process used for the new tobacco products. The deletion of (b) (4) and other bleaching agents (b) (4) in the manufacturing process for the new tobacco product does not result in a new tobacco product with characteristics that materially differ from those of the original tobacco product. The removal of these additives prevents the breakdown of (b) (4) and other (b) (4) compounds in the paper. However, the process of producing unbleached (b) (4) removes most of the (b) (4) and (b) (4) materials from the source wood, so the quantity of these compounds remaining in new tobacco product is expected to be low. In addition, these changes are not expected to result in any change in product performance or other characteristics that could impact consumer use with a slightly higher amount of (b) (4) in the new tobacco product compared 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 these modifications 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 tobacco product is eligible for modification through the Exemption Request pathway because it can be legally marketed in the United States. The original tobacco product is a grandfathered product; i.e., was 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 product exempt and made a finding of no significant impact.

An exempt order should be issued for the new tobacco product in EX0000892, as identified on the cover page of this review.