

# Technical Project Lead (TPL) Review of Exemption Requests: EX0001026 – EX0001028

Common Attributes of EX	( Request					
Applicant	Vandenberg Special Products B.V.					
Product category	Roll-Your-Own Tobacco Products					
Product subcategory	Non-Filtered Cigarette Tubes¹					
EX Request Included in th	nis Review					
Tobacco Product	New	Original				
Submission tracking	EX0001026	GF1804836				
number						
Product name	Cones Unbleached King Size Bulk	Cones Bulk Unpackaged 109mm				
Eligibility status	Not applicable	Grandfathered				
Marketing order date	Not applicable	Not applicable				
Abbreviated report date	Not applicable	Not applicable				
Package type	Box	Box				
Package quantity	1000 Tubes	1000 Tubes				
Characterizing flavor	None	None				
Length	109 mm	109 mm				
Diameter	12.50-12.55 mm (top);	12.50-12.55 mm (top);				
	5.90–5.95 mm (bottom)	5.90-5.95 mm (bottom)				
Product modifications	Addition/Deletion of tobacco additives  • Deletion of (0)(4)	and other bleaching agents (1) (4)				
Tobacco Product	New	Original				
Submission tracking number	EX0001027	GF1804838				
Product name	Cones Unbleached King Size 12 Piece	Cones 12 Piece 109mm				
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	12 Tubes	12 Tubes				
Characterizing flavor	None	None				
Length	109 mm	109 mm				
Diameter	12.91–12.96 mm (top);	12.91–12.96 mm (top);				
	5.49-5.53 mm (bottom)	5.49–5.53 mm (bottom)				
	Addition/Deletion of tobacco additives	s:				
Product modifications	Deletion of (6) (4)	and other bleaching agents (6)(4)				

 $^{\rm 1}$  Manufacturer identifies the subcategory of the new and original tobacco products as paper cones.

Tobacco Product	New	Original				
Submission tracking	EX0001028	GF1804837				
number						
Product name	Cones Unbleached King Size 3 Piece	Cones 3 Piece 109mm				
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	3 Tubes	3 Tubes				
Characterizing flavor	None	None				
Length	109 mm	109 mm				
Diameter	12.91-12.96 mm (top);	12.91–12.96 mm (top);				
	5.49-5.53 mm (bottom)	5.49–5.53 mm (bottom)				
	Addition/Deletion of tobacco additives:					
Product modifications	<ul> <li>Deletion of (b) (4)</li> </ul>	and other bleaching agents (0)(4)				
Recommendation						
Issue Exempt (EX) order.						

## Technical Project Lead (TPL):

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Matthew J. Walters, Ph.D., MPH CDR, US Public Health Service Deputy Director Division of Product Science

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$\boxtimes$	Concur with TPL recommendation and basis of recomme	endation
	Concur with TPL recommendation with additional commseparate memo)	nents (see
	Do not concur with TPL recommendation (see separate	memo)
	igitally signed by Matthew R. Holman -S	

Matthew R. Holman, Ph.D.

Director

Office of Science

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#### 1. BACKGROUND

#### 1.1. ORIGINAL TOBACCO PRODUCT

The original tobacco products are roll-your own tobacco products, non-filtered cigarette tubes manufactured by the applicant as indicated on the cover page of this review.

### 1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

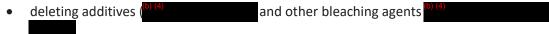
On March 23, 2020, FDA received three Exemption Requests (EX0001026 – EX0001028) from Vandenberg Special Products B.V. On April 2, 2020, FDA issued an Acceptance letter to the applicant. On May 5, 2020, FDA issued a Deficiency letter to the applicant. On June 3, 2020, FDA received the applicant's response (EX0001135) to the Deficiency letter.

#### 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 product contains the following modification compared to the original tobacco product:



#### 2. REGULATORY REVIEW

Regulatory reviews were completed by Michael Jokoh and Kim Jordan on April 1, 2020. The reviews conclude that the Exemption Requests are 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 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 review dated April 25, 2020, concludes that the original tobacco products are grandfathered products. Therefore, the original tobacco products are eligible for modifications under the Exemption Request pathway.<sup>2</sup>

<sup>&</sup>lt;sup>2</sup> 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 Stephanie Daniels on April 16, 2020 and June 25, 2020.

The final review states that the new tobacco products have been modified by deleting tobacco and bleaching agents are used in the manufacturing of the original additives. 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 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 products by deletion of and other bleaching agents (19) (4) and (b) (4) ) from the manufacturing process are collectively minor modifications. The deletion of and other bleaching agents and of the manufacturing process for the new tobacco products does not result in a new tobacco product with characteristics that materially differ from those of the original tobacco products. The removal of these additives prevents the breakdown of these and other compounds in the paper. However, the process of producing removes most of the (b) (4) and (a) (4) materials from the source wood, so the quantity of these compounds remaining in new tobacco products 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 (4) in the new tobacco products compared to the original tobacco products.

#### 5. ENVIRONMENTAL DECISION

Environmental reviews were completed by Thomas Creaven on April 23, 2020 and on June 24, 2020.

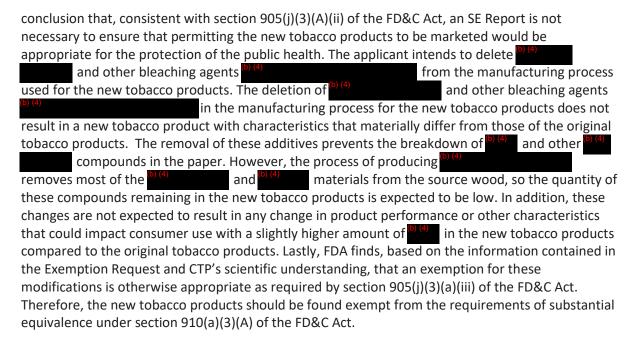
A finding of no significant impact (FONSI) was signed by Luis Valerio, Ph.D. on June 26, 2020. The FONSI was supported by an environmental assessment prepared by FDA on June 26, 2020.

#### 6. CONCLUSION AND RECOMMENDATION

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

• deleting additives (19,4) and other bleaching agents (19,4) and other bl

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 reviews that the and bleaching agents are deletions of tobacco additives. In addition, it is my



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 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.

FDA has examined the environmental effects of finding the new tobacco products exempt and made a finding of no significant impact.

Exempt orders should be issued for the new tobacco products in EX0001026 – EX0001028, as identified on the cover page of this review.