FDA U.S. FOOD & DRUG ADMINISTRATION

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 Tubes[1]	
EX Request Included in this Review		
Tobacco Product	**New**	**Original**
Submission tracking number	EX0001026	GF1804836
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); 5.90–5.95 mm (bottom)	12.50–12.55 mm (top); 5.90–5.95 mm (bottom)
Product modifications	Addition/Deletion of tobacco additives: • Deletion of (b) (4) and other bleaching agents (b) (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); 5.49–5.53 mm (bottom)	12.91–12.96 mm (top); 5.49–5.53 mm (bottom)
Product modifications	Addition/Deletion of tobacco additives: • Deletion of (b) (4) and other bleaching agents (b) (4)	

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

Tobacco Product	New	Original
Submission tracking number	EX0001028	GF1804837
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); 5.49–5.53 mm (bottom)	12.91–12.96 mm (top); 5.49–5.53 mm (bottom)
Product modifications	Addition/Deletion of tobacco additives: • Deletion of (b) (4) [redacted] and other bleaching agents (b) (4) [redacted]	
Recommendation		
Issue Exempt (EX) order.		

Technical Project Lead (TPL):

Digitally signed by Matthew J. Walters -S
Date: 2020.07.07 16:31:57 -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: 2020.07.07 16:41:38 -04'00'

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

TABLE OF CONTENTS

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:

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

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.[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 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 additives. (b) (4) and bleaching agents 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 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 (b) (4) and other bleaching agents ((b) (4) and (b) (4)) from the manufacturing process are collectively minor modifications. The deletion of (b) (4) and other bleaching agents ((b) (4) and (b) (4)) in 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 (b) (4) and other (b) (4) compounds in the paper. However, the process of producing (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 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 (b) (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 ((b) (4) and other bleaching agents ((b) (4) and (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 reviews 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 products to be marketed would be appropriate for the protection of the public health. The applicant intends to delete [redacted] and other bleaching agents [redacted] from the manufacturing process used for the new tobacco products. The deletion of [redacted] and other bleaching agents [redacted] in 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 [redacted] and other [redacted] compounds in the paper. However, the process of producing [redacted] removes most of the [redacted] and [redacted] materials from the source wood, so the quantity of these compounds remaining in the 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 [redacted] in the new tobacco products compared to the original tobacco 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 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.