U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

July 08, 2020

EXEMPT

Vandenberg Special Products B.V.
Attention: Bryan M. Haynes, Esq.
Troutman Sanders LLP
1001 Haxall Point
Richmond, VA 23219

FDA Submission Tracking Numbers (STNs): Multiple STNs**,** see Appendix A

Dear Mr. Haynes:

We completed review of your EX REQs[1] and determined that the new tobacco products listed in Appendix A are exempt from the requirements of Substantial Equivalence.[2]

Our finding does not mean we "approved" the new products specified in Appendix A; therefore, you may not promote or in any way represent the new tobacco products specified in Appendix A, or the labeling, as being "approved" by FDA (see Section 301(tt) of the FD&C Act).

To market the new tobacco products that are the subject of these EX REQs, the following must be met:

1. **Submit a report under section 905(j)(1) (Abbreviated Report) that includes the information required in sections 905(j)(1)(A)(ii) and 905(j)(1)(B); and**
2. **Ninety days have passed since FDA receipt of your Abbreviated Report.**

See Appendix B for FDA's recommended format for submitting of an Abbreviated Report.

In accordance with 40 CFR 1506.6, we will make your Environmental Assessment (EA) publicly available.

All regulated tobacco products, including the tobacco products specified in Appendix A, are subject to the requirements of the FD&C Act and its implementing regulations. It is your responsibility to ensure the tobacco products specified in Appendix A comply with all applicable statutory and regulatory requirements. FDA will monitor your compliance with all applicable statutes and regulations.

[1] 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)
[2] See section 910(a)(3)(a) of the FD&C Act

We encourage you to submit all regulatory correspondence electronically via the CTP Portal[3,4] using eSubmitter.[5] Alternatively, submissions may be mailed to:

Food and Drug Administration
Center for Tobacco Products
Document Control Center (DCC)
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

The CTP Portal and FDA's Electronic Submission Gateway (ESG) are generally available 24 hours a day, seven days a week; if the upload is successful, submissions are considered received by DCC on the day of upload. Submissions delivered to DCC by courier or physical mail will be considered timely if received during delivery hours on or before the due date[6]; if the due date falls on a weekend or holiday, the delivery must be received on or before the preceding business day. We are unable to accept regulatory submissions by e-mail.

If you have any questions, please contact Michael Jokoh, Regulatory Health Project Manager, at (301) 796-0502 or Michael.Jokoh@fda.hhs.gov.

Sincerely,

Digitally signed by Matthew R. Holman -S
Date: 2020.07.08 09:00:15 -04'00'

Matthew R. Holman, Ph.D.
Director
Office of Science
Center for Tobacco Products

Enclosures:

Appendix A – New and Corresponding Original Tobacco Products Subject of This Letter
Appendix B – FDA's Recommended Format for Submitting an Abbreviated Report

[3] For more information about CTP Portal, see https://www.fda.gov/tobacco-products/manufacturing/submit-documents-ctp-portal
[4] FDA's Electronic Submission Gateway (ESG) is still available as an alternative to the CTP Portal.
[5] For more information about eSubmitter, see http://www.fda.gov/ForIndustry/FDAeSubmitter
[6] https://www.fda.gov/tobacco-products/about-center-tobacco-products-ctp/contact-ctp

Appendix A

New and Corresponding Original Tobacco Products Subject of This Letter

Common Attributes of EX REQs	
Date of Submission:	March 20, 2020
Date of Receipt:	March 23, 2020
Product Manufacturer:	Vandenberg Special Products B.V.
Product Category:	Roll-Your-Own Tobacco Products
Product Sub-Category:	Non-Filtered Cigarette Tube[7]

EX Request Included in this Review		
Tobacco Product	**New**	**Original**
Submission tracking number	EX0001026	GF1804836
Product name	Cones Unbleached King Size Bulk[8]	Cones Bulk Unpackaged 109mm[8]
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[8]	Cones 12 Piece 109 mm[8]
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)	

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

8 Brand/sub-brand or other commercial name used in commercial distribution.

Tobacco Product	New	Original
Submission tracking number	EX0001028	GF1804837
Product name	Cones Unbleached King Size 3 Piece[8]	Cones 3 Piece 109mm[8]
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) and other bleaching agents (b) (4)	

Appendix B

FDA's Recommended Format for Submitting an Abbreviated Report

Mock-up Tobacco Company

April 3, 2015

US Department of Health and Human Services
Food and Drug Administration
Center for Tobacco Products
Document Control Center
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: Abbreviated Report

To Whom It May Concern:

Mock-Up Tobacco Company provides this Abbreviated Report at least 90 days prior to the introduction or delivery for introduction into interstate commerce for commercial distribution of the new product, Cigarette Brand A. We submitted an Exemption Request (EX0000XXX) under section 905(j)(3) for the new product on February 1, 2015, and received a found exempt order from FDA on March 20, 2015.

I, John Doe, on behalf of Mock-Up Tobacco Company, certify that Cigarette Brand A is modified within the meaning of section 905(j)(3), the modifications are to a product that is commercially marketed and in compliance with the requirements of the Federal Food, Drug, and Cosmetic Act, all the modifications are covered by exemptions granted by the Secretary pursuant to section 905(j)(3), and I have taken actions to comply with the requirements under section 907 that are applicable to the product. I certify that this information is true and correct, and that I am authorized to submit this on the company's behalf. I understand that under section 1001 of title 18 of the United States Code, anyone who knowingly and willfully makes a materially false, fictitious, or fraudulent statement to the Government of the United States is subject to criminal penalties.

Sincerely,
John Doe **[ink or digital signature]**
Vice President
Mock-Up Tobacco Company