



July 08, 2021

EXEMPT

R.J. Reynolds Tobacco Company
Attention: Michael Ogden, Ph.D., Senior Vice President - Scientific & Regulatory Affairs
RAI Services Company
401 N Main St.
Winston Salem, NC 27101

FDA Submission Tracking Numbers (STNs): EX0001392-PD1, EX0001395-PD1, see Appendix A

Dear Dr. Ogden:

We completed review of your EX REQs¹ 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 date⁶; 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 Barbara Banchemo, Regulatory Health Project Manager, at (301) 796-1937 or Barbara.Banchemo@fda.hhs.gov.

Sincerely,

Todd L.Cecil, Ph.D.
Deputy Director for Regulatory Management
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:	December 21, 2020	
Date of Receipt:	December 21, 2020	
Product Manufacturer:	R.J. Reynolds Tobacco Company	
Product Category:	Cigarettes	
Product Sub-Category:	Combusted, Filtered	
	New Tobacco Product	Original Tobacco Product
	EX0001392-PD1: Camel Crush Smooth Menthol Silver Box ⁷	SE0006134: Camel Crush ⁷
Package Type:	Box	Box
Package Quantity:	20 cigarettes	20 cigarettes
Characterizing Flavor:	Menthol	Menthol
Eligibility Status:	Not Applicable	Previously Found SE
Marketing authorization date:	Not Applicable	March 25, 2013
Length:	83 mm	83 mm
Diameter:	7.8 mm	7.8 mm
Ventilation:	32%	32%
Additional property:	Crushable Menthol Capsule in Filter	Crushable Menthol Capsule in Filter
Modifications:		
Addition/Deletion of tobacco additives:		
<ul style="list-style-type: none"> • Deletion of white tipping paper ((b) (4) [REDACTED] ^{(b) (4)} MM]; target: ^{(b) (4)} mg/cigarette) • Addition of white tipping paper ((b) (4) [REDACTED] ^{(b) (4)} MM]; target ^{(b) (4)} mg/cigarette) • Deletion of menthol capsule from the filter (b) (4) [REDACTED].) • Addition of menthol capsule in the filter (b) (4) [REDACTED].) • (b) (4) [REDACTED] 		
Increase/Decrease in quantity of existing additives:		
<ul style="list-style-type: none"> • Increasing the quantity of tipping paper adhesive (b) (4) [REDACTED]) 		

⁷ Brand/sub-brand or other commercial name used in commercial distribution.

	New Tobacco Product	Original Tobacco Product
	EX0001395-PD1: Camel Crush Smooth Menthol Silver Box ⁷	SE0006134: Camel Crush ⁷
Package Type:	Box	Box
Package Quantity:	20 cigarettes	20 cigarettes
Characterizing Flavor:	Menthol	Menthol
Eligibility Status:	Not Applicable	Previously Found SE
Marketing authorization date:	Not Applicable	March 25, 2013
Length:	83 mm	83 mm
Diameter:	7.8 mm	7.8 mm
Ventilation:	32%	32%
Additional property:	Crushable Menthol Capsule in Filter	Crushable Menthol Capsule in Filter
Modifications:		
Addition/Deletion of tobacco additives:		
<ul style="list-style-type: none"> • Deletion of white tipping paper (b) (4) .; (b) (4) MM]; target: (b) (4) mg/cigarette) • Addition of white tipping paper (b) (4) (b) (4) MM]; target: (b) (4) mg/cigarette) • Deletion of menthol capsule from the filter ((b) (4) .) • Addition of menthol capsule in the filter ((b) (4) .) • (b) (4) 		
Increase/Decrease in quantity of existing additives:		
<ul style="list-style-type: none"> • Increasing the quantity of tipping paper adhesive (b) (4) 		