



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

August 05, 2021

EXEMPT

ITG Brands, LLC
Attention: Carole Folmar, JD, Senior Director, Product Integrity and Compliance
714 Green Valley Rd.
Greensboro, NC 27408

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

Dear Ms. Folmar:

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 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 product specified in Appendix A comply with all applicable statutory and regulatory requirements. FDA will monitor your compliance with all applicable statutes and regulations.

¹ Request for Exemption from Substantial Equivalence (EX REQ) 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 Kenna Randall, Regulatory Health Project Manager, at 301-796-4164 or Kenna.Randall@fda.hhs.gov.

Sincerely,

Digitally signed by Todd L. Cecil -S
Date: 2021.08.05 14:55:43 -04'00'

Todd L. Cecil, Ph.D.
Deputy Director
Office of Science
Center for Tobacco Products

Enclosures:

Appendix A – New and 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 A⁷
New and Original Tobacco Products Subject of This Letter

Common Attributes		
Submission date	February 01, 2021	
Receipt date	February 01, 2021	
Applicant	ITG Brands LLC	
Product manufacturer	ITG Brands LLC	
Product category	Cigarette	
Product subcategory	Combusted, Filtered	
Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001504-PD1	EX0000443
Product name	Kool 100s Box	Kool 100s Box
Eligibility status	Not applicable	Previously Found Exempt
Marketing authorization date	Not applicable	March 29, 2019
Abbreviated report date	Not applicable	April 17, 2019
Package type	Box	Box
Package quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	Menthol	Menthol
Diameter	7.89 mm	7.89 mm
Product length	97 mm	97 mm
Ventilation	23%	23%
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of Fire Standard Compliant (FSC) cigarette paper (b)(4) • Addition of FSC cigarette paper (b)(4) 	
Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001504-PD3	EX0000445
Product name	Kool Blue Box	Kool Blue Box
Eligibility status	Not applicable	Previously Found Exempt
Marketing authorization date	Not applicable	March 29, 2019
Abbreviated report date	Not applicable	April 17, 2019
Package type	Box	Box
Package quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	Menthol	Menthol
Diameter	7.79 mm	7.79 mm
Product length	83 mm	83 mm
Ventilation	29%	29%
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of FSC cigarette paper (b)(4) • Addition of FSC cigarette paper (b)(4) 	

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

Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001504-PD5	EX0000446
Product name	Kool Box	Kool Box
Eligibility status	Not applicable	Previously Found Exempt
Marketing authorization date	Not applicable	March 29, 2019
Abbreviated report date	Not applicable	April 17, 2019
Package type	Box	Box
Package quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	Menthol	Menthol
Diameter	7.79 mm	7.79 mm
Product length	83 mm	83 mm
Ventilation	10%	10%
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of FSC cigarette paper (b)(4) • Addition of FSC cigarette paper () 	

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