



REDACTED

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

June 22, 2020

FILING

E-Alternative Solutions, LLC
Attention: D. Christopher Howard, Vice President, General Counsel and Chief Compliance Officer
459 E. 16th Street
Jacksonville, Florida 32206

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

Dear Mr. Howard:

We completed a preliminary review of your PMTAs¹ and determined that these applications meet the filing requirements for a new tobacco product seeking a marketing order under section 910(b) of the FD&C Act.² As a result, the applications for the new tobacco products identified in Appendix A are filed, effective the date of this letter.

The decision to file these PMTAs does not mean FDA evaluated the adequacy of the data submitted or issued an authorization order. Rather, it represents a decision by the Center for Tobacco Products that the applications are sufficiently complete to enter substantive review phase. Please note, our filing review is only a preliminary evaluation of the applications and not indicative of deficiencies that may be identified during a substantive review. We will contact you if we have a request for any additional information.

Your tobacco products specified in Appendix A are subject to the requirements of Chapter IX of the FD&C Act and its regulations. It is your responsibility to ensure that the tobacco products specified in Appendix A comply with all applicable statutory and regulatory requirements, including those which may be forthcoming. For more information on your compliance responsibilities under the FD&C Act, we encourage you to visit our website.³ You may also obtain information by contacting us at 1-877-CTP-1373, AskCTP@fda.hhs.gov, or SmallBiz.Tobacco@fda.hhs.gov.

¹ Premarket Tobacco Product Applications (PMTAs) submitted under section 910 of the Federal Food, Drug, and Cosmetic Act (FD&C Act)

² Federal Food, Drug, and Cosmetic Act (FD&C Act)

³ <https://www.fda.gov/tobacco-products>

If you have any questions, please contact Megan Nguyen, Regulatory Health Project Manager, at (301) 796 -7826 or Megan.Nguyen@fda.hhs.gov.

Sincerely,

Digitally signed by Megan J. Schroeder -S
Date: 2020.06.22 14:49:44 -04'00'

Megan Schroeder, Ph.D.
Branch Chief, Behavioral and Clinical Pharmacology
Division of Individual Health Science
Office of Science
Center for Tobacco Products

Enclosure:

Appendix A – New Tobacco Products Subject of This Letter

Appendix A
New Tobacco Products Subject of This Review

Common Attributes of PMTA	
Submission date	June 5, 2020
Receipt date	June 9, 2020
Applicant	E-Alternative Solutions, LLC
Product category	ENDS (Electronic Nicotine Delivery System)
Product subcategory	Closed E-Cigarette
Attributes⁴	New Tobacco Product
STN	PM0000795
Product name	Leap Go Smooth Tobacco 5% Nicotine ⁵
Package type	Box
Package quantity	1 e-cigarette
Characterizing flavor	Tobacco
Length	112 mm
Diameter	9.2 mm
E-liquid volume	1.25 ml
Nicotine concentration	5.0%
Wattage	1.176 WH
Battery capacity	280 mAh
Additional Properties	Nicotine Salt
Attributes⁴	New Tobacco Product
STN	PM0000796
Product name	Leap Go Mint 5% Nicotine ⁵
Package type	Box
Package quantity	1 e-cigarette
Characterizing flavor	Mint
Length	112 mm
Diameter	9.2 mm
E-liquid volume	1.25 ml
Nicotine concentration	5.0%
Wattage	1.176 WH
Battery capacity	280 mAh
Additional Properties	Nicotine Salt

⁴ Properties to uniquely identify the new tobacco products were provided by the applicant as of the date of this letter, and not confirmed by FDA. Upon scientific review, the unique identification may be revised.

⁵ Brand/sub-brand or other commercial name used in commercial distribution.

Attributes⁴	New Tobacco Product
STN	PM0000797
Product name	Leap Go Mango 5% Nicotine ⁵
Package type	Box
Package quantity	1 e-cigarette
Characterizing flavor	Mango
Length	112 mm
Diameter	9.2 mm
E-liquid volume	1.25 ml
Nicotine concentration	5.0%
Wattage	1.176 WH
Battery capacity	280 mAh
Additional Properties	Nicotine Salt