



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

June 26, 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 Luis G. Valerio

-S

Date: 2020.06.26 12:00:28 -04'00'

Luis G. Valerio, Jr., Ph.D., ATS
Associate Director, Division of Nonclinical 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 15, 2020
Receipt date	June 15, 2020
Applicant	E-Alternative Solutions, LLC
[REDACTED]	[REDACTED]
Product category	ENDS (Electronic Nicotine Delivery System)
Product subcategory	ENDS Component
Attributes⁴	New Tobacco Product
STN	PM0000798
Product name	Leap Device Kit ⁵
Package type	Box
Package quantity	1 device
Characterizing flavor	None
Length	80 mm
Diameter	22 mm x 9 mm
Wattage	1.48 Wh
Battery capacity	400 mAh

Common Attributes of PMTA	
Submission date	June 15, 2020
Receipt date	June 15, 2020
Applicant	E-Alternative Solutions, LLC
[REDACTED]	[REDACTED]
Product category	ENDS (Electronic Nicotine Delivery System)
Product subcategory	Closed E-Liquid
Attributes⁴	New Tobacco Product
STN	PM0000799
Product name	Leap Pod Apple Strawberry, 2.4% Nicotine ⁵
Package type	Pod
Package quantity	2 Pods
Characterizing flavor	Apple Strawberry
Length	39.8 mm
Diameter	20.8 mm x 5.9 mm
E-liquid volume	1.5 mL
Nicotine concentration	24 mg/mL
[REDACTED]	[REDACTED]

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	PM0000800
Product name	Leap Pod Apple Strawberry, 4.8% Nicotine ⁵
Package type	Pod
Package quantity	2 Pods
Characterizing flavor	Apple Strawberry
Length	39.8 mm
Diameter	20.8 mm x 5.9 mm
E-liquid volume	1.5 mL
Nicotine concentration	48 mg/mL
██████████	██████████
Attributes⁴	New Tobacco Product
STN	PM0000801
Product name	Leap Pod Arctic Berry, 2.4% Nicotine ⁵
Package type	Pod
Package quantity	2 Pods
Characterizing flavor	Berry
Length	39.8 mm
Diameter	20.8 mm x 5.9 mm
E-liquid volume	1.5 mL
Nicotine concentration	24 mg/mL
██████████	██████████
Attributes⁴	New Tobacco Product
STN	PM0000802
Product name	Leap Pod Arctic Berry, 4.8% Nicotine ⁵
Package type	Pod
Package quantity	2 Pods
Characterizing flavor	Berry
Length	39.8 mm
Diameter	20.8 mm x 5.9 mm
E-liquid volume	1.5 mL
Nicotine concentration	48 mg/mL
██████████	██████████
Attributes⁴	New Tobacco Product
STN	PM0000803
Product name	Leap Pod Mango, 2.4% Nicotine ⁵
Package type	Pod
Package quantity	2 Pods
Characterizing flavor	Mango
Length	39.8 mm
Diameter	20.8 mm x 5.9 mm
E-liquid volume	1.5 mL
Nicotine concentration	24 mg/mL
██████████	██████████

Attributes⁴	New Tobacco Product
STN	PM0000804
Product name	Leap Pod Mango, 4.8% Nicotine ⁵
Package type	Pod
Package quantity	2 Pods
Characterizing flavor	Mango
Length	39.8 mm
Diameter	20.8 mm x 5.9 mm
E-liquid volume	1.5 mL
Nicotine concentration	48 mg/mL
██████████	██████████
Attributes⁴	New Tobacco Product
STN	PM0000805
Product name	Leap Pod Watermelon Kiwi, 2.4% Nicotine ⁵
Package type	Pod
Package quantity	2 Pods
Characterizing flavor	Watermelon Kiwi
Length	39.8 mm
Diameter	20.8 mm x 5.9 mm
E-liquid volume	1.5 mL
Nicotine concentration	24 mg/mL
██████████	██████████
Attributes⁴	New Tobacco Product
STN	PM0000806
Product name	Leap Pod Watermelon Kiwi, 4.8% Nicotine ⁵
Package type	Pod
Package quantity	2 Pods
Characterizing flavor	Watermelon Kiwi
Length	39.8 mm
Diameter	20.8 mm x 5.9 mm
E-liquid volume	1.5 mL
Nicotine concentration	48 mg/mL
██████████	██████████
Attributes⁴	New Tobacco Product
STN	PM0000807
Product name	Leap Pod Island Cream, 2.4% Nicotine ⁵
Package type	Pod
Package quantity	2 Pods
Characterizing flavor	Coconut Cream
Length	39.8 mm
Diameter	20.8 mm x 5.9 mm
E-liquid volume	1.5 mL
Nicotine concentration	24 mg/mL
██████████	██████████

Attributes⁴	New Tobacco Product
STN	PM0000808
Product name	Leap Pod Island Cream, 4.8% Nicotine ⁵
Package type	Pod
Package quantity	2 Pods
Characterizing flavor	Coconut Cream
Length	39.8 mm
Diameter	20.8 mm x 5.9 mm
E-liquid volume	1.5 mL
Nicotine concentration	48 mg/mL
██████████	██████████
Attributes⁴	New Tobacco Product
STN	PM0000809
Product name	Leap Pod Carolina Tobacco, 2.4% Nicotine ⁵
Package type	Pod
Package quantity	2 Pods
Characterizing flavor	None
Length	39.8 mm
Diameter	20.8 mm x 5.9 mm
E-liquid volume	1.5 mL
Nicotine concentration	24 mg/mL ⁶
██████████	██████████
Attributes⁴	New Tobacco Product
STN	PM0000810
Product name	Leap Pod Carolina Tobacco, 4.8% Nicotine ⁵
Package type	Pod
Package quantity	2 Pods
Characterizing flavor	None
Length	39.8 mm
Diameter	20.8 mm x 5.9 mm
E-liquid volume	1.5 mL
Nicotine concentration	48 mg/mL
██████████	██████████
Attributes⁴	New Tobacco Product
STN	PM0000811
Product name	Leap Pod Kentucky Tobacco, 2.4% Nicotine ⁵
Package type	Pod
Package quantity	2 Pods
Characterizing flavor	None
Length	39.8 mm
Diameter	20.8 mm x 5.9 mm
E-liquid volume	1.5 mL
Nicotine concentration	24 mg/mL
██████████	██████████

⁶ Applicant provided 2.4 mg/mL; FDA interprets as 24 mg/mL per calculations provided in application.

Attributes⁴	New Tobacco Product
STN	PM0000812
Product name	Leap Pod Kentucky Tobacco, 4.8% Nicotine ⁵
Package type	Pod
Package quantity	2 Pods
Characterizing flavor	None
Length	39.8 mm
Diameter	20.8 mm x 5.9 mm
E-liquid volume	1.5 mL
Nicotine concentration	48 mg/mL
██████████	██████████
Attributes⁴	New Tobacco Product
STN	PM0000813
Product name	Leap Pod Georgia Tobacco, 2.4% Nicotine ⁵
Package type	Pod
Package quantity	2 Pods
Characterizing flavor	None
Length	39.8 mm
Diameter	20.8 mm x 5.9 mm
E-liquid volume	1.5 mL
Nicotine concentration	24 mg/mL
██████████	██████████
Attributes⁴	New Tobacco Product
STN	PM0000814
Product name	Leap Pod Georgia Tobacco, 4.8% Nicotine ⁵
Package type	Pod
Package quantity	2 Pods
Characterizing flavor	None
Length	39.8 mm
Diameter	20.8 mm x 5.9 mm
E-liquid volume	1.5 mL
Nicotine concentration	48 mg/mL
██████████	██████████
Attributes⁴	New Tobacco Product
STN	PM0000815
Product name	Leap Pod Rough-Cut Tobacco, 2.4% Nicotine ⁵
Package type	Pod
Package quantity	2 Pods
Characterizing flavor	None
Length	39.8 mm
Diameter	20.8 mm x 5.9 mm
E-liquid volume	1.5 mL
Nicotine concentration	24 mg/mL
██████████	██████████

Attributes⁴	New Tobacco Product
STN	PM0000816
Product name	Leap Pod Rough-Cut Tobacco, 4.8% Nicotine ⁵
Package type	Pod
Package quantity	2 Pods
Characterizing flavor	None
Length	39.8 mm
Diameter	20.8 mm x 5.9 mm
E-liquid volume	1.5 mL
Nicotine concentration	48 mg/mL
██████████	██████████
Attributes⁴	New Tobacco Product
STN	PM0000817
Product name	Leap Pod Mint, 2.4% Nicotine ⁵
Package type	Pod
Package quantity	2 Pods
Characterizing flavor	Mint
Length	39.8 mm
Diameter	20.8 mm x 5.9 mm
E-liquid volume	1.5 mL
Nicotine concentration	24 mg/mL
██████████	██████████
Attributes⁴	New Tobacco Product
STN	PM0000818
Product name	Leap Pod Mint, 4.8% Nicotine ⁵
Package type	Pod
Package quantity	2 Pods
Characterizing flavor	Mint
Length	39.8 mm
Diameter	20.8 mm x 5.9 mm
E-liquid volume	1.5 mL
Nicotine concentration	48 mg/mL
██████████	██████████
Attributes⁴	New Tobacco Product
STN	PM0000819
Product name	Leap Pod Menthol, 2.4% Nicotine ⁵
Package type	Pod
Package quantity	2 Pods
Characterizing flavor	Menthol
Length	39.8 mm
Diameter	20.8 mm x 5.9 mm
E-liquid volume	1.5 mL
Nicotine concentration	24 mg/mL
██████████	██████████

Attributes⁴	New Tobacco Product
STN	PM0000820
Product name	Leap Pod Menthol, 4.8% Nicotine ⁵
Package type	Pod
Package quantity	2 Pods
Characterizing flavor	Menthol
Length	39.8 mm
Diameter	20.8 mm x 5.9 mm
E-liquid volume	1.5 mL
Nicotine concentration	48 mg/mL
██████████	██████████
Attributes⁴	New Tobacco Product
STN	PM0000821
Product name	Leap Pod Kentucky Menthol, 2.4% Nicotine ⁵
Package type	Pod
Package quantity	2 Pods
Characterizing flavor	Menthol
Length	39.8 mm
Diameter	20.8 mm x 5.9 mm
E-liquid volume	1.5 mL
Nicotine concentration	24 mg/mL
██████████	██████████
Attributes⁴	New Tobacco Product
STN	PM0000822
Product name	Leap Pod Kentucky Menthol, 4.8% Nicotine ⁵
Package type	Pod
Package quantity	2 Pods
Characterizing flavor	Menthol
Length	39.8 mm
Diameter	20.8 mm x 5.9 mm
E-liquid volume	1.5 mL
Nicotine concentration	48 mg/mL
██████████	██████████