



U.S. Food & Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993  
[www.fda.gov](http://www.fda.gov)

June 19, 2020

**ACCEPTANCE**

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 accept your PMTAs<sup>1</sup> for the tobacco products identified in Appendix A.

Your PMTAs will move forward in the review process. FDA may request to conduct inspections, which may include manufacturing inspections and clinical and nonclinical research inspections, to verify the information submitted in your PMTAs. The results of these inspections may also be used to verify the information submitted in any additional applications that reference the same manufacturing and research information. To ensure that the appropriate records and personnel will be available during the inspections, FDA will notify the point(s) of contact identified prior to the inspection start date.

We will notify you if samples are required for independent testing and verification. If samples are required, you will be notified in a Samples Request letter which will include both the numbers of samples required and the laboratory address where samples must be received. Upon receipt of a Samples Request letter, you will be required to have the laboratory listed in the letter receive all samples listed within 14 calendar days of the request. In general, for ENDS testing we may request a minimum of 35 device starter kits<sup>[1]</sup> for each tobacco product as well as 2 x 50 mL bottles of the selected e-liquid (note: if the tobacco product is a closed ENDS tobacco product, samples collected prior to product fill are preferred. Where this is not possible, a sufficient number of product/cartridges necessary to provide an equivalent volume of e-liquid may be requested).

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

<sup>[1]</sup> Starter kits are described as the ENDS device, charging cable, and cartridge/pods, as appropriate

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

Sincerely,

Digitally signed by Stephanie Durkin -  
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Date: 2020.06.19 08:54:28 -04'00'





Stephanie Durkin, MS  
Lead Regulatory Health Project Manager  
Division of Regulatory Project Management  
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 Letter

<b>Common Attributes of PMTA</b>	
Submission date	June 15, 2020
Receipt date	June 15, 2020
Applicant	E-Alternative Solutions, LLC
	
Product category	ENDS (Electronic Nicotine Delivery System)
Product subcategory	ENDS Component
<b>Attributes<sup>2</sup></b>	<b>New Tobacco Product</b>
<b>STN</b>	<b>PM0000798</b>
Product name	Leap Device Kit <sup>3</sup>
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

<b>Common Attributes of PMTA</b>	
Submission date	June 15, 2020
Receipt date	June 15, 2020
Applicant	E-Alternative Solutions, LLC
	
Product category	ENDS (Electronic Nicotine Delivery System)
Product subcategory	Closed E-Liquid
<b>Attributes<sup>2</sup></b>	<b>New Tobacco Product</b>
<b>STN</b>	<b>PM0000799</b>
Product name	Leap Pod Apple Strawberry, 2.4% Nicotine <sup>3</sup>
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
	

<sup>2</sup> 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.

<sup>3</sup> Brand/sub-brand or other commercial name used in commercial distribution.

<b>Attributes<sup>2</sup></b>	<b>New Tobacco Product</b>
<b>STN</b>	<b>PM0000800</b>
Product name	Leap Pod Apple Strawberry, 4.8% Nicotine <sup>3</sup>
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
██████████	██████████
<b>Attributes<sup>2</sup></b>	<b>New Tobacco Product</b>
<b>STN</b>	<b>PM0000801</b>
Product name	Leap Pod Arctic Berry, 2.4% Nicotine <sup>3</sup>
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
██████████	██████████
<b>Attributes<sup>2</sup></b>	<b>New Tobacco Product</b>
<b>STN</b>	<b>PM0000802</b>
Product name	Leap Pod Arctic Berry, 4.8% Nicotine <sup>3</sup>
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
██████████	██████████
<b>Attributes<sup>2</sup></b>	<b>New Tobacco Product</b>
<b>STN</b>	<b>PM0000803</b>
Product name	Leap Pod Mango, 2.4% Nicotine <sup>3</sup>
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
██████████	██████████

<b>Attributes<sup>2</sup></b>	<b>New Tobacco Product</b>
<b>STN</b>	<b>PM0000804</b>
Product name	Leap Pod Mango, 4.8% Nicotine <sup>3</sup>
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
██████████	██████████
<b>Attributes<sup>2</sup></b>	<b>New Tobacco Product</b>
<b>STN</b>	<b>PM0000805</b>
Product name	Leap Pod Watermelon Kiwi, 2.4% Nicotine <sup>3</sup>
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
██████████	██████████
<b>Attributes<sup>2</sup></b>	<b>New Tobacco Product</b>
<b>STN</b>	<b>PM0000806</b>
Product name	Leap Pod Watermelon Kiwi, 4.8% Nicotine <sup>3</sup>
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
██████████	██████████
<b>Attributes<sup>2</sup></b>	<b>New Tobacco Product</b>
<b>STN</b>	<b>PM0000807</b>
Product name	Leap Pod Island Cream, 2.4% Nicotine <sup>3</sup>
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
██████████	██████████

<b>Attributes<sup>2</sup></b>	<b>New Tobacco Product</b>
<b>STN</b>	<b>PM0000808</b>
Product name	Leap Pod Island Cream, 4.8% Nicotine <sup>3</sup>
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
██████████	██████████
<b>Attributes<sup>2</sup></b>	<b>New Tobacco Product</b>
<b>STN</b>	<b>PM0000809</b>
Product name	Leap Pod Carolina Tobacco, 2.4% Nicotine <sup>3</sup>
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 <sup>4</sup>
██████████	██████████
<b>Attributes<sup>2</sup></b>	<b>New Tobacco Product</b>
<b>STN</b>	<b>PM0000810</b>
Product name	Leap Pod Carolina Tobacco, 4.8% Nicotine <sup>3</sup>
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
██████████	██████████
<b>Attributes<sup>2</sup></b>	<b>New Tobacco Product</b>
<b>STN</b>	<b>PM0000811</b>
Product name	Leap Pod Kentucky Tobacco, 2.4% Nicotine <sup>3</sup>
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
██████████	██████████

<sup>4</sup> Applicant provided 2.4 mg/mL; FDA interprets as 24 mg/mL per calculations provided in application.

<b>Attributes<sup>2</sup></b>	<b>New Tobacco Product</b>
<b>STN</b>	<b>PM0000812</b>
Product name	Leap Pod Kentucky Tobacco, 4.8% Nicotine <sup>3</sup>
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
██████████	██████████
<b>Attributes<sup>2</sup></b>	<b>New Tobacco Product</b>
<b>STN</b>	<b>PM0000813</b>
Product name	Leap Pod Georgia Tobacco, 2.4% Nicotine <sup>3</sup>
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
██████████	██████████
<b>Attributes<sup>2</sup></b>	<b>New Tobacco Product</b>
<b>STN</b>	<b>PM0000814</b>
Product name	Leap Pod Georgia Tobacco, 4.8% Nicotine <sup>3</sup>
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
██████████	██████████
<b>Attributes<sup>2</sup></b>	<b>New Tobacco Product</b>
<b>STN</b>	<b>PM0000815</b>
Product name	Leap Pod Rough-Cut Tobacco, 2.4% Nicotine <sup>3</sup>
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
██████████	██████████

<b>Attributes<sup>2</sup></b>	<b>New Tobacco Product</b>
<b>STN</b>	<b>PM0000816</b>
Product name	Leap Pod Rough-Cut Tobacco, 4.8% Nicotine <sup>3</sup>
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
██████████	██████████
<b>Attributes<sup>2</sup></b>	<b>New Tobacco Product</b>
<b>STN</b>	<b>PM0000817</b>
Product name	Leap Pod Mint, 2.4% Nicotine <sup>3</sup>
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
██████████	██████████
<b>Attributes<sup>2</sup></b>	<b>New Tobacco Product</b>
<b>STN</b>	<b>PM0000818</b>
Product name	Leap Pod Mint, 4.8% Nicotine <sup>3</sup>
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
██████████	██████████
<b>Attributes<sup>2</sup></b>	<b>New Tobacco Product</b>
<b>STN</b>	<b>PM0000819</b>
Product name	Leap Pod Menthol, 2.4% Nicotine <sup>3</sup>
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
██████████	██████████



<b>Attributes<sup>2</sup></b>	<b>New Tobacco Product</b>
<b>STN</b>	<b>PM0000820</b>
Product name	Leap Pod Menthol, 4.8% Nicotine <sup>3</sup>
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
██████████	██████████
<b>Attributes<sup>2</sup></b>	<b>New Tobacco Product</b>
<b>STN</b>	<b>PM0000821</b>
Product name	Leap Pod Kentucky Menthol, 2.4% Nicotine <sup>3</sup>
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
██████████	██████████
<b>Attributes<sup>2</sup></b>	<b>New Tobacco Product</b>
<b>STN</b>	<b>PM0000822</b>
Product name	Leap Pod Kentucky Menthol, 4.8% Nicotine <sup>3</sup>
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
██████████	██████████