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

November 04, 2019

SUBSTANTIALLY EQUIVALENT

Top Tobacco, LP
Attention: Carl Ioos, Senior Vice President
2301 Ravine Way
Glenview, IL 60025

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

Dear Mr. Ioos:

We completed our review of your SE Reports[1] and determined that the new tobacco products are substantially equivalent to the corresponding predicate tobacco products listed in Appendix A and are in compliance with the requirements of the FD&C Act. Under the provisions of section 910 and 905(j) of the FD&C Act, you may introduce or deliver for introduction into interstate commerce the new tobacco products subject of this letter.

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).

For information on how fulfill the provisions of section 910(a)(4) of the FD&C Act, refer to Appendix B.

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 complies with all applicable statutory and regulatory requirements. FDA will monitor your compliance with all applicable statutes and regulations.

[1] Substantially Equivalent (SE) Reports submitted under section 905(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)

If you have any questions, please contact Donna Cheung, Regulatory Health Project Manager, at (240) 402-5340 or Donna.Cheung@fda.hhs.gov.

Sincerely,

Digitally signed by Matthew R. Holman -S
Date: 2019.11.04 17:26:11 -05'00'

Matthew R. Holman, Ph.D.
Director
Office of Science
Center for Tobacco Products

Enclosures:

Appendix A – New and Corresponding Predicate Tobacco Products Subject of This Letter
Appendix B – Health Information Summary

Appendix A

New and Corresponding Predicate Tobacco Products Subject of This Letter

Common Attributes of SE Reports		
Date of Submission:	August 2, 2019	
Date of Receipt:	August 2, 2019	
Product Manufacturer:	Top Tobacco, LP	
Product Category:	Pipe Tobacco Products	
Product Sub-Category:	Pipe Tobacco Filler	
	New Tobacco Product Specific Attributes	**Predicate Tobacco Product Specific Attributes**
Submission Tracking Number:	SE0015380	GF1804249
Product Name:[2]	SMOKER FRIENDLY Regular 0.75 Pouch	Gambler Regular Pouch (0.65 oz)
Package Type:	Pouch	Pouch
Package Quantity:	0.75 oz.	0.65 oz.
Characterizing Flavor:[3]	None	None
Eligibility Status:	N/A	Grandfathered
Submission Tracking Number:	SE0015381	GF1804246
Product Name:[2]	SMOKER FRIENDLY Green 0.75 oz. Pouch	Gambler Menthol Pouch (0.65 oz)
Package Type:	Pouch	Pouch
Package Quantity:	0.75 oz.	0.65 oz.
Characterizing Flavor:[3]	Menthol	Menthol
Eligibility Status:	N/A	Grandfathered

[2] Brand/sub-brand or other commercial name used in commercial distribution.

[3] As provided by the applicant's certification statement. For product quantity change SE Reports, FDA does not conduct substantive scientific review to evaluate the information contained in the applicant's certification statement.

Appendix B

Health Information Summary

Your SE Reports did not provide a summary of any health information related to the new tobacco products, required by section 910(a)(4) of the FD&C Act; however, your SE Reports stated that such information will be available upon request to any person. Consistent with the requirements of section 910(a)(4), you may wish to consider providing the following when information is requested:

A. A copy of your final SE Reports upon which the Substantially Equivalent order was based, redacted only to the extent necessary to exclude patient identifiers and trade secret and confidential commercial information as defined in 21 CFR 20.61 and 20.63.
B. Any research or data you have in your possession or otherwise know of specifically regarding the adverse health effects of the new tobacco products, or the following statement if such statement is accurate: "[Insert manufacturer name] does not have or know of any research or data regarding any adverse health effects specifically related to [insert tobacco product name]."

Alternatively, you may provide the following when information is requested:

Description of the new tobacco products
Description of the predicate tobacco products
List of all differences in characteristics between the new and predicate tobacco products
Summary of the evidence and scientific rationale concerning why the differences in characteristics do not raise different questions of public health
Any research or data you have in your possession or otherwise know of regarding the adverse health effects of the new tobacco product, or the following statement if such statement is accurate: "[Insert manufacturer name] does not have or know of any research or data regarding any adverse health effects specifically related to [insert tobacco product name]."

There may be other accurate, complete, and not false or misleading ways to satisfy the requirements of section 910(a)(4) not included above. If you wish to discuss other ways to meet the requirements of section 910(a)(4), submit a meeting request to us.