

Technical Project Lead (TPL) Review of SE Reports

New Tobacco Products Subject of this Review	
Submission tracking numbers (STNs)	SE0018586, SE0019884 -SE0019897
Common Attributes	
Submission date	September 8, 2020
Receipt date	September 8, 2020
Applicant	U.S. Flue-Cured Tobacco Growers Inc.
Product manufacturer	U.S. Flue-Cured Tobacco Growers Inc.
Application type	Regular
Product category	Pipe Tobacco Products
Product subcategory	Pipe Tobacco Filler
Cross-Referenced Submissions	
All new tobacco products	None
Supporting FDA Memoranda Relied Upon in this Review	
All new tobacco products	None
Recommendation	
Issue Substantially Equivalent (SE) order(s) for the new tobacco product(s) subject of this review.	

Technical Project Lead (TPL):

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Senior Regulatory Scientist, Division of Product Science
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Signatory Decision: Concur with TPL recommendation and basis of recommendation

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1. BACKGROUND

1.1. NEW AND PREDICATE TOBACCO PRODUCTS

The applicant submitted information for the new and predicate tobacco products listed in detail in the Appendix.

1.2. REGULATORY ACTIVITY

See Appendices for tobacco products and amendments.

1.3. SCOPE OF REVIEW

This review captures all compliance and scientific reviews completed for the new tobacco products subject of this review.

Table 1. Disciplines reviewed

Discipline	Cycle 1: Reviewer(s)	Review Date
Regulatory	Crystal Caesar	10/23/2020
Chemistry	Melis Coraggio	1/22/2021
Engineering	Milagros Torres-Garcia	1/22/2021
Environmental Science	Meena Aladdin	1/7/2021

2. COMPLIANCE REVIEW

The Office of Compliance and Enforcement (OCE) completed reviews to determine whether the applicant established that the predicate tobacco products are grandfathered products (i.e., were commercially marketed in the United States as of February 15, 2007). The OCE reviews dated December 09, 2020 and December 10, 2020, conclude that the evidence submitted by the applicant is adequate to demonstrate that the predicate tobacco products are grandfathered and, therefore, are eligible predicate tobacco products.

OCE also completed a review to determine whether the new tobacco products are in compliance with the Federal Food, Drug, and Cosmetic Act (FD&C Act) (see section 910(a)(2)(A)(i)(II) of the FD&C Act). The OCE review dated January 29, 2021 concludes that the new tobacco products are in compliance with the FD&C Act.

3. SCIENTIFIC REVIEW

Scientific reviews were completed by the Office of Science (OS) for the following disciplines:

3.1. CHEMISTRY

The final chemistry review concludes that the new tobacco products have different characteristics compared to the corresponding predicate tobacco product, but the differences do not cause the new tobacco products to raise different questions of public health from a chemistry perspective.

The applicant provided a certification statement for all SE reports stating that the only modification to the new tobacco products is the tobacco cut size. The engineering reviewer deferred the 75% increase in cut size in all new products for evaluation. All new tobacco products are cut to (b) (4) mm and the corresponding predicate tobacco products are cut to (b) (4) mm. Therefore, the new tobacco products are more coarse than the corresponding predicate tobacco products. In a combusted tobacco product such as pipe tobacco filler, the tobacco cut size could impact the packing density of the tobacco product which may impact smoke yields of HPHCs. However, there is currently a lack of scientific evidence to indicate that the larger cut size for pipe tobacco would have an adverse effect on HPHC yields upon combustion. Therefore, in this instance, changes in pipe tobacco cut size do not cause the new tobacco products to raise different questions of public health from a chemistry perspective.

Therefore, the differences in characteristics between the new and corresponding predicate tobacco products do not cause the new tobacco products to raise different questions of public health from a chemistry perspective.

3.2. ENGINEERING

The final engineering review concludes that the new tobacco products have different characteristics compared to the predicate tobacco product, but the differences do not cause the new tobacco products to raise different questions of public health from an engineering perspective.

For all SE Reports, the tobacco cut size increased by 75% which was deferred to chemistry. Chemistry evaluated the tobacco cut size differences as discussed in Section 3.1 above and determined that the differences in tobacco cut size do not cause the new tobacco products to raise different questions of public health from a chemistry perspective.

Therefore, the differences in characteristics between the new and predicate tobacco product do not cause the new tobacco products to raise different questions of public health from an engineering perspective.

4. ENVIRONMENTAL DECISION

The final environmental review found that all of the SE Reports lack the first-year market volume projections for the new and predicate tobacco products as well as the current market volume and fifth-year market volume projections for the predicate tobacco products. Marketing information is used to quantitatively assess the environmental impact of manufacturing, use, and disposal of the new tobacco products as compared to the predicate tobacco products.

Therefore, additional information is needed to determine whether to prepare an Environmental Impact Statement (EIS) or Finding of No Significant Impact (FONSI).

5. CONCLUSION AND RECOMMENDATION

The new and the predicate tobacco products have the following differences in characteristics:

- For all SE Reports, tobacco cut size increased by 75% in the new products. The tobacco cut size is (b) (4) mm in all of the new tobacco products and (b) (4) mm in all corresponding predicate tobacco products.

I concur with the conclusions of all the scientific reviews that the applicant has demonstrated that these differences in characteristics do not cause the new tobacco products to raise different questions of public health as described in Section 3.1-3.2 above. Engineering identified a 75% increase in tobacco cut size in all SE Reports and deferred this difference to chemistry for evaluation. The tobacco cut size is (b) (4) mm in all of the new tobacco products and (b) (4) mm in all corresponding predicate tobacco products. Although the tobacco cut size could impact the packing density of the tobacco product which may impact smoke yields of HPHCs, there is currently a lack of scientific evidence to indicate that the larger cut size for pipe tobacco would have an adverse effect on HPHC yields upon combustion. Thus, in this instance, the changes in pipe tobacco cut size do not cause the new tobacco products to raise different questions of public health from a chemistry perspective. Therefore, the differences in characteristics between the new and predicate product do not cause the new tobacco products to raise different questions of public health.

The predicate tobacco products meet statutory requirements because it was determined that they are grandfathered products (i.e., were commercially marketed in the United States as of February 15, 2007).

FDA examined the environmental effects of finding these new tobacco products substantially equivalent and found additional information is necessary to determine the impact of the action. Without this information, FDA is precluded from issuing SE orders.

Therefore, an Environmental Information Request letter should be issued requesting the following information:

1. All of your SE Reports lack the first-year market volume projections for the new and predicate tobacco products as well as the current market volume and fifth-year market volume projections for the predicate tobacco products. Marketing information is used to quantitatively assess the environmental impact of manufacturing, use, and disposal of the new tobacco products as compared to the predicate tobacco products. In Table 1, provide the first-year market volume projections for the new and predicate tobacco products, as well as the current market volume and fifth-year market projections for the predicate tobacco products, in their indicated units of measure. Note any information you deem confidential so that it can be placed in a confidential appendix to the public environmental assessment document. A table is provided below.

Table 1. Market volume for the new and predicate tobacco products.

STN	Current-Year Market Volume (number of bags)		First-Year Market Volume Projection (number of bags)		Fifth-Year Market Volume Projection (number of bags)	
	New Product	Predicate Product	New Product	Predicate Product	New Product	Predicate Product
SE0018586	(b) (4)				(b) (4)	
SE0019884						
SE0019885						
SE0019886						
SE0019887						
SE0019888						
SE0019889						
SE0019890						
SE0019891						
SE0019892						
SE0019893						
SE0019894						
SE0019895						
SE0019896						
SE0019897						

If the applicant adequately responds to the request and an EIS or FONSI is completed, SE order letters should be issued for the new tobacco products in SE0018586, SE0019884, SE0019885, SE0019886, SE0019887, SE0019888, SE0019889, SE0019890, SE0019891, SE0019892, SE0019893, SE0019894, SE0019895, SE0019896 and SE0019897, as identified on the cover page of this review.

6. APPENDICES

Appendix A. New and predicate tobacco products

Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0018586	Not Applicable
Product name	1839 Pipe Tobacco Blue 6 oz. Bag ^a	1839 RYO Mild Flavor 6oz. Bag ^a
Product category	Pipe Tobacco Products	Roll-Your-Own Tobacco Products
Product subcategory	Pipe Tobacco Filler	Roll-Your-Own Tobacco Filler
Eligibility status	Not Applicable	Grandfathered
Package type	Bag	Bag
Package quantity	6 oz.	6 oz.
Characterizing flavor	None	None
STN	SE0019884	Not Applicable
Product name	1839 Pipe Tobacco Blue 16oz. Bag ^a	1839 RYO Mild Flavor 16oz. Bag ^a
Product category	Pipe Tobacco Products	Roll-Your-Own Tobacco Products
Product subcategory	Pipe Tobacco Filler	Roll-Your-Own Tobacco Filler
Eligibility status	Not Applicable	Grandfathered
Package type	Bag	Bag
Package quantity	16 oz.	16 oz.
Characterizing flavor	None	None
STN	SE0019885	Not Applicable
Product name	1839 Pipe Tobacco Green 6oz. Bag ^a	1839 RYO Menthol 6oz. Bag ^a
Product category	Pipe Tobacco Products	Roll-Your-Own Tobacco Products
Product subcategory	Pipe Tobacco Filler	Roll-Your-Own Tobacco Filler
Eligibility status	Not applicable	Grandfathered
Package type	Bag	Bag
Package quantity	6 oz.	6 oz.
Characterizing flavor	Menthol	Menthol

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

Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0019886	Not Applicable
Product name	1839 Pipe Tobacco Green 16oz. Bag ^a	1839 RYO Menthol 16oz. Bag ^a
Product category	Pipe Tobacco Products	Roll-Your-Own Tobacco Products
Product subcategory	Pipe Tobacco Filler	Roll-Your-Own Tobacco Filler
Eligibility status	Not applicable	Grandfathered
Package type	Bag	Bag
Package quantity	16 oz.	16 oz.
Characterizing flavor	Menthol	Menthol
STN	SE0019887	Not Applicable
Product name	1839 Pipe Tobacco Red 6oz. Bag ^a	1839 RYO Full Flavor 6oz. Bag ^a
Product category	Pipe Tobacco Products	Roll-Your-Own Tobacco Products
Product subcategory	Pipe Tobacco Filler	Roll-Your-Own Tobacco Filler
Eligibility status	Not applicable	Grandfathered
Package type	Bag	Bag
Package quantity	6 oz.	6 oz.
Characterizing flavor	None	None
STN	SE0019888	Not Applicable
Product name	1839 Pipe Tobacco Red 16oz. Bag ^a	1839 RYO Full Flavor 16oz. Bag ^a
Product category	Pipe Tobacco Products	Roll-Your-Own Tobacco Products
Product subcategory	Pipe Tobacco Filler	Roll-Your-Own Tobacco Filler
Eligibility status	Not applicable	Grandfathered
Package type	Bag	Bag
Package quantity	16 oz.	16 oz.
Characterizing flavor	None	None

Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0019889	Not Applicable
Product name	Traffic Pipe Tobacco Blue 16oz. Bag ^a	1839 RYO Mild Flavor 16oz. Bag ^a
Product category	Pipe Tobacco Products	Roll-Your-Own Tobacco Products
Product subcategory	Pipe Tobacco Filler	Roll-Your-Own Tobacco Filler
Eligibility status	Not applicable	Grandfathered
Package type	Bag	Bag
Package quantity	16 oz.	16 oz.
Characterizing flavor	None	None
STN	SE0019890	Not Applicable
Product name	Traffic Pipe Tobacco Green 16oz. Bag ^a	1839 RYO Menthol 16oz. Bag ^a
Product category	Pipe Tobacco Products	Roll-Your-Own Tobacco Products
Product subcategory	Pipe Tobacco Filler	Roll-Your-Own Tobacco Filler
Eligibility status	Not applicable	Grandfathered
Package type	Bag	Bag
Package quantity	16 oz.	16 oz.
Characterizing flavor	Menthol	Menthol
STN	SE0019891	Not Applicable
Product name	Traffic Pipe Tobacco Red 16oz. Bag ^a	1839 RYO Full Flavor 16oz. Bag ^a
Product category	Pipe Tobacco Products	Roll-Your-Own Tobacco Products
Product subcategory	Pipe Tobacco Filler	Roll-Your-Own Tobacco Filler
Eligibility status	Not applicable	Grandfathered
Package type	Bag	Bag
Package quantity	16 oz.	16 oz.
Characterizing flavor	None	None

Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0019892	Not Applicable
Product name	Wildhorse Pipe Tobacco Blue 6oz. Bag ^a	1839 RYO Mild Flavor 6oz. Bag ^a
Product category	Pipe Tobacco Products	Roll-Your-Own Tobacco Products
Product subcategory	Pipe Tobacco Filler	Roll-Your-Own Tobacco Filler
Eligibility status	Not applicable	Grandfathered
Package type	Bag	Bag
Package quantity	6 oz.	6 oz.
Characterizing flavor	None	None
STN	SE0019893	Not Applicable
Product name	Wildhorse Pipe Tobacco Blue 16oz. Bag ^a	1839 RYO Mild Flavor 16oz. Bag ^a
Product category	Pipe Tobacco Products	Roll-Your-Own Tobacco Products
Product subcategory	Pipe Tobacco Filler	Roll-Your-Own Tobacco Filler
Eligibility status	Not applicable	Grandfathered
Package type	Bag	Bag
Package quantity	16 oz.	16 oz.
Characterizing flavor	None	None
STN	SE0019894	Not Applicable
Product name	Wildhorse Pipe Tobacco Green 6oz. Bag ^a	1839 RYO Menthol 6oz. Bag ^a
Product category	Pipe Tobacco Products	Roll-Your-Own Tobacco Products
Product subcategory	Pipe Tobacco Filler	Roll-Your-Own Tobacco Filler
Eligibility status	Not applicable	Grandfathered
Package type	Bag	Bag
Package quantity	6 oz.	6 oz.
Characterizing flavor	Menthol	Menthol

Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0019895	Not Applicable
Product name	Wildhorse Pipe Tobacco Green 16oz. Bag ^a	1839 RYO Menthol 16oz. Bag ^a
Product category	Pipe Tobacco Products	Roll-Your-Own Tobacco Products
Product subcategory	Pipe Tobacco Filler	Roll-Your-Own Tobacco Filler
Eligibility status	Not applicable	Grandfathered
Package type	Bag	Bag
Package quantity	16 oz.	16 oz.
Characterizing flavor	Menthol	Menthol
STN	SE0019896	Not Applicable
Product name	Wildhorse Pipe Tobacco Red 6oz. Bag ^a	1839 RYO Full Flavor 6oz. Bag ^a
Product category	Pipe Tobacco Products	Roll-Your-Own Tobacco Products
Product subcategory	Pipe Tobacco Filler	Roll-Your-Own Tobacco Filler
Eligibility status	Not applicable	Grandfathered
Package type	Bag	Bag
Package quantity	6 oz.	6 oz.
Characterizing flavor	None	None
STN	SE0019897	Not Applicable
Product name	Wildhorse Pipe Tobacco Red 16oz. Bag ^a	1839 RYO Full Flavor 16oz. Bag ^a
Product category	Pipe Tobacco Products	Roll-Your-Own Tobacco Products
Product subcategory	Pipe Tobacco Filler	Roll-Your-Own Tobacco Filler
Eligibility status	Not applicable	Grandfathered
Package type	Bag	Bag
Package quantity	16 oz.	16 oz.
Characterizing flavor	None	None