Technical Project Lead (TPL) Review:

SE0010959, SE0010960, SE0010961, SE0010965, SE0010966, SE0010975, SE0010976, SE0010980, SE0010981, SE0010985, SE0010986, SE0010988-SE0010997, SE0011004

SE0010959: 1839 Regular 100 mm 200 Count	
Package Type	Box
Package Quantity	200 count
Length	100 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None
SE0010960: 1839 Smooth 100 mm 200 Count	
Package Type	Box
Package Quantity	200 count
Length	100 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None
SE0010961: Hot Rod Regular 100 mm 200 Count	
Package Type	Box
Package Quantity	200 count
Length	100 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None
SE0010965: Great Choice Regular 100 mm 200 Count	
Package Type	Box
Package Quantity	200 count
Length	100 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None
SE0010966: Great Choice Smooth 100 mm 200 Count	
Package Type	Box
Package Quantity	200 count
Length	100 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None

SE0010975: Kentucky Select Regular 100 mm 200 Count	
Package Type	Box
Package Quantity	200 count
Length	100 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None
SE0010976: Kentucky Select Smooth 100 mm 200 Count	
Package Type	Box
Package Quantity	200 count
Length	100 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None
SE0010980: Wild Bill's Regular 100 mm 200 Count	
Package Type	Box
Package Quantity	200 count
Length	100 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None
SE0010981: Wild Bill's Smooth 100 mm 200 Count	
Package Type	Box
Package Quantity	200 count
Length	100 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None

SE0010985: Wild Horse Regular 100 mm 200 Count	
Package Type	Box
Package Quantity	200 count
Length	100 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None

SE0010986: Wild Horse Smooth 100 mm 200 Count	
Package Type	Box
Package Quantity	200 count
Length	100 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None

SE0010988: Hot Rod Smooth 100 mm 200 Count	
Package Type	Box
Package Quantity	200 count
Length	100 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None

SE0010989: Colonial Regular 100 mm Size 200 Count	
Package Type	Box
Package Quantity	200 count
Length	100 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None

SE0010990: Express Smooth 100 mm Size 200 Count	
Package Type	Box
Package Quantity	200 count
Length	100 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None

SE0010991: Express Regular 100 mm Size 200 Count	
Package Type	Box
Package Quantity	200 count
Length	100 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None

SE0010992: Pioneer Regular 100 mm Size 200 Count

Package Type	Box
Package Quantity	200 count
Length	100 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None

SE0010993: Pioneer Smooth 100 mm Size 200 Count

Package Type	Box
Package Quantity	200 count
Length	100 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None

SE0010994: Buckeye's Best Regular 100 mm Size 200 Count

Package Type	Box
Package Quantity	200 count
Length	100 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None

SE0010995: Buckeye's Best Smooth 100 mm Size 200 Count

Package Type	Box
Package Quantity	200 count
Length	100 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None

SE0010996: Jimmies Regular 100 mm Size 200 Count

Package Type	Box
Package Quantity	200 count
Length	100 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None

SE0010997: Jimmies Smooth 100 mm Size 200 Count

Package Type	Box
Package Quantity	200 count
Length	100 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None

SE0011004: Colonial Smooth 100 mm 200 Count	
Package Type	Box
Package Quantity	200 count
Length	100 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None
Common Attributes of SE Reports	
Applicant	Midwest Tobacco Tube Inc. dba Great Midwest Tube
Report Type	Regular Same Characteristics
Product Category	Roll-Your-Own Tobacco
Product Sub-Category	Filtered Cigarette Tube
Recommendation	
Issue Substantially Equivalent (SE) orders.	

Technical Project Lead (TPL):

Digitally signed by Colleen K. Rogers -S
Date: 2015.10.07 08:13:16 -04'00'

Colleen K. Rogers, Ph.D.
Deputy Director
Division of Product Science

Signatory Decision:

☒ Concur with TPL recommendation and basis of recommendation

☐ Concur with TPL recommendation with additional comments (see separate memo)

☐ Do not concur with TPL recommendation (see separate memo)

Digitally signed by David Ashley -S
Date: 2015.10.07 11:39:37 -04'00'

David L. Ashley, Ph.D.
RADM, U.S. Public Health Service
Director
Office of Science

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1. BACKGROUND

1.1. PREDICATE TOBACCO PRODUCTS

The applicant submitted the following predicate tobacco products:

SE0010959	1839 Regular 100 mm 200 Count
Product Name	Cheap Tobacco Regular 100 mm Size 200 Count
Package Type	Box
Package Quantity	200 count
Length	100 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None
SE0010960	**1839 Smooth 100 mm 200 Count**
Product Name	Cheap Tobacco Smooth 100 mm Size 200 Count
Package Type	Box
Package Quantity	200 count
Length	100 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None
SE0010961	**Hot Rod Regular 100 mm 200 Count**
Product Name	Cheap Tobacco Regular 100 mm Size 200 Count
Package Type	Box
Package Quantity	200 count
Length	100 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None
SE0010965	**Great Choice Regular 100 mm 200 Count**
Product Name	Cheap Tobacco Regular 100 mm Size 200 Count
Package Type	Box
Package Quantity	200 count
Length	100 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None

SE0010966	Great Choice Smooth 100 mm 200 Count
Product Name	Cheap Tobacco Smooth 100 mm Size 200 Count
Package Type	Box
Package Quantity	200 count
Length	100 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None
SE0010975	**Kentucky Select Regular 100 mm 200 Count**
Product Name	Cheap Tobacco Regular 100 mm Size 200 Count
Package Type	Box
Package Quantity	200 count
Length	100 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None
SE0010976	**Kentucky Select Smooth 100 mm 200 Count**
Product Name	Cheap Tobacco Smooth 100 mm Size 200 Count
Package Type	Box
Package Quantity	200 count
Length	100 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None

SE0010980	Wild Bill's Regular 100 mm 200 Count
Product Name	Cheap Tobacco Regular 100 mm Size 200 Count
Package Type	Box
Package Quantity	200 count
Length	100 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None
SE0010981	Wild Bill's Smooth 100 mm 200 Count
Product Name	Cheap Tobacco Smooth 100 mm Size 200 Count
Package Type	Box
Package Quantity	200 count
Length	100 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None
SE0010985	Wild Horse Regular 100 mm 200 Count
Product Name	Cheap Tobacco Regular 100 mm Size 200 Count
Package Type	Box
Package Quantity	200 count
Length	100 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None
SE0010986	Wild Horse Smooth 100 mm 200 Count
Product Name	Cheap Tobacco Smooth 100 mm Size 200 Count
Package Type	Box
Package Quantity	200 count
Length	100 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None
SE0010988	Hot Rod Smooth 100 mm 200 Count
Product Name	Cheap Tobacco Smooth 100 mm Size 200 Count
Package Type	Box
Package Quantity	200 count
Length	100 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None

SE0010989	Colonial Regular 100 mm Size 200 Count
Product Name	Cheap Tobacco Regular 100 mm Size 200 Count
Package Type	Box
Package Quantity	200 count
Length	100 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None
SE0010990	**Express Smooth 100 mm Size 200 Count**
Product Name	Cheap Tobacco Smooth 100 mm Size 200 Count
Package Type	Box
Package Quantity	200 count
Length	100 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None
SE0010991	**Express Regular 100 mm Size 200 Count**
Product Name	Cheap Tobacco Regular 100 mm Size 200 Count
Package Type	Box
Package Quantity	200 count
Length	100 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None
SE0010992	**Pioneer Regular 100 mm Size 200 Count**
Product Name	Cheap Tobacco Regular 100 mm Size 200 Count
Package Type	Box
Package Quantity	200 count
Length	100 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None
SE0010993	**Pioneer Smooth 100 mm Size 200 Count**
Product Name	Cheap Tobacco Smooth 100 mm Size 200 Count
Package Type	Box
Package Quantity	200 count
Length	100 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None

SE0010994	Buckeye's Best Regular 100 mm Size 200 Count
Product Name	Cheap Tobacco Regular 100 mm Size 200 Count
Package Type	Box
Package Quantity	200 count
Length	100 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None
SE0010995	**Buckeye's Best Smooth 100 mm Size 200 Count**
Product Name	Cheap Tobacco Smooth 100 mm Size 200 Count
Package Type	Box
Package Quantity	200 count
Length	100 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None
SE0010996	**Jimmies Regular 100 mm Size 200 Count**
Product Name	Cheap Tobacco Regular 100 mm Size 200 Count
Package Type	Box
Package Quantity	200 count
Length	100 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None
SE0010997	**Jimmies Smooth 100 mm Size 200 Count**
Product Name	Cheap Tobacco Smooth 100 mm Size 200 Count
Package Type	Box
Package Quantity	200 count
Length	100 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None
SE0011004	**Colonial Smooth 100 mm 200 Count**
Product Name	Cheap Tobacco Smooth 100 mm Size 200 Count
Package Type	Box
Package Quantity	200 count
Length	100 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None

The predicate tobacco products are roll-your-own tobacco filtered cigarette tubes manufactured by the applicant.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

The Same Characteristics SE Reports were received by FDA on March 9 and 13, 2015. On April 28, 2014, FDA requested additional information from the applicant to uniquely identify the new and predicate tobacco products. In response, the applicant submitted an amendment (SE0011712) on April 29, 2015. On May 8, 2015, FDA requested additional information regarding the Environmental Assessment from the applicant. In response, the applicant submitted amendments (SE0011846 for SE0010989-SE0010997 and SE0011004 and SE0011851 for SE0010959, SE0010960, SE0010961, SE0010965, SE0010966, SE0010975, SE0010976, SE0010980, SE0010981, SE0010985, SE0010986, and SE0010988) on May 18, 2015.

Product Name	SE Report	Amendments
1839 Regular 100 mm 200 Count	SE0010959	SE0011712 SE0011851
1839 Smooth 100 mm 200 Count	SE0010960	
Hot Rod Regular 100 mm 200 Count	SE0010961	
Great Choice Regular 100 mm 200 Count	SE0010965	
Great Choice Smooth 100 mm 200 Count	SE0010966	
Kentucky Select Regular 100 mm 200 Count	SE0010975	
Kentucky Select Smooth 100 mm 200 Count	SE0010976	
Wild Bill's Regular 100 mm 200 Count	SE0010980	
Wild Bill's Smooth 100 mm 200 Count	SE0010981	
Wild Horse Regular 100 mm 200 Count	SE0010985	
Wild Horse Smooth 100 mm 200 Count	SE0010986	
Hot Rod Smooth 100 mm 200 Count	SE0010988	
Colonial Regular 100 mm 200 Count	SE0010989	SE0011712 SE0011846
Express Smooth 100 mm 200 Count	SE0010990	
Express Regular 100 mm 200 Count	SE0010991	
Pioneer Regular 100 mm 200 Count	SE0010992	
Pioneer Smooth 100 mm 200 Count	SE0010993	
Buckeye's Best Regular 100 mm 200 Count	SE0010994	
Buckeye's Best Smooth 100 mm 200 Count	SE0010995	
Jimmies Regular 100 mm 200 Count	SE0010996	
Jimmies Smooth 100 mm 200 Count	SE0010997	
Colonial Smooth 100 mm 200 Count	SE0011004	

1.3. SCOPE OF REVIEW

This review captures all regulatory, compliance, and scientific reviews completed for these SE Reports.

2. REGULATORY REVIEW

A regulatory review was completed by Grace Kaiyuan on October 6, 2015. The review concludes that each SE Report includes all of the information recommended in the 2015 SE FAQ guidance document for a Same Characteristics SE Report:

1. The SE Reports are identified as "Same Characteristics SE Reports."
2. The new tobacco products are fully identified and manufactured by the applicant.
3. The predicate products are fully identified and manufactured by the applicant.
4. There is a statement indicating that the applicant intends to market the new and predicate tobacco products.
5. An Environmental Assessment was provided.
6. A health information statement was provided indicating that the applicant will make a health information summary available upon request by any person in accordance with section 910(a)(4) of the FD&C Act.
7. A statement explaining the applicant's actions to comply with any standards under section 907 of the FD&C Act was provided.
8. An adequate certification statement that was signed by a responsible official who is authorized to act on behalf of the company was provided.

3. 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 as of February 15, 2007). The OCE reviews dated April 13, 14, and 17, 2015, conclude that the evidence submitted by the applicant is adequate to demonstrate that the predicate tobacco products are eligible predicate tobacco products based on a cross-reference to previously finalized standalone grandfathered reviews of the same 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), as required by section 905(j)(1)(A)(i) of the FD&C Act. The OCE review dated September 23, 2014, concludes that the new tobacco products are in compliance with the FD&C Act.

4. SCIENTIFIC REVIEW

Scientific review was not initiated by the Office of Science (OS) because the characteristics of the new and corresponding predicate tobacco products are the same (i.e., the new and predicate products have identical characteristics). Therefore, scientific review is unnecessary.

5. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on August 28, 2015. The FONSI was supported by an environmental assessment prepared by FDA on August 28, 2015.

6. CONCLUSION AND RECOMMENDATION

In all SE Reports, the product names differ between the new and corresponding predicate tobacco products, but the characteristics of the new and corresponding tobacco predicate products are the same, meaning identical in characteristics. The SE Reports include all of the information needed by FDA to make a substantial equivalence determination.

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

All of the new tobacco products are currently in compliance with the FD&C Act. I concur with these reviews and recommend that SE order letters be issued.

FDA examined the environmental effects of finding these new tobacco products substantially equivalent and made a finding of no significant impact.

SE order letters should be issued for the new tobacco products in SE0010959, SE0010960, SE0010961, SE0010965, SE0010966, SE0010975, SE0010976, SE0010980, SE0010981, SE0010985, SE0010986, SE0010988-SE0010997, and SE0011004, as identified on the cover page of this review.