



**Technical Project Lead (TPL) Review:
SE0012908, SE0012912 - SE0012936, SE0012938,
and SE0012946 - SE0012952**

SE0012908: ABADIE 1-1/2 SIZE	
Package Type	Booklet
Package Quantity	32 papers
Length	77.5 mm
Width	68.5 mm
Characterizing Flavor	None
SE0012912: JOB 1.5 GOLD	
Package Type	Booklet
Package Quantity	24 papers
Length	77.5 mm
Width	68.5 mm
Characterizing Flavor	None
SE0012913: TOP STANDARD	
Package Type	Booklet
Package Quantity	100 papers
Length	70 mm
Width	39 mm
Characterizing Flavor	None
SE0012914: ZIG-ZAG 1¼ SIZE FRENCH ORANGE	
Package Type	Booklet
Package Quantity	32 papers
Length	77 mm
Width	44 mm
Characterizing Flavor	None
SE0012915: ROLLING STANDARD	
Package Type	Booklet
Package Quantity	50 papers
Length	69 mm
Width	36 mm
Characterizing Flavor	None

SE0012916: ZIG-ZAG KING SIZE	
Package Type	Booklet
Package Quantity	32 papers
Length	98 mm
Width	53 mm
Characterizing Flavor	None
SE0012917: VENTURA WHITES	
Package Type	Booklet
Package Quantity	32 papers
Length	70 mm
Width	39 mm
Characterizing Flavor	None
SE0012918: ZIG-ZAG KUTCORNERS SLOW BURNING	
Package Type	Booklet
Package Quantity	32 papers
Length	70 mm
Width	38 mm
Characterizing Flavor	None
SE0012919: JOB 1.0 SILVER	
Package Type	Booklet
Package Quantity	32 papers
Length	69 mm
Width	36 mm
Characterizing Flavor	None
SE0012920: TOP 1-1/2 SIZE	
Package Type	Booklet
Package Quantity	24 papers
Length	77.5 mm
Width	68.5 mm
Characterizing Flavor	None
SE0012921: OCB ORGANIC HEMP KING SIZE SLIM	
Package Type	Booklet
Package Quantity	32 papers
Length	109 mm
Width	44 mm
Characterizing Flavor	None

SE0012922: OCB UNGUMMED	
Package Type	Booklet
Package Quantity	150 papers
Length	70 mm
Width	39 mm
Characterizing Flavor	None
SE0012923: OCB YELLOW CIGARETTE PAPERS WITH TIPS	
Package Type	Booklet
Package Quantity	24 papers
Length	109 mm
Width	44 mm
Characterizing Flavor	None
Paper Tip Package Type	Booklet
Paper Tip Package Quantity	24 Tips
Paper Tip Characterizing Flavor	None
Paper Tip Length	55mm
Paper Tip Width	20 mm
SE0012924: ZIG-ZAG WHITE	
Package Type	Booklet
Package Quantity	32 papers
Length	70 mm
Width	38 mm
Characterizing Flavor	None
SE0012925: JOB 1.0 GOLD	
Package Type	Booklet
Package Quantity	48 papers
Length	69 mm
Width	36 mm
Characterizing Flavor	None
SE0012926: JOB TRIBAL KING SIZE	
Package Type	Booklet
Package Quantity	32 papers
Length	109 mm
Width	44 mm
Characterizing Flavor	None
SE0012927: OCB ORGANIC HEMP SINGLE WIDE	
Package Type	Booklet
Package Quantity	100 papers

Length	69 mm
Width	36 mm
Characterizing Flavor	None
SE0012928: OCB SLIM LONG CIGARETTE PAPERS WITH TIPS	
Package Type	Booklet
Package Quantity	24 papers
Length	77 mm
Width	44 mm
Characterizing Flavor	None
Paper Tip Package Type	Booklet
Paper Tip Package Quantity	24 tips
Paper Tip Characterizing Flavor	None
Paper Tip Length	40 mm
Paper Tip Width	20 mm
SE0012929: JOB SINGLE WIDE (WHITE)	
Package Type	Booklet
Package Quantity	32 papers
Length	69 mm
Width	36 mm
Characterizing Flavor	None
SE0012930: ABADIE 1-1/4 SIZE	
Package Type	Booklet
Package Quantity	32 papers
Length	77 mm
Width	44 mm
Characterizing Flavor	None
SE0012931: JOB BROWN DOUBLE WIDE	
Package Type	Booklet
Package Quantity	24 papers
Length	77 mm
Width	77.5 mm
Characterizing Flavor	None
SE0012932: ABADIE SINGLE WIDTH	
Package Type	Booklet
Package Quantity	32 papers
Length	69 mm
Width	36 mm
Characterizing Flavor	None

SE0012933: OCB ORGANIC HEMP 1-1/4 SIZE	
Package Type	Booklet
Package Quantity	50 papers
Length	77 mm
Width	44 mm
Characterizing Flavor	None
SE0012934: JOB BROWN 1-1/4	
Package Type	Booklet
Package Quantity	24 papers
Length	77 mm
Width	44 mm
Characterizing Flavor	None
SE0012935: JOB BROWN 1-1/2	
Package Type	Booklet
Package Quantity	24 papers
Length	77.5 mm
Width	68.5 mm
Characterizing Flavor	None
SE0012936: JOB FRENCH WHITE	
Package Type	Booklet
Package Quantity	24 papers
Length	77 mm
Width	44 mm
Characterizing Flavor	None
SE0012938: JOB DOUBLE WIDE GOLD	
Package Type	Booklet
Package Quantity	32 papers
Length	77 mm
Width	77.5 mm
Characterizing Flavor	None
SE0012946: JOB CUTCORNERS (WHITE)	
Package Type	Booklet
Package Quantity	32 papers
Length	70 mm
Width	38 mm
Characterizing Flavor	None
SE0012947: JOB 1-1/4 (ORANGE)	
Package Type	Booklet
Package Quantity	24 papers

Length	77 mm
Width	44 mm
Characterizing Flavor	None
SE0012948: JOB 1-1/2 (WHITE) 99¢	
Package Type	Booklet
Package Quantity	24 papers
Length	77.5 mm
Width	68.5 mm
Characterizing Flavor	None
SE0012949: JOB 1.5 SLIM GOLD	
Package Type	Booklet
Package Quantity	32 papers
Length	77 mm
Width	53 mm
Characterizing Flavor	None
SE0012950: JOB 1.5 SILVER	
Package Type	Booklet
Package Quantity	32 papers
Length	77.5 mm
Width	68.5 mm
Characterizing Flavor	None
SE0012951: JOB 1.25 SILVER	
Package Type	Booklet
Package Quantity	32 papers
Length	77 mm
Width	44 mm
Characterizing Flavor	None
SE0012952: JOB 1.25 GOLD	
Package Type	Booklet
Package Quantity	24 papers
Length	77 mm
Width	44 mm
Characterizing Flavor	None
Common Attributes of SE Reports	
Applicant	Republic Tobacco, LP
Report Type	Regular
Product Category	Roll-Your-Own Tobacco Product
Product Sub-Category	Rolling Paper; Paper Tip (bundled)
Recommendation	

Issue Substantially Equivalent (SE) orders.

Technical Project Lead (TPL):

Matthew J. Walters -S
2017.06.30 10:54:03 -04'00'

Matthew J. Walters, Ph.D., M.P.H.
CDR, United States Public Health Services
Deputy Director
Division of Product Science
Office of Science
Center for Tobacco Products

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 Matthew R. Holman -S
Date: 2017.06.30 11:26:42 -04'00'

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

TABLE OF CONTENTS

1. BACKGROUND	9
1.1. PREDICATE TOBACCO PRODUCTS	9
1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW	16
1.3. SCOPE OF REVIEW	21
2. REGULATORY REVIEW	21
3. COMPLIANCE REVIEW	22
4. SCIENTIFIC REVIEW	22
4.1. CHEMISTRY	22
4.2. ENGINEERING	23
5. ENVIRONMENTAL DECISION	23
6. CONCLUSION AND RECOMMENDATION	23

1. BACKGROUND

1.1. PREDICATE TOBACCO PRODUCTS

The applicant submitted the following predicate tobacco products:

SE0012908: ABADIE 1-1/2 SIZE	
Product Name	ABADIE 1-1/2 WIDTH
Package Type	Booklet
Package Quantity	32 papers
Length	77.5 mm
Width	68.5 mm
Characterizing Flavor	None
SE0012912: JOB 1.5 GOLD	
Product Name	J<>B 1.5 GOLD 24's
Package Type	Booklet
Package Quantity	24 papers
Length	77.5 mm
Width	68.5 mm
Characterizing Flavor	None
SE0012913: TOP STANDARD	
Product Name	TOP CIG PAPER 24's
Package Type	Booklet
Package Quantity	100 papers
Length	70 mm
Width	39 mm
Characterizing Flavor	None
SE0012914: ZIG-ZAG 1¼ SIZE FRENCH ORANGE	
Product Name	FRENCH ORANGE
Package Type	Booklet
Package Quantity	32 papers
Length	77 mm
Width	44 mm
Characterizing Flavor	None

SE0012915: ROLLING STANDARD	
Product Name	ROLLING CIGARETTE PAPER 40'S
Package Type	Booklet
Package Quantity	50 papers
Length	69 mm
Width	36 mm
Characterizing Flavor	None
SE0012916: ZIG-ZAG KING SIZE	
Product Name	KING SIZE
Package Type	Booklet
Package Quantity	32 papers
Length	98 mm
Width	53 mm
Characterizing Flavor	None
SE0012917: VENTURA WHITES	
Product Name	VENTURA WHITES 24 CT
Package Type	Booklet
Package Quantity	32 papers
Length	70 mm
Width	39 mm
Characterizing Flavor	None
SE0012918: ZIG-ZAG KUTCORNERS SLOW BURNING	
Product Name	KC SLOW BURNING
Package Type	Booklet
Package Quantity	32 papers
Length	70 mm
Width	38 mm
Characterizing Flavor	None
SE0012919: JOB 1.0 SILVER	
Product Name	J<>B 1.0 SILVER 24'S
Package Type	Booklet
Package Quantity	32 papers
Length	69 mm
Width	36 mm
Characterizing Flavor	None

SE0012920: TOP 1-1/2 SIZE	
Product Name	TOP 1-1/2 24'S
Package Type	Booklet
Package Quantity	24 papers
Length	77.5 mm
Width	68.5 mm
Characterizing Flavor	None
SE0012921: OCB ORGANIC HEMP KING SIZE SLIM	
Product Name	OCB ORGANIC HEMP KING SIZE SLIM
Package Type	Booklet
Package Quantity	32 papers
Length	109 mm
Width	44 mm
Characterizing Flavor	None
SE0012922: OCB UNGUMMED	
Product Name	OCB CIG PAPER 24'S
Package Type	Booklet
Package Quantity	150 papers
Length	70 mm
Width	39 mm
Characterizing Flavor	None
SE0012923: OCB YELLOW CIGARETTE PAPERS WITH TIPS	
Product Name	OCB YELLOW CIG PAPER
Package Type	Booklet
Package Quantity	24 papers
Length	109 mm
Width	44 mm
Characterizing Flavor	None
Paper Tip Package Type	Booklet
Paper Tip Quantity	24 Tips
Paper Tip Characterizing Flavor	None
Paper Tip Length	55 mm
Paper Tip Width	20 mm
SE0012924: ZIG-ZAG WHITE	
Product Name	WHITE
Package Type	Booklet
Package Quantity	32 papers
Length	70 mm

Width	38 mm
Characterizing Flavor	None
SE0012925: JOB 1.0 GOLD	
Product Name	J<>B 1.0 GOLD 24'S
Package Type	Booklet
Package Quantity	48 papers
Length	69 mm
Width	36 mm
Characterizing Flavor	None
SE0012926: JOB TRIBAL KING SIZE	
Product Name	JOB TRIBAL KING SIZE
Package Type	Booklet
Package Quantity	32 papers
Length	109 mm
Width	44 mm
Characterizing Flavor	None
SE0012927: OCB ORGANIC HEMP SINGLE WIDE	
Product Name	OCB ORGANIC HEMP SINGLE WIDE
Package Type	Booklet
Package Quantity	100 papers
Length	69 mm
Width	36 mm
Characterizing Flavor	None
SE0012928: OCB SLIM LONG CIGARETTE PAPERS WITH TIPS	
Product Name	OCB SLIM LONG
Package Type	Booklet
Package Quantity	24 papers
Length	77 mm
Width	44 mm
Characterizing Flavor	None
Paper Tip Package Type	Booklet
Paper Tip Package Quantity	24 Tips
Paper Tip Characterizing Flavor	None
Paper Tip Length	40 mm
Paper Tip Width	20 mm
SE0012929: JOB SINGLE WIDE (WHITE)	
Product Name	J<>B SINGLE WIDE WHITE 24'S
Package Type	Booklet

Package Quantity	32 papers
Length	69 mm
Width	36 mm
Characterizing Flavor	None
SE0012930: ABADIE 1-1/4 SIZE	
Product Name	ABADIE 1-1/4 WIDTH
Package Type	Booklet
Package Quantity	32 papers
Length	77 mm
Width	44 mm
Characterizing Flavor	None
SE0012931: JOB BROWN DOUBLE WIDE	
Product Name	J<>B DBL WIDE BROWN 24'S
Package Type	Booklet
Package Quantity	24 papers
Length	77 mm
Width	77.5 mm
Characterizing Flavor	None
SE0012932: ABADIE SINGLE WIDTH	
Product Name	ABADIE SINGLE WIDTH
Package Type	Booklet
Package Quantity	32 papers
Length	69 mm
Width	36 mm
Characterizing Flavor	None
SE0012933: OCB ORGANIC HEMP 1-1/4 SIZE	
Product Name	OCB ORGANIC HEMP 1-1/4 SIZE
Package Type	Booklet
Package Quantity	50 papers
Length	77 mm
Width	44 mm
Characterizing Flavor	None
SE0012934: JOB BROWN 1-1/4	
Product Name	J<>B 1-1/4 BROWN 24'S
Package Type	Booklet
Package Quantity	24 papers
Length	77 mm
Width	44 mm
Characterizing Flavor	None

SE0012935: JOB BROWN 1-1/2	
Product Name	J<>B 1-1/2 BROWN 24'S
Package Type	Booklet
Package Quantity	24 papers
Length	77.5 mm
Width	68.5 mm
Characterizing Flavor	None
SE0012936: JOB FRENCH WHITE	
Product Name	J<>B FRENCH LIGHT 24'S
Package Type	Booklet
Package Quantity	24 papers
Length	77 mm
Width	44 mm
Characterizing Flavor	None
SE0012938: JOB DOUBLE WIDE GOLD	
Product Name	J<>B DOUBLE WIDE GOLD 24'S
Package Type	Booklet
Package Quantity	32 papers
Length	77 mm
Width	77.5 mm
Characterizing Flavor	None
SE0012946: JOB CUTCORNERS (WHITE)	
Product Name	J<>B CUTCORNERS SLOW 24'S
Package Type	Booklet
Package Quantity	32 papers
Length	70 mm
Width	38 mm
Characterizing Flavor	None
SE0012947: JOB 1-1/4 (ORANGE)	
Product Name	J<>B 1-1/4 ORANGE 24'S
Package Type	Booklet
Package Quantity	24 papers
Length	77 mm
Width	44 mm
Characterizing Flavor	None

SE0012948: JOB 1-1/2 (WHITE) 99¢	
Product Name	J<>B 1-1/2 WHITE \$.99
Package Type	Booklet
Package Quantity	24 papers
Length	77.5 mm
Width	68.5 mm
Characterizing Flavor	None
SE0012949: JOB 1.5 SLIM GOLD	
Product Name	J<>B 1.5 SLIM GOLD 24'S
Package Type	Booklet
Package Quantity	32 papers
Length	77 mm
Width	53 mm
Characterizing Flavor	None
SE0012950: JOB 1.5 SILVER	
Product Name	J<>B 1.5 SILVER 24'S
Package Type	Booklet
Package Quantity	32 papers
Length	77.5 mm
Width	68.5 mm
Characterizing Flavor	None
SE0012951: JOB 1.25 SILVER	
Product Name	J<>B 1.25 SILVER 24'S
Package Type	Booklet
Package Quantity	32 papers
Length	77 mm
Width	44 mm
Characterizing Flavor	None
SE0012952: JOB 1.25 GOLD	
Product Name	J<>B 1.25 GOLD 24'S
Package Type	Booklet
Package Quantity	24 papers
Length	77 mm
Width	44 mm
Characterizing Flavor	None

The predicate tobacco products are roll-your-own (RYO) rolling papers manufactured by the applicant.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

The applicant submitted these SE reports on February 12, 2016. FDA issued acknowledgment letters on March 1, 2016. The applicant submitted an amendment (SE0013017) on March 16, 2016, in response to OCE's information request to clarify the predicate names. Following scientific review, FDA issued an advice/Information request (A/I) letter to the applicant on April 26, 2016. The applicant submitted an amendment (SE0013357) on May 12, 2016 and an amendment (SE0013457) on June 22, 2016 in response to the A/I letter. FDA issued a Preliminary Finding letter to the applicant on August 16, 2016. The applicant submitted amendment (SE0013676) on September 1, 2016. FDA issued a second Preliminary Finding letter to the applicant on November 29, 2016. FDA issued a correction letter to applicant on December 9, 2016. The applicant submitted an amendment (SE0013796) on December 23, 2016 in response to the second Preliminary Finding letter. The applicant submitted another amendment (SE0013846) on January 23, 2017 in response to an additional clarification questions.

Product Name	SE Report	Amendments
ABADIE 1-1/2 SIZE	SE0012908	SE0013017 SE0013357 SE0013457 SE0013676 SE0013796 SE0013846
JOB 1.5 GOLD	SE0012912	SE0013017 SE0013357 SE0013457 SE0013676 SE0013796 SE0013846
TOP STANDARD	SE0012913	SE0013017 SE0013357 SE0013457 SE0013676 SE0013796 SE0013846
ZIG-ZAG 1¼ SIZE FRENCH ORANGE	SE0012914	SE0013017 SE0013357 SE0013457 SE0013676 SE0013796 SE0013846

Product Name	SE Report	Amendments
ROLLING STANDARD	SE0012915	SE0013017 SE0013357 SE0013457 SE0013676 SE0013796 SE0013846
ZIG-ZAG KING SIZE	SE0012916	SE0013017 SE0013357 SE0013457 SE0013676 SE0013796 SE0013846
VENTURA WHITES	SE0012917	SE0013017 SE0013357 SE0013457 SE0013676 SE0013796 SE0013846
ZIG-ZAG KUTCORNERS SLOW BURNING	SE0012918	SE0013017 SE0013357 SE0013457 SE0013676 SE0013796 SE0013846
JOB 1.0 SILVER	SE0012919	SE0013017 SE0013357 SE0013457 SE0013676 SE0013796 SE0013846
TOP 1-1/2 SIZE	SE0012920	SE0013017 SE0013357 SE0013457 SE0013676 SE0013796 SE0013846

Product Name	SE Report	Amendments
OCB ORGANIC HEMP KING SIZE SLIM	SE0012921	SE0013017 SE0013357 SE0013457 SE0013676 SE0013796 SE0013846
OCB UNGUMMED	SE0012922	SE0013017 SE0013357 SE0013457 SE0013676 SE0013796 SE0013846
OCB YELLOW CIGARETTE PAPERS WITH TIPS	SE0012923	SE0013017 SE0013357 SE0013457 SE0013676 SE0013796 SE0013846
ZIG-ZAG WHITE	SE0012924	SE0013017 SE0013357 SE0013457 SE0013676 SE0013796 SE0013846
JOB 1.0 GOLD	SE0012925	SE0013017 SE0013357 SE0013457 SE0013676 SE0013796 SE0013846
JOB TRIBAL KING SIZE	SE0012926	SE0013357 SE0013457 SE0013676 SE0013796 SE0013846
OCB ORGANIC HEMP SINGLE WIDE	SE0012927	SE0013357 SE0013457 SE0013676 SE0013796 SE0013846

Product Name	SE Report	Amendments
OCB SLIM LONG CIGARETTE PAPERS WITH TIPS	SE0012928	SE0013017 SE0013357 SE0013457 SE0013676 SE0013796 SE0013846
JOB SINGLE WIDE (WHITE)	SE0012929	SE0013017 SE0013357 SE0013457 SE0013676 SE0013796 SE0013846
ABADIE 1-1/4 SIZE	SE0012930	SE0013017 SE0013357 SE0013457 SE0013676 SE0013796 SE0013846
JOB BROWN DOUBLE WIDE	SE0012931	SE0013017 SE0013357 SE0013457 SE0013676 SE0013796 SE0013846
ABADIE SINGLE WIDTH	SE0012932	SE0013017 SE0013357 SE0013457 SE0013676 SE0013796 SE0013846
OCB ORGANIC HEMP 1-1/4 SIZE	SE0012933	SE0013357 SE0013457 SE0013676 SE0013796 SE0013846
JOB BROWN 1-1/4	SE0012934	SE0013017 SE0013357 SE0013457 SE0013676 SE0013796 SE0013846

Product Name	SE Report	Amendments
JOB BROWN 1-1/2	SE0012935	SE0013017 SE0013357 SE0013457 SE0013676 SE0013796 SE0013846
JOB FRENCH WHITE	SE0012936	SE0013017 SE0013357 SE0013457 SE0013676 SE0013796 SE0013846
JOB DOUBLE WIDE GOLD	SE0012938	SE0013017 SE0013357 SE0013457 SE0013676 SE0013796 SE0013846
JOB CUTCORNERS (WHITE)	SE0012946	SE0013017 SE0013357 SE0013457 SE0013676 SE0013796 SE0013846
JOB 1-1/4 (ORANGE)	SE0012947	SE0013017 SE0013357 SE0013457 SE0013676 SE0013796 SE0013846
JOB 1-1/2 (WHITE) 99¢	SE0012948	SE0013017 SE0013357 SE0013457 SE0013676 SE0013796 SE0013846

Product Name	SE Report	Amendments
JOB 1.5 SLIM GOLD	SE0012949	SE0013017 SE0013357 SE0013457 SE0013676 SE0013796 SE0013846
JOB 1.5 SILVER	SE0012950	SE0013017 SE0013357 SE0013457 SE0013676 SE0013796 SE0013846
JOB 1.25 SILVER	SE0012951	SE0013017 SE0013357 SE0013457 SE0013676 SE0013796 SE0013846
JOB 1.25 GOLD	SE0012952	SE0013017 SE0013357 SE0013457 SE0013676 SE0013796 SE0013846

1.3. SCOPE OF REVIEW

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

2. REGULATORY REVIEW

Regulatory reviews were completed by Sarah Webster on February 26, 2016.

The reviews note that the applicant did not provide a side-by-side quantitative comparison of the new tobacco product and predicate tobacco product with respect to other features of a tobacco product. However during scientific review of the reports the applicant provided this information in response to FDA's deficiency letters. Therefore the SE Reports are administratively complete.

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 March 29, 2016, March 30, 2016, and October 25, 2016, conclude that the evidence submitted by the applicant is adequate to demonstrate that the following predicate tobacco products are grandfathered and, therefore, are eligible predicate tobacco products: SE0012908, SE0012912-SE0012920, SE0012922-SE0012926, SE0012928-SE0012932, SE0012934-SE0012936, SE0012938, & SE0012946-SE0012952.

The following predicate tobacco products were previously found Substantially Equivalent (SE) and, therefore, are eligible predicate tobacco products: SE0012921, SE0012927, and SE0012933.

OCE completed reviews 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 reviews dated February 13, 2017¹, April 6, 2017, and June 13, 2017, conclude that the new tobacco products are in compliance with the FD&C Act.

4. SCIENTIFIC REVIEW

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

4.1. CHEMISTRY

Chemistry reviews were completed by Delshanee Kotandeniya and Megan Mekoli on April 8, 2016, and by Delshanee Kotandeniya on August 8, 2016, and October 11, 2016.

The final chemistry review concludes that the new tobacco products have different characteristics related to product composition compared to the predicate tobacco products but the differences do not cause the new tobacco products to raise different questions of public health. The new tobacco products have the following key differences in product composition compared to the predicate tobacco products:

- 100% (b) (4)
- 7% - 1500% (b) (4) [SE0012908, SE0012912 – SE0012914, SE0012916, SE0012919 - SE0012920, SE0012922,

¹ A correction was made to the February 13, 2017 review and finalized on June 27, 2017 to correct the product names for SE0012908.

- SE0012925 - SE0012926, SE0012928, SE0012930 – SE0012932, SE0012934 - SE0012935, SE0012938, and SE0012947 – SE0012952]
- 21% (b) (4) [SE0012924]

Although there are differences in product composition, there are only minor and statistically insignificant differences between TNCO yields of the the new and corresponding predicate tobacco products. Therefore, the differences in characteristics related to product composition between the new and corresponding predicate tobacco products do not cause the new tobacco products to raise different questions of public health.

4.2. ENGINEERING

Engineering reviews were completed by Komal Ahuja on April 15, 2016, and by Madison Rohrbaugh on August 8, 2016.

The final engineering review concludes that the new tobacco products have different characteristics related to product design compared to the corresponding predicate tobacco products but the differences do not cause the new tobacco products to raise different questions of public health. The review identified the following issue:

- Change in (b) (4)

Although there are differences in (b) (4), there are only minor and statistically insignificant differences between the TNCO yields of the new and corresponding predicate tobacco products. Therefore, the differences in characteristics related to product design between the new and corresponding predicate tobacco products do not cause the new tobacco products to raise different questions of public health.

5. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on March 16, 2017. The FONSI was supported by an environmental assessment prepared by FDA on March 17, 2017, and an addendum on June 20, 2017.

6. CONCLUSION AND RECOMMENDATION

The following are the key differences in characteristics between the new and corresponding predicate tobacco products:

- Different (b) (4)
- 100 percent (b) (4)

- 7% - 1500% (b)(4)
- 21 percent (b)(4)

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco products to raise different questions of public health. Although there are differences in characteristics, there are only minor and statistically insignificant differences between the TNCO yields of the new and corresponding predicate tobacco products. Therefore, the differences in characteristics between the new and corresponding predicate products do not cause the new tobacco products to raise different questions of public health.

The predicate tobacco products meet statutory requirements because they are either grandfathered products (i.e., were commercially marketed in the United States as of February 15, 2007) (SE0012908, SE0012912-SE0012920, SE0012922-SE0012926, SE0012928-SE0012932, SE0012934-SE0012936, SE0012938, and SE0012946-SE0012952) or they are products that were previously found to be substantially equivalent by FDA (SE0012921, SE0012927 and SE0012933).

The new tobacco products are currently in compliance with the FD&C Act. In addition, all of the scientific reviews conclude that the differences between the new and corresponding predicate tobacco products are such that the new tobacco products do not raise different questions of public health. 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 SE0012908, SE0012912 - SE0012936, SE0012938, and SE0012946 - SE0012952, as identified on the cover page of this review.

² SE0012908, SE0012912 – SE0012914, SE0012916, SE0012919 - SE0012920, SE0012922, SE0012925 - SE0012926, SE0012928, SE0012930 – SE0012932, SE0012934 - SE0012935, SE0012938, and SE0012947 – SE0012952

³ SE0012924