

Technical Project Lead (TPL) Review: SE0011107, SE0011111, SE0011112, SE0011115, SE0011117-SE0011120, SE0011135, and SE0011184-SE0011187

SE0011107: Job Double Wide Gold	
Package Type	Booklet
Package Quantity	24 papers
Paper Length	77 mm
Paper Width	77.5 mm
Characterizing Flavor ¹	None
SE0011111: Job 1.25 Silver	
Package Type	Booklet
Package Quantity	24 papers
Paper Length	77 mm
Paper Width	44 mm
Characterizing Flavor ¹	None
SE0011112: Job 1.0 Gold	
Package Type	Booklet
Package Quantity	32 papers
Paper Length	70 mm
Paper Width	38 mm
Characterizing Flavor ¹	None
SE0011115: Job 1.5 Slim Gold	
Package Type	Booklet
Package Quantity	24 papers
Paper Length	77 mm
Paper Width	53 mm
Characterizing Flavor ¹	None
SE0011117: OCB Organic Hemp 1-1/4	
Package Type	Booklet
Package Quantity	24 papers
Paper Length	77 mm
Paper Width	44 mm
Characterizing Flavor ¹	None
Additional Property	Organic Hemp

¹ As provided by 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.

SE0011118: OCB Organic Hemp Single Wide	
Package Type	Booklet
Package Quantity	50 papers
Paper Length	69 mm
Paper Width	36 mm
Characterizing Flavor ¹	None
Additional Property	Organic Hemp
SE0011119: OCB Organic Hemp Single Wide	
Package Type	Booklet
Package Quantity	24 papers
Paper Length	69 mm
Paper Width	36 mm
Characterizing Flavor ¹	None
Additional Property	Organic Hemp
SE0011120: OCB Organic Hemp King Size Slim	
Package Type	Booklet
Package Quantity	24 papers
Paper Length	109 mm
Paper Width	44 mm
Characterizing Flavor ¹	None
Additional Property	Organic Hemp
SE0011135: Top Silver King Size	
Package Type	Box
Package Quantity	250 tubes
Length	84 mm
Diameter	8.1 mm
Ventilation	(b) (4)
Characterizing Flavor ¹	None
SE0011184: Top Menthol King Size	
Package Type	Box
Package Quantity	250 tubes
Length	84 mm
Diameter	8.1 mm
Ventilation	(b) (4)
Characterizing Flavor ¹	Menthol
SE0011185: Top Menthol King Size	
Package Type	Box
Package Quantity	250 tubes
Length	84 mm
Diameter	8.1 mm
Ventilation	(b) (4)
Characterizing Flavor ¹	Menthol
Additional Property:	Retail price printed on package

SE0011186: Altessse Regular King Size	
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Diameter	8.1 mm
Ventilation	(b) (4)
Characterizing Flavor ¹	None
SE0011187: Altessse Regular King Size	
Package Type	Box
Package Quantity	250 tubes
Length	84 mm
Diameter	8.1 mm
Ventilation	(b) (4)
Characterizing Flavor	None
Common Attributes of SE Reports	
Applicant	Republic Tobacco, LP
Report Type	Regular Product Quantity Change
Product Category	Roll-Your-Own Tobacco
Product Sub-Category	Rolling papers (SE0011107, SE0011111, SE0011112, SE0011115, SE0011117-SE0011120) and Filtered cigarette tubes (SE0011135 and SE0011184-SE0011187)
Recommendation	
Issue Substantially Equivalent (SE) orders.	

Technical Project Lead (TPL):

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Date: 2017.12.12 15:37:03 -05'00'

Colleen K. Rogers, Ph.D.
Director
Division of Product Science
Office of 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 Matthew R. Holman -S
Date: 2017.12.12 16:13:53 -05'00'

Matthew R. Holman, Ph.D.
Director
Office of Science

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1. BACKGROUND

1.1. PREDICATE TOBACCO PRODUCTS

The predicate tobacco products have identical properties to the corresponding new tobacco products except for product quantity. The predicate tobacco products have the following product quantities:

SE0011107: Job Double Wide Gold	
Product Name	Job Double Wide Gold
Product Quantity	32 papers
SE0011111: Job 1.25 Silver	
Product Name	Job 1.25 Silver
Product Quantity	32 papers
SE0011112: Job 1.0 Gold	
Product Name	Job 1.0 Gold 24's
Product Quantity	48 papers
SE0011115: Job 1.5 Slim Gold	
Product Name	Job 1.5 Slim Gold
Product Quantity	32 papers
SE0011117: OCB Organic Hemp 1-1/4	
Product Name	OCB Organic Hemp 1-1/4
Product Quantity	50 papers
SE0011118: OCB Organic Hemp Single Wide	
Product Name	OCB Organic Hemp Single Wide
Product Quantity	100 papers
SE0011119: OCB Organic Hemp Single Wide	
Product Name	OCB Organic Hemp Single Wide
Product Quantity	100 papers
SE0011120: OCB Organic Hemp King Size Slim	
Product Name	OCB Organic Hemp King Size Slim
Product Quantity	32 papers
SE0011135: Top Silver King Size	
Product Name	Top Silver King Size
Product Quantity	200 tubes
SE0011184: Top Menthol King Size	
Product Name	Top Menthol King Size
Product Quantity	200 tubes
SE0011185: Top Menthol King Size	
Product Name	Top Menthol King Size
Product Quantity	200 tubes
SE0011186: Altess Regular King Size	
Product Name	Altess Regular King Size
Product Quantity	100 tubes

SE0011187: Altesse Regular King Size	
Product Name	Altesse Regular King Size
Product Quantity	100 tubes

The predicate tobacco products are manufactured by the applicant.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On April 2, 2015, FDA received 13 Product Quantity Change SE Reports from Republic Tobacco, LP. FDA issued Acknowledgment letters to the applicant on April 22, 2015. On May 6, 2015, a teleconference was held between FDA and the applicant to request additional information for unique identification of the new and predicate tobacco products for these SE Reports. The applicant submitted a response (SE0011758) on May 11, 2015. On May 28, 2015, the Office of Compliance and Enforcement (OCE), emailed the applicant to request information for SE0011107, SE0011111-SE0011112, SE0011115, and SE0011184-SE0011197. The applicant submitted a response (SE0011919) on June 2, 2015. On June 18, 2015, the applicant submitted an amendment (SE0011981) pertaining to their June 2, 2015, submission for SE0011112. FDA issued a Preliminary Finding letter on August 18, 2017, which identified environmental deficiencies in the applicant's SE Reports. The applicant submitted a response (SE0014324) on September 13, 2017. On November 27, 2017, OCE requested information for SE0011112. The applicant submitted a response (SE0014425) on December 1, 2017.

Product Name	SE Report	Amendments
Job Double Wide Gold	SE0011107	SE0011758 SE0011919 SE0014324
Job 1.25 Silver	SE0011111	SE0011758 SE0011919 SE0014324
Job 1.0 Gold	SE0011112	SE0011758 SE0011919 SE0011981 SE0014324 SE0014425
Job 1.5 Slim Gold	SE0011115	SE0011758 SE0011919 SE0014324
OCB Organic Hemp 1-1/4	SE0011117	SE0011758 SE0014324
OCB Organic Hemp Single Wide	SE0011118	SE0011758 SE0014324
OCB Organic Hemp Single Wide	SE0011119	SE0011758 SE0014324
OCB Organic Hemp King Size Slim	SE0011120	SE0011758 SE0014324
Top Silver King Size	SE0011135	SE0011758 SE0014324

Top Menthol King Size	SE0011184	SE0011758 SE0011919 SE0014324
Top Menthol King Size	SE0011185	SE0011758 SE0011919 SE0014324
Altesse Regular King Size	SE0011186	SE0011758 SE0011919 SE0014324
Altesse Regular King Size	SE0011187	SE0011758 SE0011919 SE0014324

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 Ryan Nguy on April 22, 2015, and Sarah Webster on November 9, 2017.

The final review concludes that 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 eligible predicate tobacco products. The OCE reviews dated June 15, 2015; June 16, 2015; and June 17, 2015, conclude that the evidence submitted by the applicant is adequate to demonstrate that the predicate tobacco products in SE0011107, SE0011111, SE0011112², SE0011115, and SE0011184-SE0011187 are grandfathered and, therefore, are eligible predicate tobacco products.

The predicate tobacco products in SE0011117-SE0011120 and SE0011135 were previously determined to be substantially equivalent by FDA as shown in the table below. Therefore, these products are eligible predicate tobacco products.

SE Report	Predicate Tobacco Product Name	Predicate Tobacco Product Found SE Under	Date
SE0011117	OCB Organic Hemp 1-1/4	SE0003299	October 9, 2013
SE0011118	OCB Organic Hemp Single Wide	SE0003297	October 9, 2013
SE0011119	OCB Organic Hemp Single Wide	SE0003297	October 9, 2013
SE0011120	OCB Organic Hemp King Size Slim	SE0003298	October 9, 2013

² On December 11, 2017, an addendum corrected the predicate tobacco product length.

SE0011135	Top Silver King Size	SE0010369	March 27, 2015
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OCE also completed reviews 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 reviews dated June 16, 2015; August 6, 2015; and October 31, 2017, conclude that the new tobacco products are in compliance with the FD&C Act.

4. SCIENTIFIC REVIEW

Scientific review was completed by the Office of Science (OS) for the following discipline:

4.1. SOCIAL SCIENCE

A social science review was completed by David Portnoy on August 5, 2015.

The social science review concludes that the new tobacco products have different characteristics compared to the corresponding predicate tobacco products but the differences do not cause the new tobacco products to raise different questions of public health from a social science perspective. The review identified the following differences between the new and corresponding predicate tobacco products:

- SE0011107: Decrease of 25% (32 to 24 rolling papers)
- SE0011111: Decrease of 25% (32 to 24 rolling papers)
- SE0011112: Decrease of 33% (48 to 32 rolling papers)
- SE0011115: Decrease of 25% (32 to 24 rolling papers)
- SE0011117: Decrease of 52% (50 to 24 rolling papers)
- SE0011118: Decrease of 50% (100 to 50 rolling papers)
- SE0011119: Decrease of 76% (100 to 24 rolling papers)
- SE0011120: Decrease of 25% (32 to 24 rolling papers)
- SE0011135: Increase of 25% (200 to 250 filtered cigarette tubes)
- SE0011184: Increase of 25% (200 to 250 filtered cigarette tubes)
- SE0011185: Increase of 25% (200 to 250 filtered cigarette tubes)
- SE0011186: Increase of 100% (100 to 200 filtered cigarette tubes)
- SE0011187: Increase of 150% (100 to 250 filtered cigarette tubes)

The social science reviewer states that there is currently no available scientific evidence that these minor changes in the number of rolling papers or filtered cigarette tubes influences consumer perceptions of harm or use intentions. Further, the reviewer states that evidence from other consumer products suggests that these changes in the number of rolling papers or filtered cigarette tubes would not cause the new tobacco products to raise different questions of public health from a social science perspective. Therefore, the review concludes that the differences between the new and predicate tobacco products do not cause the new tobacco products to raise different questions of public health.

As explained in FDA's Guidance for Industry: Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions (3rd Edition), smaller product

quantities may allow for increased product uptake due to lower barriers to trying the product, are associated with lower product harm perceptions, and reduce product costs or increase product availability, all of which may affect use intentions and behavior, including initiation among youth. However, as explained below, I find that when that evidence is viewed in the context of the evidence provided in the SE Reports, as well as other scientific literature and FDA's general experience reviewing SE Reports, given the current state of the evidence, for the type of product in SE0011107, SE0011111, SE0011112, SE0011115, and SE0011117-SE0011120, cigarette rolling papers, a decrease in product quantity would not cause a new tobacco product to raise different questions of public health.

First, based on FDA's experience and knowledge it is very unlikely that youth would initiate tobacco use with the new tobacco products in SE0011107, SE0011111, SE0011112, SE0011115, and SE0011117-SE0011120. This is because cigarette rolling papers require other tobacco products like tobacco filler and filters in order to be assembled into a finished product that is ready for use. As a result, this requires additional time, effort and expense, which disincentivizes youth from initiating with these types of products. Further, I agree with the social science reviewer that there is currently no available scientific evidence specific to cigarette rolling papers showing that these decreases in product quantity for cigarette rolling papers would influence consumer perceptions of harm or use intentions.

Second, although not evaluated by the social science reviewer for these particular SE Reports, scientific literature suggests that for consumer products that are "usage-invariant" (i.e., products which have price insensitive demand functions), "low convenience" (i.e., products that require preparation and for which consumption costs time, comfort, and effort) and "low salience" (i.e., products that are not noticeable, easily remembered, or recalled), increasing the product quantity generally would not impact consumer use.^{3,4} Similarly, a decrease in the product quantity of usage-invariant, low convenience, and low salience products also generally would not impact consumer use and behavior, including initiation among youth. A decrease in product quantity for a usage-invariant product generally would not affect initiation because youth generally would not initiate despite a corresponding decrease in price. A decrease in product quantity for a low convenience product also generally would not affect initiation because, as explained above, youth generally would not initiate if product consumption requires additional time and effort to use the product. A decrease in product quantity for a low salience product generally would not affect youth initiation because the product remains not noticeable, easily remembered, or recalled. There is a high likelihood that cigarette rolling papers are usage-invariant (since there is no benefit of using a decreased number of rolling papers per quantity of RYO tobacco), low convenience (since they must be used with other products and require additional preparation before consumption), and low salience (since they are not highly visible, requiring little storage space). Based on the foregoing, as well as FDA's general experience reviewing SE Reports for this type of product, I find that, based on the current state of the evidence, a 25-76% decrease in product quantity of rolling paper does not cause the new tobacco products in SE0011107, SE0011111, SE0011112, SE0011115, and SE0011117-SE0011120 to raise different questions of public health.

³ Chandon, P. & Wansink, B. (2002). When are stockpiled products consumed faster? A convenience-salience framework of postpurchase consumption incidence and quantity. *Journal of Marketing Research*, 321-335.

⁴ Wansink, B. (1996). Can package size accelerate usage volume? *Journal of Marketing*, 60, 1-14.

With regard to SE0011135 and SE0011184-SE0011187, as explained in FDA's SE FAQ Guidance, increasing product quantity can potentially reduce cessation behaviors and increase tobacco product use among current users. However, when that evidence is viewed in the context of the evidence provided in these SE Reports, as well as other scientific literature and FDA's general experience reviewing SE Reports, based on the current state of the evidence, for the type of products at issue here—cigarette tubes—an increase in product quantity would not cause a new tobacco product to raise different questions of public health. As indicated above, scientific literature suggests that for consumer products that are "usage-invariant" (i.e., products which have price insensitive demand functions), "low convenience" (i.e., products that require preparation and for which consumption costs time, comfort, and effort) and "low salience" (i.e., products that are not noticeable, easily remembered, or recalled), increasing the product quantity generally would not impact consumer use. Given the likelihood that cigarette tubes are usage-invariant (since there is no benefit of using an increased number of cigarette tubes per quantity of RYO tobacco), low convenience (since they must be used with other products and require additional preparation before consumption), and low salience (since they are not highly visible, requiring little storage space), I find that, based on the current state of the evidence, an increase of product quantity of 25-150% in cigarette tubes does not cause the new tobacco products in SE0011135 and SE0011184-SE0011187 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 December 12, 2017. The FONSI was supported by an environmental assessment prepared by FDA on December 12, 2017.

6. CONCLUSION AND RECOMMENDATION

The product characteristics of the new and corresponding predicate tobacco products are the same except for the following product quantity changes:

- SE0011107: Decrease of 25% (32 to 24 rolling papers)
- SE0011111: Decrease of 25% (32 to 24 rolling papers)
- SE0011112: Decrease of 33% (48 to 32 rolling papers)
- SE0011115: Decrease of 25% (32 to 24 rolling papers)
- SE0011117: Decrease of 52% (50 to 24 rolling papers)
- SE0011118: Decrease of 50% (100 to 50 rolling papers)
- SE0011119: Decrease of 76% (100 to 24 rolling papers)
- SE0011120: Decrease of 25% (32 to 24 rolling papers)
- SE0011135: Increase of 25% (200 to 250 filtered cigarette tubes)
- SE0011184: Increase of 25% (200 to 250 filtered cigarette tubes)
- SE0011185: Increase of 25% (200 to 250 filtered cigarette tubes)
- SE0011186: Increase of 100% (100 to 200 filtered cigarette tubes)
- SE0011187: Increase of 150% (100 to 250 filtered cigarette tubes)

The social science review concludes that these differences in product quantity do not cause the new tobacco products to raise different questions of public health. I concur with the conclusion of the social science review.

The predicate tobacco products in SE0011107, SE0011111, SE0011112, SE0011115, and SE0011184-SE0011187 meet statutory requirements because they are grandfathered products (i.e., were commercially marketed in the United States as of February 15, 2007).

The predicate products in SE0011117-SE0011120 and SE0011135 meet statutory requirements because they were determined to be substantially equivalent by FDA under SE0003299, SE0003297, SE0003298, or SE0010369.

Where an applicant supports a showing of SE by comparing the new tobacco product to a tobacco product that FDA previously found SE, in order to issue an SE order, FDA must find that the new tobacco product is substantially equivalent to a tobacco product commercially marketed in the United States as of February 15, 2007 (see section 910(a)(2)(A)(i)(I) of the FD&C Act).

The predicate tobacco products in SE0011117-SE0011120 and SE0011135 were previously determined to be substantially equivalent by FDA under SE0003299 (predicate for SE0011117), SE0003297 (predicate for SE0011118 and SE0011119), SE0003298 (predicate for SE0011120), and SE0010369 (predicate for SE0011135). The SE Reports for SE0003297-SE0003299 utilized a predicate tobacco product determined to be grandfathered by OCE on May 23, 2012⁵ (JOB Tribal King Size). SE0010369 utilized a predicate tobacco product determined to be grandfathered by OCE on May 9, 2014 (Top Regular King Size).

Comparison of the new tobacco products in SE0011117-SE0011120 to the grandfathered product in SE0003299, SE0003297, and SE0003298 (JOB Tribal King Size) reveal the following key differences in characteristics:

- SE0011117:
 - Decrease in product quantity of 25% (32 to 24 rolling papers)
 - Decrease in cigarette paper length (109 mm to 77 mm)
 - Decrease in (b) (4) (b) (4)
 - Increase in (b) (4)
 - Decrease in (b) (4) (b) (4)
- SE0011118:
 - Increase in product quantity of 56% (32 to 50 rolling papers)
 - Decrease in cigarette paper length (109 mm to 69 mm)
 - Decrease in cigarette paper width (44 mm to 36 mm)
 - Decrease in (b) (4) (b) (4)
 - Increase in (b) (4)
 - Decrease in (b) (4) (b) (4)
- SE0011119:
 - Decrease in product quantity of 25% (32 to 24 rolling papers)
 - Decrease in cigarette paper length (109 mm to 69mm)

⁵ This review was amended on June 7, 2013, to add package type, quantity, and size of the new and predicate tobacco products.

- o Decrease in cigarette paper width (44 mm to 36 mm)
 - o Decrease in (b) (4)
 - o Increase in (b) (4)
 - o Decrease in (b) (4)
- SE0011120:
 - o Decrease in product quantity of 25% (32 to 24 rolling papers)
 - o Decrease in (b) (4)
 - o Increase in (b) (4)
 - o Decrease in (b) (4)

The differences in characteristics listed above, other than the differences in product quantity, are the same differences in characteristics identified for the new and grandfathered tobacco products in SE0003299, SE0003297, and SE0003298. Therefore, these differences do not cause the new tobacco products in SE0011117-SE0011120 to raise different questions of public health. Additionally, for the same reasons as discussed above, the differences in product quantity between the new tobacco products in SE0011117-SE0011120 and the grandfathered tobacco product do not cause the new tobacco products to raise different questions of public health. Therefore, whether comparing the new tobacco products in SE0011117-SE0011120 to the predicate or grandfathered tobacco product, the new tobacco products do not raise different questions of public health.

Comparison of the new tobacco product in SE0011135 to the grandfathered tobacco product in SE0010369 (Top Regular King Size) reveals the following key differences in characteristics:

- Increase in product quantity of 25% (200 to 250 cigarette tubes)
- Increase in (b) (4) in cigarette paper, tipping paper, and plugwrap
- Addition of (b) (4) and (b) (4) increase in (b) (4) in tipping paper
- Increase in (b) (4) in cigarette paper
- Addition of (b) (4) to cigarette paper and tipping paper
- Removal of (b) (4) from plugwrap
- Increase in (b) (4) in filter acetate tow
- Increase in (b) (4) in filter acetate tow
- Decreased (b) (4)
- Increased (b) (4)
- Increased (b) (4)
- Increased (b) (4)
- Increased (b) (4)
- Decreased (b) (4)
- Addition of silver ink and removal of black ink from tipping paper

The differences in characteristics listed above, other than the differences in product quantity, are the same differences in characteristics identified for the new and grandfathered tobacco products in SE0010369. Therefore, these differences do not cause the new tobacco product in SE0011135 to raise different questions of public health. Additionally, for the same reasons as discussed above, the differences in product quantity between the new tobacco product in SE0011135 and the grandfathered tobacco product do not cause the new tobacco product to raise different questions of public health. Therefore, whether comparing the new tobacco product in SE0011135 to the

TPL Review for SE0011107, SE0011111, SE0011112, SE0011115, SE0011117-SE0011120, SE0011135, and SE0011184-SE0011187

predicate or grandfathered tobacco product, the new tobacco product does not raise different questions of public health.

The new tobacco products are currently in compliance with the FD&C Act.

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 SE0011107, SE0011111, SE0011112, SE0011115, SE0011117-SE0011120, SE0011135, and SE0011184-SE0011187 as identified on the cover page of this review.