

Technical Project Lead (TPL) Review: SE0015484 – SE0015498

SE0015484: EC Pipe Blue 1 oz	
Package Type	Bag
Package Quantity	1 ounce
Characterizing Flavor ¹	None
SE0015485: EC Pipe Blue 3 oz	
Package Type	Bag
Package Quantity	3 ounces
Characterizing Flavor ¹	None
SE0015486: EC Pipe Blue 6 oz	
Package Type	Bag
Package Quantity	6 ounces
Characterizing Flavor ¹	None
SE0015487: EC Pipe Blue 8 oz	
Package Type	Bag
Package Quantity	8 ounces
Characterizing Flavor ¹	None
SE0015488: EC Pipe Blue 12 oz	
Package Type	Bag
Package Quantity	12 ounces
Characterizing Flavor ¹	None
SE0015489: EC Pipe Red 1 oz	
Package Type	Bag
Package Quantity	1 ounce
Characterizing Flavor ¹	None
SE0015490: EC Pipe Red 3 oz	
Package Type	Bag
Package Quantity	3 ounces
Characterizing Flavor ¹	None
SE0015491: EC Pipe Red 6 oz	
Package Type	Bag
Package Quantity	6 ounces
Characterizing Flavor ¹	None
SE0015492: EC Pipe Red 8 oz	
Package Type	Bag
Package Quantity	8 ounces
Characterizing Flavor ¹	None

¹ 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.

SE0015493: EC Pipe Red 12 oz	
Package Type	Bag
Package Quantity	12 ounces
Characterizing Flavor¹	None
SE0015494: EC Pipe Menthol 1 oz	
Package Type	Bag
Package Quantity	1 ounce
Characterizing Flavor¹	Menthol
SE0015495: EC Pipe Menthol 3 oz	
Package Type	Bag
Package Quantity	3 ounces
Characterizing Flavor¹	Menthol
SE0015496: EC Pipe Menthol 6 oz	
Package Type	Bag
Package Quantity	6 ounces
Characterizing Flavor¹	Menthol
SE0015497: EC Pipe Menthol 8 oz	
Package Type	Bag
Package Quantity	8 ounces
Characterizing Flavor¹	Menthol
SE0015498: EC Pipe Menthol 12 oz	
Package Type	Bag
Package Quantity	12 ounces
Characterizing Flavor¹	Menthol
Attributes of SE Reports	
Applicant	Alliance One Specialty Products, LLC
Report Type	Regular Product Quantity Change
Product Category	Pipe tobacco product
Product Sub-Category	Pipe tobacco filler
Recommendation	
Issue Substantially Equivalent (SE) orders.	

Technical Project Lead (TPL):

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Date: 2020.02.06 08:52:37 -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: 2020.02.06 09:02:08 -05'00'

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

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1. BACKGROUND

1.1. PREDICATE TOBACCO PRODUCTS

The applicant submitted the following predicate tobacco products:

SE0015484: EC Pipe Blue 1 oz SE0015485: EC Pipe Blue 3 oz SE0015486: EC Pipe Blue 6 oz SE0015487: EC Pipe Blue 8 oz SE0015488: EC Pipe Blue 12 oz	
Product Name	Light Fine Cut
Package Type	Bag
Package Quantity	1 pound ²
Characterizing Flavor¹	None
SE0015489: EC Pipe Red 1 oz SE0015490: EC Pipe Red 3 oz SE0015491: EC Pipe Red 6 oz SE0015492: EC Pipe Red 8 oz SE0015493: EC Pipe Red 12 oz	
Product Name	American Blend Regular Fine Cut
Package Type	Bag
Package Quantity	1 pound ²
Characterizing Flavor¹	None
SE0015494: EC Pipe Menthol 1 oz SE0015495: EC Pipe Menthol 3 oz SE0015496: EC Pipe Menthol 6 oz SE0015497: EC Pipe Menthol 8 oz SE0015498: EC Pipe Menthol 12 oz	
Product Name	American Blend Menthol Fine Cut
Package Type	Bag
Package Quantity	1 pound ²
Characterizing Flavor¹	Menthol

The predicate tobacco products are pipe tobacco filler manufactured by the applicant.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On September 18, 2019, FDA received 15 Product Quantity Change SE Reports (SE0015484-SE0015498) from Alliance One Specialty Products, LLC. On October 7, 2019, FDA issued an Acceptance letter to the applicant. On October 4, 2019, the Office of Compliance and Enforcement (OCE) contacted the applicant via email to request additional information on the predicate tobacco products in SE0015484 - SE0015488 and SE0015494 - SE0015498. In response, FDA received amendment SE0015530 on October 9, 2019.

² 1 pound equals 16 ounces

Product Name	SE Report	Amendments
EC Pipe Blue 1 oz	SE0015484	SE0015530
EC Pipe Blue 3 oz	SE0015485	
EC Pipe Blue 6 oz	SE0015486	
EC Pipe Blue 8 oz	SE0015487	
EC Pipe Blue 12 oz	SE0015488	
EC Pipe Red 1 oz	SE0015489	None
EC Pipe Red 3 oz	SE0015490	
EC Pipe Red 6 oz	SE0015491	
EC Pipe Red 8 oz	SE0015492	
EC Pipe Red 12 oz	SE0015493	
EC Pipe Menthol 1 oz	SE0015494	SE0015530
EC Pipe Menthol 3 oz	SE0015495	
EC Pipe Menthol 6 oz	SE0015496	
EC Pipe Menthol 8 oz	SE0015497	
EC Pipe Menthol 12 oz	SE0015498	

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 Nikole Ayala-Agosto on October 7, 2019 and December 13, 2019.

The final review concludes that the SE Reports are administratively complete.

3. COMPLIANCE REVIEW

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 other than exclusively in test markets as of February 15, 2007). The OCE reviews dated October 22, 2019, and October 23, 2019, 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 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 December 12, 2019, and February 4, 2020, conclude that the new tobacco products are in compliance with the FD&C Act.

4. SCIENTIFIC REVIEW

A 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 James Henrie on November 7, 2019.

The social science review concludes that the new tobacco products have different characteristics from 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 product quantity decreases between the new and corresponding predicate tobacco products:

- SE0015484, SE0015489, and SE0015494: 94% decrease (16 ounces to 1 ounce)
- SE0015485, SE0015490, and SE0015495: 81% decrease (16 ounces to 3 ounces)
- SE0015486, SE0015491, and SE0015496: 63% decrease (16 ounces to 6 ounces)
- SE0015487, SE0015492, and SE0015497: 50% decrease (16 ounces to 8 ounces)
- SE0015488, SE0015493, and SE0015498: 25% decrease (16 ounces to 12 ounces)

The review concludes that there is currently no available scientific evidence on the influence that the pipe tobacco filler package quantity has on consumer perceptions of harm or use intentions to indicate that decreases of these magnitudes would cause the new tobacco products to raise different questions of public health from a social science perspective. Therefore, the review concludes that the difference in characteristics between the new and corresponding predicate tobacco products does not cause the new tobacco products to raise different questions of public health from a social science perspective.

The Office of Science (OS) prepared a memorandum³ summarizing its current thinking on product quantity changes in statutorily regulated tobacco products that, at this time, changes in tobacco product quantity do not cause such new tobacco products to raise different questions of public health. As explained below, the conclusions in the December 7, 2017, memorandum are applicable to the new tobacco products that are the subject of these SE Reports (i.e., pipe tobacco filler, a deemed tobacco product).

With respect to product quantity decreases, even though some of the currently available scientific evidence is specific to tobacco products, the studies do not separate the effect of reduced price from the effect of decreased size on consumption or initiation. Accordingly, I find that the memorandum's conclusion that, based on the currently available evidence and CTP's experience in reviewing SE Reports, decreases in product quantity for statutory tobacco products do not cause those new tobacco products to raise different questions of public health, also applies to pipe tobacco filler.

³ See memorandum on product quantity changes, dated December 7, 2017. When the memorandum was signed, CTP had yet to receive any Product Quantity Change SE Reports for deemed tobacco products.

Based on the foregoing, I find that, based on the current state of the evidence, a 94% (in SE0015484, SE0015489, and SE0015494), 81% (in SE0015485, SE0015490, and SE0015495), 63% (in SE0015486, SE0015491, and SE0015496), 50% (in SE0015487, SE0015492, and SE0015497), or 25% (in SE0015488, SE0015493, and SE0015498) decrease in product quantity of pipe tobacco filler does not cause the new tobacco products in these SE Reports to raise different questions of public health. 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 social science perspective.

5. ENVIRONMENTAL DECISION

An environmental review was completed by Susana Addo Ntim on November 4, 2019.

The environmental review found that the submitted Environmental Assessment (EA) does not provide enough information for an EA as required in 21 CFR 25.40. Therefore, additional information is needed to determine whether to prepare an Environmental Impact Statement (EIS) or Finding of No Significant Impact (FONSI).

6. CONCLUSION AND RECOMMENDATION

The tobacco product characteristics of the new and corresponding predicate tobacco products are identical except for the following decreases in product quantity:

- SE0015484, SE0015489, and SE0015494: 94% decrease (16 ounces to 1 ounce)
- SE0015485, SE0015490, and SE0015495: 81% decrease (16 ounces to 3 ounces)
- SE0015486, SE0015491, and SE0015496: 63% decrease (16 ounces to 6 ounces)
- SE0015487, SE0015492, and SE0015497: 50% decrease (16 ounces to 8 ounces)
- SE0015488, SE0015493, and SE0015498: 25% decrease (16 ounces to 12 ounces)

The social science review and the finalized memorandum³ conclude that based on OS's experience and the currently available evidence, the decreases in product quantity in SE0015484 – SE0015498 do not cause the new tobacco products to raise different questions of public health. I concur with this conclusion.

The predicate tobacco products in SE0015484 – SE0015498 meet statutory requirements because it was determined that they are grandfathered products (i.e., were commercially marketed in the United States other than exclusively in test markets as of February 15, 2007).

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

FDA examined the environmental effects of finding the 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.

An Environmental Information Request letter should be issued to the applicant requesting the following information:

1. All of your SE Reports lack individual environmental assessments (EA); that is, one EA for each new tobacco product. FDA’s regulations implementing the National Environmental Policy Act (NEPA) of 1969 (21 CFR 25.15(a)) require that “[a]ll applications or petitions requesting agency action require the submission of an [environmental assessment] or a claim of categorical exclusion.” An EA shall include, at a minimum, brief discussions of the need for the proposed action, of alternatives as required by section 102(2)(E) of NEPA, of the environmental impacts of the proposed action and alternatives, a listing of the agencies and persons consulted, and the relevant environmental issues relating to the use and disposal of each new tobacco product. The environmental issues may be different for each product depending on product-specific information, manufacturing, and projected sales. Therefore, the environmental impact of each proposed action is evaluated for each product in an accompanying EA. Submit an EA for each SE Report, as provided in 21 CFR 25.40(a).
2. All of your SE Reports state that you would continue marketing the predicate tobacco products under different names after receiving marketing orders for the new tobacco products. However, you did not provide market volume projections for the predicate tobacco products. In your EA, you provided first- and fifth-year market volume projections for three tobacco products [EC Pipe Blue (16 oz), EC Pipe Red (16 oz), and EC Pipe Menthol (16 oz)] with the same properties and quantity of pipe tobacco as the predicate tobacco products. Clarify whether the market volume projections provided are representative of the predicate tobacco products. If not, provide the first- and fifth-year market volume projections for the predicate tobacco products. A table is included for this information; however, you can submit this information with an alternative approach if it provides the first- 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 and predicate tobacco products.

STN	Predicate Tobacco Product		First-Year Market Volume		Fifth-Year Market Volume	
	STN	Name	Number of Bags	Pounds	Number of Bags	Pounds
SE0015484	GF1907295	Light Fine Cut				
SE0015485						
SE0015486						
SE0015487						
SE0015488						
SE0015489	GF1907293	American Blend Regular Fine Cut				
SE0015490						
SE0015491						
SE0015492						
SE0015493						
SE0015494	GF1907294	American Blend Menthol Fine Cut				
SE0015495						
SE0015496						

STN	Predicate Tobacco Product		First-Year Market Volume		Fifth-Year Market Volume	
	STN	Name	Number of Bags	Pounds	Number of Bags	Pounds
SE0015497						
SE0015498						

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 SE0015484 – SE0015498, as identified on the cover page of this review.