

Technical Project Lead (TPL) Review of SE Reports

New Products Subject of this Review	
Submission tracking numbers (STNs)	SE0016771-SE0016776, see Appendix A
Common Attributes	
Submission date	July 2, 2020
Receipt date	July 2, 2020
Applicant	Alliance One Speciality Products LLC
Product manufacturer	Eastern Carolina Packaging, LLC ¹
Application type	Regular Product Quantity
Product category	Pipe Tobacco Products
Product subcategory	Pipe Tobacco Filler
Supporting FDA Memoranda Relied Upon in this Review	
All STNs	Addendum to Memorandum: Product quantity changes in Substantial Equivalence Reports (SE Reports) for statutorily regulated tobacco products (December 31, 2019).
Recommendation	
Issue Substantially Equivalent (SE) orders for the new tobacco products subject of this review.	

Technical Project Lead (TPL):

Digitally signed by Cristi L. Stark -S
Date: 2021.12.22 13:39:23 -05'00'
For

Sharyn Miller, M.P.S.
Senior Regulatory Health Project Manager
Division of Regulatory Project Management
Office of Science

Signatory Decision:

Concur with TPL recommendation and basis of recommendation

Digitally signed by Todd L. Cecil -S
Date: 2021.12.22 14:28:44 -05'00'

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

¹ A subsidiary of Alliance One Specialty Products, LLC

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1. BACKGROUND

1.1. NEW AND PREDICATE PRODUCTS

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

1.2. REGULATORY ACTIVITY

See Appendix for products.

1.3. SCOPE OF REVIEW

This review captures all compliance, regulatory, and scientific reviews completed for the new products that are the subject of this review.

Table 1. Disciplines reviewed

Discipline	Cycle 1	
	Reviewer(s)	Review Date
Regulatory	Nikole Ayala-agosto	7/8/2020
	Rida Tariq	12/22/2021
Environmental science	Chad Baisden	10/4/2021

2. COMPLIANCE REVIEW

The Office of Compliance and Enforcement (OCE) completed a review to determine whether the applicant established that the predicate product is a grandfathered product (i.e., was commercially marketed in the United States as of February 15, 2007). The OCE review dated September 10, 2021, concludes that the evidence submitted by the applicant is adequate to demonstrate that the predicate product is grandfathered and, therefore, is an eligible predicate product.

OCE also completed a review to determine whether the new 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 October 20, 2021, concludes that the new products are in compliance with the FD&C Act.

3. SCIENTIFIC REVIEW

Full scientific review was not initiated by the Office of Science (OS) because the product characteristics of the new and corresponding predicate tobacco products are identical except for the following changes in product quantity:

SE Report	New Product Quantity	Predicate Product Quantity	% Change
SE0016771	1 ounce	6 ounces	↓83
SE0016772	2 ounces	6 ounces	↓67
SE0016773	3 ounces	6 ounces	↓50
SE0016774	8 ounces	6 ounces	↑33

SE Report	New Product Quantity	Predicate Product Quantity	% Change
SE0016775	12 ounces	6 ounces	↑100
SE0016776	16 ounces	6 ounces	↑167

OS prepared memoranda² summarizing its current thinking on product quantity changes. Existing data on product quantity changes are limited and do not address the size threshold (i.e., how much of a change in product quantity) necessary to raise different questions of public health. 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 out the effect of reduced price from size on consumption or initiation. Thus, based upon the currently available science and CTP's experience in reviewing SE Reports, product quantity changes do not cause new tobacco products to raise different questions of public health. Therefore, scientific review is unnecessary.

4. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Luis Valerio, Ph.D. on October 12, 2021. The FONSI was supported by an environmental assessment prepared by FDA on October 12, 2021.

5. CONCLUSION AND RECOMMENDATION

The product characteristics of the new and corresponding predicate tobacco products is identical except for a change in product quantity:

- 83% decrease - SE0016771
- 67% decrease - SE0016772
- 50% decrease - SE0016773
- 33% increase - SE0016774
- 100% increase - SE0016775
- 167% increase - SE0016776

The OS memoranda¹ concludes that based on OS' experience and the currently available evidence, the difference in product quantity does not cause the new tobacco products to raise different questions of public health. I concur with this conclusion.

The predicate product meets statutory requirements because it was determined that it is a grandfathered product (i.e., was commercially marketed in the United States as of February 15, 2007).

The new 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 products substantially equivalent and made a finding of no significant impact.

² See memorandum on product quantity changes, dated December 7, 2017, and addendum for deemed tobacco products, dated December 30, 2019.

6. APPENDICES

Appendix A. New and predicate products

Common Attributes		
Submission date	July 2, 2020	
Receipt date	July 2, 2020	
Applicant	Alliance One Speciality Products LLC	
Product category	Pipe Tobacco Products	
Product subcategory	Pipe Tobacco Filler	
Attributes	New Product ³	Predicate Product ⁴
STN	SE0016771	GF2012316
Product name ⁵	EC Pipe Gold (1 ounce)	Pipe Tobacco Natural
Eligibility status	Not applicable	Grandfathered
Package type	Bag	Bag
Package quantity	1 ounce	6 ounces
Characterizing flavor ⁶	None	None
STN	SE0016772	GF2012316
Product name ²	EC Pipe Gold (2 ounce)	Pipe Tobacco Natural
Eligibility status	Not applicable	Grandfathered
Package type	Bag	Bag
Package quantity	2 ounces	6 ounces
Characterizing flavor ³	None	None
STN	SE0016773	GF2012316
Product name ²	EC Pipe Gold (3 ounce)	Pipe Tobacco Natural
Eligibility status	Not applicable	Grandfathered
Package type	Bag	Bag
Package quantity	3 ounces	6 ounces
Characterizing flavor ³	None	None
STN	SE0016774	GF2012316
Product name ²	EC Pipe Gold (8 ounce)	Pipe Tobacco Natural
Eligibility status	Not applicable	Grandfathered
Package type	Bag	Bag
Package quantity	8 ounces	6 ounces
Characterizing flavor ³	None	None

³ The manufacturer for the new product is Eastern Carolina Packaging, LLC, a subsidiary of Alliance One Specialty Products, LLC.

⁴ (b) (4)

⁵ Brand/sub-brand or other commercial name used in commercial distribution.

⁶ 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.

STN	SE0016775	GF2012316
Product name ²	EC Pipe Gold (12 ounce)	Pipe Tobacco Natural
Eligibility status	Not applicable	Grandfathered
Package type	Bag	Bag
Package quantity	12 ounces	6 ounces
Characterizing flavor ³	None	None
STN	SE0016776	GF2012316
Product name ²	EC Pipe Gold (16 ounce)	Pipe Tobacco Natural
Eligibility status	Not applicable	Grandfathered
Package type	Bag	Bag
Package quantity	16 ounces	6 ounces
Characterizing flavor ³	None	None
