

Technical Project Lead (TPL) Review of SE Report

New Tobacco Product Subject of this Review	
Submission tracking numbers (STNs)	SE0016643
Common Attributes	
Submission date	June 10, 2020
Receipt date	June 10, 2020
Applicant	Altria Client Services LLC
Product manufacturer	John Middleton Co.
Application type	Regular
Product category	Cigars
Product subcategory	Filtered, Sheet-Wrapped Cigar
Cross-Referenced Submission	
SE0016643	None
Supporting FDA Memoranda Relied Upon in this Review	
SE0016643	None
Recommendation	
Issue Substantially Equivalent (SE) order(s) for the new tobacco product(s) subject of this review.	

Technical Project Lead (TPL):

Digitally signed by Karen M. Coyne -S
Date: 2020.12.30 11:12:09 -05'00'

For Gloria Kulesa
Chief, Engineering Branch 2, Division of Product Science
Office of Science

Signatory Decision:

Concur with TPL recommendation and basis of recommendation

Digitally signed by Todd L. Cecil -S
Date: 2020.12.30 11:18:17 -05'00'

Todd L. Cecil, Ph.D.
Deputy Director
Office of Science

TABLE OF CONTENTS

1. BACKGROUND.....	3
1.1. NEW AND PREDICATE TOBACCO PRODUCTS	3
1.2. REGULATORY ACTIVITY.....	3
1.3. SCOPE OF REVIEW	3
2. COMPLIANCE REVIEW	3
3. SCIENTIFIC REVIEW	4
3.1. CHEMISTRY	4
3.2. ENGINEERING	4
3.3. TOXICOLOGY.....	4
3.4. MICROBIOLOGY	4
4. ENVIRONMENTAL DECISION.....	5
5. CONCLUSION AND RECOMMENDATION	5
6. APPENDICES.....	7

1. BACKGROUND

1.1. NEW AND PREDICATE TOBACCO PRODUCTS

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

1.2. REGULATORY ACTIVITY

See Appendix A for tobacco products.

FDA received one SE Report from John Middleton Co. on June 10, 2020, and subsequently issued an acceptance letter on June 17, 2020.

1.3. SCOPE OF REVIEW

This review captures all compliance and scientific reviews completed for the new tobacco product subject of this review.

Discipline	Cycle 1: Reviewer(s)	Review Date
Regulatory	Travelle Mason	6/17/2020
Chemistry	Salome Bhagan	12/7/2020 ¹
Engineering	Robert Paul Borthwick	12/2/2020
Toxicology	Shannon Dunn	12/7/2020 ²
Microbiology	David Craft	12/1/2020
Environmental Science	Gerome Burke	11/12/2020

2. COMPLIANCE REVIEW

The predicate tobacco product in SE0016643 was determined to be substantially equivalent by FDA under SE0015126. Therefore, the predicate tobacco product is an eligible predicate tobacco product.

OCE also completed a review to determine whether the new tobacco product is 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 November 20, 2020, concludes that the new tobacco product is in compliance with the FD&C Act.

¹ Addendum review was completed on December 9, 2020

² Addendum review was completed on December 15, 2020

3. SCIENTIFIC REVIEW

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

3.1. CHEMISTRY

The chemistry review concludes that the new tobacco product has different characteristics compared to the predicate tobacco product, but the differences do not cause the new tobacco product to raise different questions of public health from a chemistry perspective.

For SE0016643, the applicant provided a certification statement and stated that aside from changes in the tipping papers, there are no other differences between the new and previously found SE product. There is a 2% decrease in base tipping paper in the new tobacco product compared to the predicate tobacco product. Tipping paper is made of (b) (4). From a chemistry perspective, the use of less (b) (4) is not expected to impact smoke chemistry and therefore does not cause the new tobacco product to raise different questions of public health. There is an increase of 67% of brown inks and ink extenders. The inks and ink extenders are used on the tipping papers and are unburned materials that do not combust, volatilize, or otherwise release during normal cigar consumption and also do not come into contact with the user's mouth. Therefore, the inks and ink extenders in the new tobacco products are not expected to significantly alter the smoke chemistry compared to the predicate tobacco. The new tobacco product compared to its predicate tobacco product has a 67% (b) (4) /cigar) increase in lip release which is a small increase of 0.008% relative to the tobacco filler weight (b) (4) (cigar) of the new tobacco product, and therefore, does not cause the new tobacco product to raise different questions of public health with respect to chemistry.

Therefore, the differences in characteristics between the new and predicate tobacco products do not cause the new tobacco product to raise different questions of public health from a chemistry perspective.

3.2. ENGINEERING

The engineering review did not identify any differences in characteristics between the new and predicate tobacco products that could cause the new tobacco product to raise different questions of public health from an engineering perspective.

3.3. TOXICOLOGY

The toxicology review did not identify any differences in characteristics between the new and predicate tobacco product that could cause the new tobacco product to raise different questions of public health from a toxicology perspective.

3.4. MICROBIOLOGY

The microbiology review did not identify any differences in characteristics between the new and predicate tobacco product that could cause the new tobacco product to raise different questions of public health from a microbiology perspective.

4. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Luis Valerio, Ph.D. on December 4, 2020. The FONSI was supported by an environmental assessment prepared by FDA on December 4, 2020.

5. CONCLUSION AND RECOMMENDATION

The new and the predicate tobacco products have the following characteristics:

- increase of 67% in brown inks and ink extenders
- 67% (b) (4) /cigar) increase in lip release
- 2% decrease in base tipping paper

I concur with the conclusions of all the scientific reviews that the applicant has demonstrated that these differences in characteristics do not cause the new tobacco product to raise different questions of public health as described in Section 3.1-3.4 above. The inks and ink extenders appear on the tipping papers. The tipping papers are not burned, do not combust or volatilize during normal cigar use, and do not come into contact with the user's mouth. The 67% increase in lip release is small (0.008% relative to the tobacco filler weight) and there is less (b) (4) used in the tipping paper.

Therefore, the differences in characteristics between the new and predicate product do not cause the new tobacco product to raise different questions of public health.

The predicate tobacco product in SE0016643 was previously determined to be substantially equivalent by FDA under SE0015126, as identified in the Appendix A of this review. 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).

Comparison of the new tobacco product to the grandfathered (GF) tobacco product reveals that the new tobacco product has the following differences in characteristics:

- 1–10% decrease in (b) (4) /cigar), (b) (4) /cigar), and (b) (4) cigar)
- change in product package quantity (7 to 1)

Chemistry evaluated the decreases in tobacco blend in the new tobacco product in SE0016643 and found that the expected decreases should result in lower harmful and potentially harmful constituent smoke yields in the new tobacco product compared to the GF tobacco product. Microbiology evaluated the package quantity change and determined that the decrease would not affect product stability. Therefore, the differences in characteristics between the new and grandfathered tobacco product do not cause the new tobacco product to raise different questions of public health.

The new tobacco product is currently in compliance with the FD&C Act. I concur with these reviews and recommend that an SE order letter be issued. FDA examined the environmental effects of

finding this new tobacco product substantially equivalent and made a finding of no significant impact.

6. APPENDICES

Appendix A. New and predicate tobacco products

Common Attributes		
Submission date	June 10, 2020	
Receipt date	June 10, 2020	
Applicant	Altria Client Services LLC	
Product manufacturer	John Middleton Co.	
Product category	Cigars	
Product subcategory	Filtered, Sheet-Wrapped Cigar	
Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0016643	SE0015126
Product name	Black & Mild® FT ³	Black & Mild® FT ³
Eligibility status	Not applicable	Previously Found SE
Package type	Film ⁴	Film ⁴
Package quantity	1 Cigar	1 Cigar
Characterizing flavor	None	None
Length	110 mm	110 mm
Diameter	8.9 mm	8.9 mm
Ventilation	None	None
Tip	Filter	Filter

³ Brand/sub-brand or other commercial name used in commercial distribution.

⁴ The applicant considers polypropylene plastic wrap and film to be synonymous when identifying cigar product packaging and changed the Package Type nomenclature here to align with the examples provided in the proposed rule for Content and Format of Substantial Equivalence Reports, § 1107.18(c)(7)(iii).