

Technical Project Lead (TPL) Review of SE Reports

New Products Subject of this Review ¹	
STN	SE0019991.PD1
Common Attributes	
Submission date	September 8, 2020
Receipt date	September 8, 2020
Applicant	Starbuzz Tobacco Inc.
Product manufacturer	Starbuzz Tobacco Inc.
Application type	Regular
Product category	Waterpipe Tobacco Products
Product subcategory	Waterpipe Tobacco Filler
Cross-Referenced Submissions	
All STNs	None
Supporting FDA Memoranda Relied Upon in this Review	
All STNs	None
Recommendation	
Issue Substantially Equivalent (SE) order for the new tobacco product subject of this review.	

Technical Project Lead (TPL):

Digitally signed by Charles Feng -S
Date: 2022.06.09 10:48:52 -04'00'

Charles Feng, Ph.D.
Chemistry Branch Chief, Division of Product Science
Office of Science

Signatory Decision:

Concur with TPL recommendation and basis of recommendation

Todd L. Cecil -S Digitally signed by Todd L. Cecil -S
Date: 2022.06.09 11:11:41 -04'00'

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

¹ Product details, amendments, and dates provided in the Appendix. SE means substantial equivalence (report). STN means submission tracking number.

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1. BACKGROUND

1.1. NEW AND PREDICATE PRODUCTS

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

1.2. REGULATORY ACTIVITY

See Appendix for products and amendments.

1.3. SCOPE OF REVIEW

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

Table 1. Disciplines reviewed

Discipline	Cycle 1		Cycle 2	
	Reviewer(s)	Review Date	Reviewer(s)	Review Date
Regulatory	Crystal N. Caesar	10/30/2020	Not assigned	N/A
Chemistry	Therese C. Ku	10/12/2021	Not assigned	N/A
Engineering	Shanker Pershad	10/12/2021	Lisa M. Elias-cuadrado	4/12/2022
Toxicology	Atinuke O. Ajiboye	10/12/2021	Not assigned	N/A
Microbiology	Victoria P. Quadrini	10/12/2021	Not assigned	N/A
Environmental science	Vyomesh Patel	7/28/2021	Dilip Venugopal	4/13/2022

2. COMPLIANCE REVIEW

The Office of Compliance and Enforcement (OCE) completed review to determine whether the applicant established that the predicate product is a grandfathered product (i.e., were commercially marketed in the United States as of February 15, 2007). The OCE review dated July 19, 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 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 May 4, 2022, concludes that the new product is in compliance with the Federal Food, Drug, and Cosmetic Act (FD&C Act).

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

The chemistry review found that the only difference between the new and predicate products is in the secondary packaging material. The secondary packaging in the new product contains a tin can compared to a plastic bucket in the predicate product. Because the secondary packaging does not come into contact with the new and predicate products, this change does not impact product chemistry. Therefore, the difference in characteristics between the new and corresponding predicate products does not cause the new products to raise different questions of public health from a chemistry perspective.

3.2. ENGINEERING

The final engineering review did not identify any differences in characteristics between the new and predicate products that could cause the new 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 products that could cause the new 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 products that could cause the new 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 April 19, 2022. The FONSI was supported by an environmental assessment prepared by FDA on April 19, 2022.

5. CONCLUSION AND RECOMMENDATION

The new and the predicate products have the following characteristics:

- Secondary packaging: Replacement of plastic bucket with tin can

I concur with the conclusion of the chemistry review that the applicant has demonstrated that the difference in characteristics does not cause the new product to raise different questions of public health as described in Section 3.1 above. The only difference between the new and predicate products is in the secondary packaging material. Because the secondary packaging does not come into contact with the new and predicate products, this change does not impact the product chemistry. Therefore, the difference in characteristics between the new and corresponding predicate products does not cause the new products to raise different questions of public health.

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

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

6. APPENDICES

Appendix A. New and original products ²

Common Attributes		
Submission date	September 8, 2020	
Receipt date	September 8, 2020	
Applicant	Starbuzz Tobacco Inc.	
Product manufacturer	Starbuzz Tobacco Inc.	
Product category	Waterpipe Tobacco Products	
Product subcategory	Waterpipe Tobacco Filler	
Attributes	New Product	Predicate Product
STN	SE0019991.PD1	GF1909664
Product name	Starbuzz Exotic Christmas Mix – 50 g	Starbuzz Exotic Christmas Mix – 1 kg
Eligibility status	Not Applicable	Grandfathered
Package type	Pouch	Pouch
Package quantity	50 grams(g)	1000 g
Characterizing flavor	Christmas Mix	Christmas Mix
Additional properties	Outer Package: Jar	Outer Package: Plastic Tub

² Brand/sub-brand or other commercial name used in commercial distribution.

Appendix B. Amendments

Submission Date	Receipt Date	Amendment	Applications being amended	Reviewed	Brief Description
January 11, 2022	January 11, 2022	SE0025214	All	Yes	Response to Deficiency Letter, dated October 13, 2021.