

Technical Project Lead (TPL) Review of SE Reports

New Products Subject of this Review	
Submission tracking numbers (STNs)	SE0017151.PD1-SE0017153.PD1, SE0017155.PD1, SE0017158.PD1, SE0017162.PD1
Common Attributes	
Submission date	August 10, 2020
Receipt date	August 10, 2020
Applicant	ITG Cigars Inc.
Product manufacturer	ITG Cigars Inc.
Application type	Regular
Product category	Cigars
Product subcategory	Leaf-Wrapped Cigar
Cross-Referenced Submissions	
All STNs	None
Supporting FDA Memoranda Relied Upon in this Review	
All STNs	None
Recommendation	
Issue Substantially Equivalent (SE) orders for the new tobacco products subject of this review.	

Technical Project Lead (TPL):

Digitally signed by Charles Feng -S
Date: 2022.07.20 13:41:59 -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: 2022.07.21 15:12:38 -04'00'

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

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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 and amendments.

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		Cycle 2	
	Reviewer(s)	Review Date	Reviewer(s)	Review Date
Regulatory	Elizabeth Eydelman	8/14/2020	Not assigned	N/A
Chemistry	Therese Ku	10/20/2021	Therese Ku	5/10/2022
Engineering	ShankerPershad	10/20/2021	Cao B. Chung	4/27/2022
Toxicology	Atinuke Ajiboye	10/21/2021	Sagie Wagage	5/16/2022
Microbiology	Victoria P. Quadrini	10/21/2021	Bryan Pussler	5/16/2022
Environmental	Vyomesh Patel	10/20/2021	Vyomesh Patel	4/28/2022

2. COMPLIANCE REVIEW

The Office of Compliance and Enforcement (OCE) completed reviews to determine whether the applicant established that the predicate products are grandfathered products (i.e., were commercially marketed in the United States as of February 15, 2007). The OCE reviews dated April 19, 2022, and April 20, 2022, conclude that the evidence submitted by the applicant is adequate to demonstrate that the predicate products are grandfathered and, therefore, are eligible predicate products.

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 reviews dated June 9, 2022, conclude that the new products are in compliance with the FD&C Act.

3. SCIENTIFIC REVIEW

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

3.1. CHEMISTRY

The final chemistry review concludes that the new products have different characteristics from a chemistry perspective compared to the corresponding predicate products, but the differences do not cause the new products to raise different questions of public health from a chemistry perspective.

All the new and corresponding predicate products are composed of [REDACTED]. There are differences in the cigar (b) (4) [REDACTED] (b) (4) between the new and corresponding predicate products. However, the tobacco mass as well as (b) (4) [REDACTED] decreased by (b) (4) [REDACTED] in the new products compared to the corresponding predicate products, which would decrease the smoke yields. Overall, the differences in characteristics between the new and corresponding predicate products do not cause the new products to raise different questions of public health from a chemistry perspective.

3.2. ENGINEERING

The final engineering review concludes that the new products have different characteristics from an engineering perspective compared to the corresponding predicate products, but the differences do not cause the new products to raise different questions of public health from an engineering perspective.

For all SE Reports, cigar total weight in the new products decreased by (b) (4) [REDACTED] compared to the corresponding predicate products. There was also a decrease of (b) (4) [REDACTED] for the (b) (4) [REDACTED] between the new and predicate corresponding predicate products. These differences may impact smoke chemistry (e.g., TNC0 yields). As a result, engineering deferred to chemistry for further evaluation.

Therefore, the differences in characteristics between the new and corresponding predicate products do not cause the new products to raise different questions of public health from an engineering perspective.

3.3. TOXICOLOGY

The final toxicology review concludes that the new products have different characteristics compared to the corresponding predicate products, but the differences do not cause the new products to raise different questions of public health from a toxicology perspective.

The new products have comparable amounts of (b) (4) [REDACTED] compared to the corresponding predicate products. These changes do not raise different questions of public health from a toxicological perspective.

3.4. MICROBIOLOGY

The final microbiology review concludes that the new products have different characteristics compared to the corresponding predicate products, but the differences do not cause the new products to raise different questions of public health from a microbiology perspective.

The new and corresponding predicate products contain identical container closure system (CCS), target moisture specifications, and preservatives. (b) (4)

(b) (4) the differences are determined to be too small 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 May 19, 2022. The FONSI was supported by an environmental assessment prepared by FDA on May 19, 2022.

5. CONCLUSION AND RECOMMENDATION

The new and the predicate products have the following characteristics:

- Decreases in (b) (4)
- Decreases in (b) (4)
- Decreases in (b) (4)
- Decrease in (b) (4)
- Decrease in (b) (4)
- Decreases in (b) (4)

I concur with the conclusion of the scientific reviews that the applicant has demonstrated that the differences in characteristics do not cause the new products to raise different questions of public health as described in Sections 3.1-3.4 above. All the new and corresponding predicate products are composed of (b) (4) tobaccos. There are differences in the cigar (b) (4) between the new and corresponding predicate products. However, the tobacco mass as well as (b) (4) tobaccos decreased in the new products compared to the corresponding predicate products, which would decrease the smoke yields. There are minor differences in (b) (4) quantities. Overall, these differences are not expected to significantly impact smoke HPHC yields or stability. Therefore, the differences in characteristics do not cause the new products to raise different questions of public health.

The predicate products meet statutory requirements because they were determined that they are grandfathered products (i.e., were 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.

6. APPENDICES

Appendix A. New and predicate products

Common Attributes		
Submission date	August 10, 2020	
Receipt date	August 10, 2020	
Applicant	ITG Cigars Inc.	
Product manufacturer	ITG Cigars Inc.	
Product category	Cigars	
Product subcategory	Leaf-Wrapped Cigar	
Attributes	New Product	Predicate Product
STN	SE0017151.PD1	GF1702832
Product name	Backwoods Honey Berry Cigar Single Pouch	Backwoods Honey Berry 8pk
Eligibility status	Not applicable	Grandfathered
Package type	Foil pouch	Foil pouch
Package quantity	1 cigar	8 cigars
Characterizing flavor	Honey Berry	Honey Berry
Length	106.3 mm	107.9 mm
Diameter	10.8 mm	10.5 mm
Wrapper material	(b) (4)	(b) (4)

Attributes	New Product	Predicate Product
STN	SE0017152.PD1	GF1702829
Product name	Backwoods Honey Single Pouch	Backwoods Honey 8pk
Eligibility status	Not applicable	Grandfathered
Package type	Foil pouch	Foil pouch
Package quantity	1 cigar	8 cigars
Characterizing flavor	Honey	Honey
Length	106.3 mm	107.9 mm
Diameter	10.8 mm	10.5 mm
Wrapper material	(b) (4)	
STN	SE0017153.PD1	GF1702832
Product name	Backwoods Honey Berry Cigars 3 Pouch	Backwoods Honey Berry 8pk
Eligibility status	Not applicable	Grandfathered
Package type	Foil pouch	Foil pouch
Package quantity	3 cigars	8 cigars
Characterizing flavor	Honey Berry	Honey Berry
Length	106.3 mm	107.9 mm
Diameter	10.8 mm	10.5 mm
Wrapper material	(b) (4)	
STN	SE0017155.PD1	GF1702889
Product name	Backwoods Sweet Aromatic Cigar Single Pouch	Backwoods Aromatic 8pk
Eligibility status	Not applicable	Grandfathered
Package type	Foil pouch	Foil pouch
Package quantity	1 cigar	8 cigars
Characterizing flavor	Vanilla	Vanilla
Length	106.3 mm	107.9 mm
Diameter	10.8 mm	10.5 mm
Wrapper material	(b) (4)	

Attributes	New Product	Predicate Product
STN	SE0017158.PD1	GF1702889
Product name	Backwoods Sweet Aromatic Cigars 5 Pouch	Backwoods Aromatic 8pk
Eligibility status	Not applicable	Grandfathered
Package type	Foil pouch	Foil pouch
Package quantity	5 cigars	8 cigars
Characterizing flavor	Vanilla	Vanilla
Length	106.3 mm	107.9 mm
Diameter	10.8 mm	10.5 mm
Wrapper material	(b) (4)	
STN	SE0017162.PD1	GF1702887
Product name	Backwoods Original Cigars 5 Pouch	Backwoods Original 8pk
Eligibility status	Not applicable	Grandfathered
Package type	Foil pouch	Foil pouch
Package quantity	5 cigars	8 cigars
Characterizing flavor	None	None
Length	106.3 mm	107.9 mm
Diameter	10.8 mm	10.5 mm
Wrapper material	(b) (4)	

Appendix B. Amendments

Submission Date	Receipt Date	Amendment	Applications being amended	Reviewed	Brief Description
1/7/2022	1/7/2022	SE0025195	All	Yes	Extension request
1/19/2022	1/19/2022	SE0025220	All	Yes	Response to Deficiency Letter, dated October 22, 2021.
2/17/2022	2/17/2022	SE0025250	All	Yes	Response to Deficiency Letter, dated October 22, 2021.