



U.S. Food & Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993  
[www.fda.gov](http://www.fda.gov)

July 21, 2022

## **SUBSTANTIALLY EQUIVALENT**

ITG Cigars Inc.  
Attention: Carole Folmar, JD, Sr. Director,  
Product Integrity and Compliance, and Associate General Counsel  
420 North English Street  
Greensboro, NC 27405

**FDA Submission Tracking Numbers (STNs):** Multiple STNs, see Appendix A

Dear Carole Folmar:

We completed our review of your SE Reports<sup>1</sup> and determined that the new tobacco products are substantially equivalent to the corresponding predicate tobacco products listed in Appendix A and are in compliance with the requirements of the FD&C Act. Under the provisions of section 910 and 905(j) of the FD&C Act, you may introduce or deliver for introduction into interstate commerce the new tobacco products subject of this letter.

Our finding does not mean we “approved” the new products specified in Appendix A; therefore, you may not promote or in any way represent the new tobacco products specified in Appendix A, or the labeling, as being “approved” by FDA (see Section 301(tt) of the FD&C Act).

For information on how to fulfill the provisions of section 910(a)(4) of the FD&C Act, refer to Appendix B.

In accordance with 40 CFR 1506.6, we will make your Environmental Assessment (EA) publicly available.

All regulated tobacco products, including the tobacco products specified in Appendix A, are subject to the requirements of the FD&C Act and its implementing regulations. It is your responsibility to ensure the tobacco products specified in Appendix A complies with all applicable statutory and regulatory requirements. FDA will monitor your compliance with all applicable statutes and regulations.

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<sup>1</sup> Substantially Equivalent (SE) Reports submitted under section 905(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)

If you have any questions, please contact Kenna Randall, Regulatory Health Project Manager, at 301-796-4164 or [Kenna.Randall@fda.hhs.gov](mailto:Kenna.Randall@fda.hhs.gov).

Sincerely,

**Todd L. Cecil** Digitally signed by Todd  
L. Cecil -S  
-S Date: 2022.07.21  
15:21:12 -04'00'

Todd L. Cecil, Ph.D.  
Deputy Director  
Office of Science  
Center for Tobacco Products

**Enclosures:**

Appendix A – New and Corresponding Predicate Tobacco Products Subject of This Letter  
Appendix B – Health Information Summary

**Appendix A<sup>2</sup>**  
**New and Corresponding Predicate Tobacco Products Subject of This Letter**

<b>Common Attributes of SE Reports</b>		
Submission date	August 10, 2020	
Receipt date	August 10, 2020	
Applicant	ITG Cigars Inc.	
Product manufacturer	ITG Cigars Inc.	
Product category	Cigars	
Product subcategory	Unfiltered, Leaf-Wrapped Cigar	
Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0017151.PD1	GF1702832
Product name	Backwoods Honey Berry Cigar Single Pouch	Backwoods Honey Berry 8 Pk
Eligibility status	Not applicable	Grandfathered
Package type	Foil Pouch	Foil Pouch
Package quantity	1 Cigar	8 Cigars
Characterizing flavor	Honey Berry	Honey Berry
Diameter	10.8 millimeters (mm)	10.5 mm
Length	106.3 mm	107.99 mm
Wrapper material	Leaf Tobacco	(b) (4)
STN	SE0017152.PD1	GF1702829
Product name	Backwoods Honey Cigar Single Pouch	Backwoods Honey 8 Pk
Eligibility status	Not applicable	Grandfathered
Package type	Foil Pouch	Foil Pouch
Package quantity	1 Cigar	8 Cigars
Characterizing flavor	Honey	Honey
Diameter	10.8 mm	10.5 mm
Length	106.3 mm	107.99 mm
Wrapper material	Leaf Tobacco	(b) (4)

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

STN	SE0017153.PD1	GF1702832
Product name	Backwoods Honey Berry Cigars 3 Pouch	Backwoods Honey Berry 8 Pk
Eligibility status	Not applicable	Grandfathered
Package type	Foil Pouch	Foil Pouch
Package quantity	3 Cigars	8 Cigars
Characterizing flavor	Honey Berry	Honey Berry
Diameter	10.8 mm	10.5 mm
Length	106.3 mm	107.99 mm
Wrapper material	Leaf Tobacco	(b) (4)
STN	SE0017155.PD1	GF1702889
Product name	Backwoods Sweet Aromatic Cigar Single Pouch	Backwoods Aromatic 8 Pk
Eligibility status	Not applicable	Grandfathered
Package type	Foil Pouch	Foil Pouch
Package quantity	1 Cigar	8 Cigars
Characterizing flavor	Vanilla	Vanilla
Diameter	10.8 mm	10.5 mm
Length	106.3 mm	107.99 mm
Wrapper material	Leaf Tobacco	(b) (4)
STN	SE0017158.PD1	GF1702889
Product name	Backwoods Sweet Aromatic Cigars 5 Pouch	Backwoods Aromatic 8 Pk
Eligibility status	Not applicable	Grandfathered
Package type	Foil Pouch	Foil Pouch
Package quantity	5 Cigars	8 Cigars
Characterizing flavor	Vanilla	Vanilla
Diameter	10.8 mm	10.5 mm
Length	106.3 mm	107.99 mm
Wrapper material	Leaf Tobacco	(b) (4)
STN	SE0017162.PD1	GF1702887
Product name	Backwoods Original Cigars 5 Pouch	Backwoods Original 8 Pk
Eligibility status	Not applicable	Grandfathered
Package type	Foil Pouch	Foil Pouch
Package quantity	5 Cigars	8 Cigars
Characterizing flavor	None	None
Diameter	10.8 mm	10.5 mm
Length	106.3 mm	107.9 mm
Wrapper material	Leaf Tobacco	(b) (4)

## **Appendix B**

### Health Information Summary

Your SE Reports did not provide a summary of any health information related to the new tobacco products, required by section 910(a)(4) of the FD&C Act; however, your SE Reports stated that such information will be available upon request to any person. Consistent with the requirements of section 910(a)(4), you may wish to consider providing the following when information is requested:

- A. A copy of your final SE Reports upon which the Substantially Equivalent order was based, redacted only to the extent necessary to exclude patient identifiers and trade secret and confidential commercial information as defined in 21 CFR 20.61 and 20.63.
- B. Any research or data you have in your possession or otherwise know of specifically regarding the adverse health effects of the new tobacco products, or the following statement if such statement is accurate: “[Insert manufacturer name] does not have or know of any research or data regarding any adverse health effects specifically related to [insert tobacco product name].”

Alternatively, you may provide the following when information is requested:

- Description of the new tobacco products
- Description of the predicate tobacco products
- List of all differences in characteristics between the new and predicate tobacco products
- Summary of the evidence and scientific rationale concerning why the differences in characteristics do not raise different questions of public health
- Any research or data you have in your possession or otherwise know of regarding the adverse health effects of the new tobacco product, or the following statement if such statement is accurate: “[Insert manufacturer name] does not have or know of any research or data regarding any adverse health effects specifically related to [insert tobacco product name].”

There may be other accurate, complete, and not false or misleading ways to satisfy the requirements of section 910(a)(4) not included above. If you wish to discuss other ways to meet the requirements of section 910(a)(4), submit a meeting request to us