

**Programmatic Environmental Assessment for Marketing  
Orders for New Cigars  
Manufactured by ITG Cigars Inc.**

**Prepared by Center for Tobacco Products  
U.S. Food and Drug Administration**

March 16, 2022

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**1. Applicant and Manufacturer Information**

<b>Applicant Name:</b>	ITG Cigars Inc.
<b>Applicant Address:</b>	714 Green Valley Road Greensboro, NC 27408
<b>Manufacturer Name:</b>	ITG Cigars Inc.
<b>Product Manufacturing Addresses:</b>	(b) (4)

**2. Product Information**

**New Product Submission Tracking Numbers (STN), Names, and Original Product Names**

<b>New Product Name</b>	<b>STN</b>	<b>Original Product Name</b>
HAV-A-TAMPA Jewels Original Cigars 5pk (NW)	EX0001545/PD1	Havatampa Jewels Reg 5pk
HAV-A-TAMPA Jewels Sweet Cigars 5pk (NW)	EX0001545/PD3	Havatampa Jewels Swt 5pk

**Product Identification**

<b>Product Category</b>	Cigars
<b>Product Subcategory</b>	Unfiltered, Sheet-Wrapped Cigar
<b>Number of Products per Retail Unit</b>	Five cigars per pack
<b>Product Package</b>	The packaging materials consist of an oriented polypropylene film, within a pack, and oriented polypropylene film overwrap.

**3. The Need for the Proposed Actions**

The proposed actions, requested by the applicant, are for the Food and Drug Administration (FDA) to issue exemptions from substantial equivalence (SE) reporting for marketing orders under section 905(j)(3) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for two unfiltered, sheet-wrapped tobacco products. A tobacco product that is modified by adding or deleting a tobacco additive, or increasing or decreasing the quantity of an existing tobacco additive, may be considered for exemption from demonstrating substantial equivalence if (1) the product is a modification of another tobacco product and the modification is minor, (2) the modifications are to a tobacco product that may be legally marketed under the FD&C Act, (3) an SE Report is not necessary to ensure that permitting the tobacco product to be marketed would be appropriate for the protection of public health, (4) the modified tobacco product is marketed by the same organization as the original product, and (5) an exemption is otherwise appropriate.

The applicant wishes to introduce the new products into interstate commerce for commercial distribution in the United States. The applicant must obtain written notification that FDA has granted the products exemptions from demonstrating substantial equivalence under section 905(j)(3) before submitting an abbreviated report. Ninety days after FDA receipt of the abbreviated report, the applicant may introduce or deliver for introduction into interstate commerce for commercial distribution the new products for which the applicant has obtained exemptions from demonstrating substantial equivalence.

The new products differ from the corresponding original products due to a change in the ingredients of the cigar binder and a change in the tip reinforcing tape and the associated tip reinforcing tape adhesive. (Confidential Appendix 1).

#### **4. Alternatives to the Proposed Actions**

The no-action alternative is FDA does not issue marketing orders for the new products.

#### **5. Potential Environmental Impacts of the Proposed Actions and Alternatives – Manufacturing the New Products**

There are two manufacturing facilities specified by the applicant for the manufacturing of the new products. The first manufacturing facility is located at (b) (4) [REDACTED], outside the United States. Therefore, environmental impacts associated with manufacturing at this facility will not be discussed. The applicant stated that the manufacturing facility complies with all federal, state, and local environmental regulations.

The second manufacturing facility for the new products is located at (b) (4) [REDACTED]. The Agency considered potential impacts to resources in the environment that may be affected by manufacturing the new products at this manufacturing facility and found no significant impacts based on the Agency-gathered information and the following applicant-submitted information:

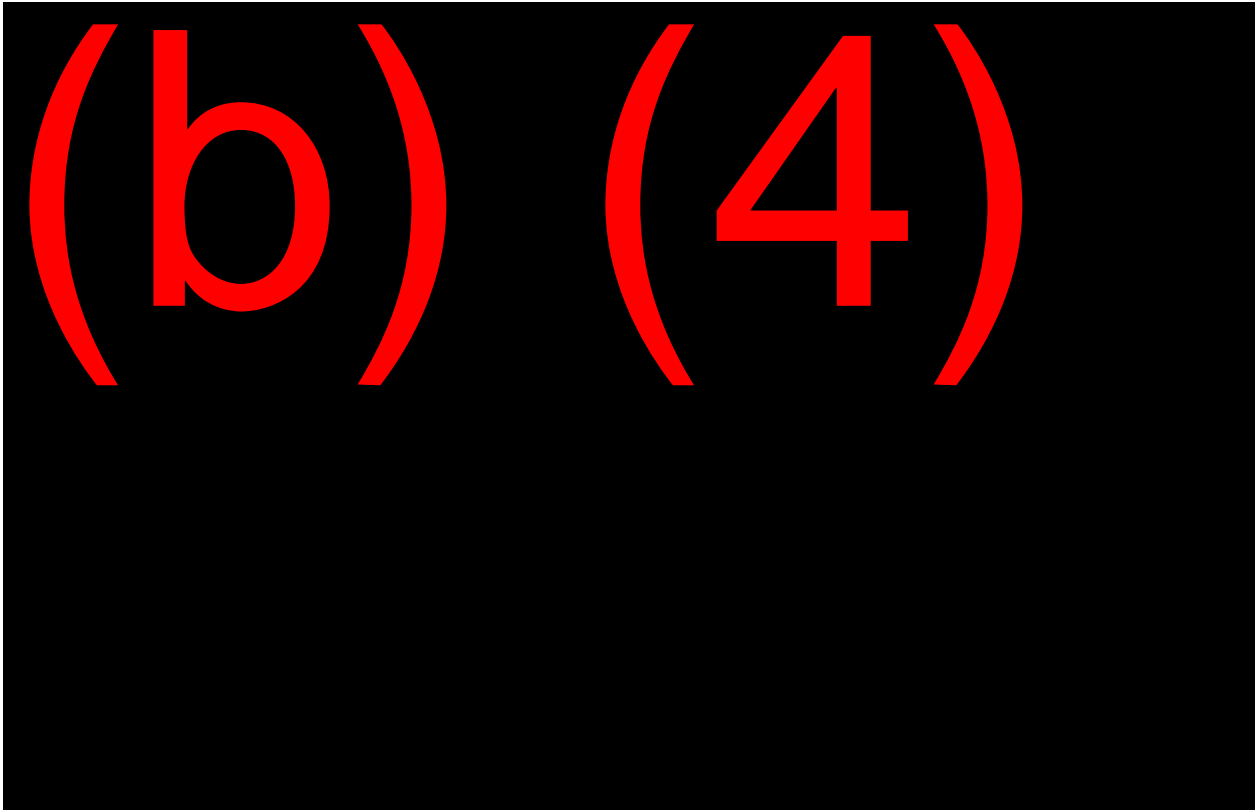
- (b) (4) [REDACTED]
- The new products will compete with similar tobacco products currently on the market.
- No facility expansion or new construction is expected due to manufacturing the new products.

##### **5.1 Affected Environment**

(b) (4) [REDACTED] The manufacturing facility is located at (b) (4) [REDACTED] (Figure 1). The facility is surrounded to the northwest by (b) (4) [REDACTED], to the north by a hospital, to the west by sport facilities and recreational parks, to the east and south by high density residential neighborhoods, and to the south by heavily forested, mountainous terrain.

The applicant stated that manufacturing the new products will not (1) require an expansion of the manufacturing facility, (2) release any new chemicals or new types of emissions into the environment, or (3) require additional environmental controls. The applicant stated that the manufacturing facility is not located within or near a habitat, critical or otherwise, of a threatened or endangered species.

Figure 1. Location of the Manufacturing Facility <sup>1</sup>



## 5.2 Air Quality

The Agency does not anticipate that manufacturing the new products will cause the release of any new chemicals or new types of emissions into the environment. The applicant stated that the materials used in manufacturing the new products are currently used in the manufacturing facility.

## 5.3 Water Resources

The Agency does not anticipate that manufacturing the new products will cause the discharge of any new chemicals into water. The applicant stated the new products will (1) not cause any new chemicals to be discharged into the water and (2) replace similar tobacco products currently manufactured at the facility.

## 5.4 Soil, Land Use, and Zoning

The Agency does not anticipate that manufacturing the new products will lead to changes in soil, land use, or zoning. The applicant stated that there will be no expected facility expansion due to manufacturing the new products. Therefore, there will be no zone change or land conversion of prime farmland, unique farmland, or farmland of statewide importance to non-agricultural use.

## 5.5 Biological Resources

The Agency does not anticipate that manufacturing the new products would jeopardize the continued existence of any listed species or result in the destruction or adverse modification of the habitat of any such species identified under the Endangered Species Act (ESA). The applicant stated that manufacturing the new product would not require expansion of the manufacturing facility. The search of the U.S. Fish and Wildlife Service (FWS) critical habitat and endangered species shows one amphibian, the golden coqui frog (*Eleutherodactylus jasper*), as threatened species and identifies five birds, six flowering plants, and one reptile as endangered species listed in Cayey, Puerto Rico or the surrounding area.<sup>2,3</sup> In addition, the applicant stated the manufacturing facility is not within or near a critical habitat or endangered animal or plant species.

## 5.6 Regulatory Compliance

The applicant stated that the manufacturing facility complies with all federal, state, and local environmental regulations. The applicant also provided the following environmental permits for the facility:

- Low emission source permit to construct and operate (b) (4) ) cigar tobacco process in accordance with provisions of the (b) (4)
- Waste water permit number (b) (4)

The Agency's search of EPA's Enforcement and Compliance History Online (ECHO) database did not reveal any violations of the environmental laws and regulations at the facility.<sup>4</sup> The applicant also stated that manufacturing the new products at the facility will comply with the ESA and the Convention on International Trade in Endangered Species of Wild Fauna and Flora.

## 5.7 Socioeconomics and Environmental Justice

No changes on socioeconomics are anticipated due to manufacturing the new products. The Agency does not anticipate any impacts on employment revenue, or taxes because the new products are intended to replace the original products.

No changes in impacts on environmental justice are anticipated. The applicant stated that the future year projections of cigarette production at the facility, including the new products will not require facility expansion. Also, as discussed, the emissions and discharges from the facility are not expected to change due to manufacturing the new products. The agency review found that the facility is not located within Native American lands.<sup>5</sup> Thus, no disproportionate impacts to environmental justice populations will occur as a result of manufacturing the new products.

## 5.8 Solid Waste and Hazardous Materials

A search in EPA's Toxic Release Inventory (TRI) database showed that in 2020, the ITG Cigars Inc. manufacturing facility released or managed 62,788 pounds of nicotine or nicotine salts (Table 1). The TRI database search did not show that the ITG Cigars Inc. manufacturing facility disposed of, treated, or

released into the environment any other reportable toxicants associated with manufacturing tobacco products. <sup>6</sup>

**Table 1. Management of Chemical Waste Associated with Manufacturing Tobacco Products at ITG Cigars Inc. in 2020 <sup>6</sup>**

Production-Related Waste Managed or Released			Chemical Mass (Pounds)
Recycled			62,635
Energy Recovery			0
Treated			0
<i>Subtotal Waste Managed</i>			62,635
On-Site Release	Air	Nicotine and Nicotine Salts	5
Off-Site Disposal/Release			148
<i>Subtotal Waste Released</i>			153
<b>Total Production-Related Waste</b>			<b>62,788</b>

The Agency does not foresee that the introduction of the new products will notably affect the current manufacturing waste generated from the facilities' production of tobacco products. The Agency anticipates the waste generated due to manufacturing the new products will be released to the environment and disposed of in landfills in the same manner as any other waste generated from any other products manufactured in the same facilities. The applicant stated that manufacturing the new products will not require any additional environmental controls for waste disposal. Therefore, no new or revised waste permit or construction of new waste management facilities are expected.

### 5.9 Floodplains, Wetlands, and Coastal Zones

The applicante stated that there will be no facility expansion due to manufacturing the new products and the applicant did not propose any land disturbance; therefore, there will be no effects on floodplains, wetlands, or coastal zones.

### 5.10 Impacts of the No-Action Alternative

The environmental impacts of the no-action alternative will not change the existing condition of manufacturing at the listed facility, as many similar tobacco products will continue to be manufactured.

## 6. Potential Environmental Impacts of the Proposed Actions and Alternatives – Use of the New Products

The Agency evaluated potential impacts of the new products' use to resources in the environment and found no significant impacts based on Agency-gathered information and the applicant's submitted information. Included in the information that the Agency considered were projected first- and fifth-year market volumes and documented cigar use in the United States (Confidential Appendix 2 and Figure 1).

## 6.1 Affected Environment

The affected environment includes human and natural environments in the United States because the marketing orders will allow for the introduction of the new products into interstate commerce.

## 6.2 Air Quality

The impact from use of combusted tobacco products includes exposure to secondhand smoke (SHS) produced from burned cigars, cigarettes, cigarillos and pipes. Particles emitted by smoking might remain on surfaces, be re-emitted back into the gas phase, or react with oxidants and other compounds in the environment to yield secondary pollutants, thirdhand smoke (THS). These pollutants coexist in a mixture in the environment alongside SHS. <sup>7,8</sup>

There is no safe level of exposure to SHS. <sup>9,10</sup> Even low levels of SHS can harm children and adults in many ways, including the following:

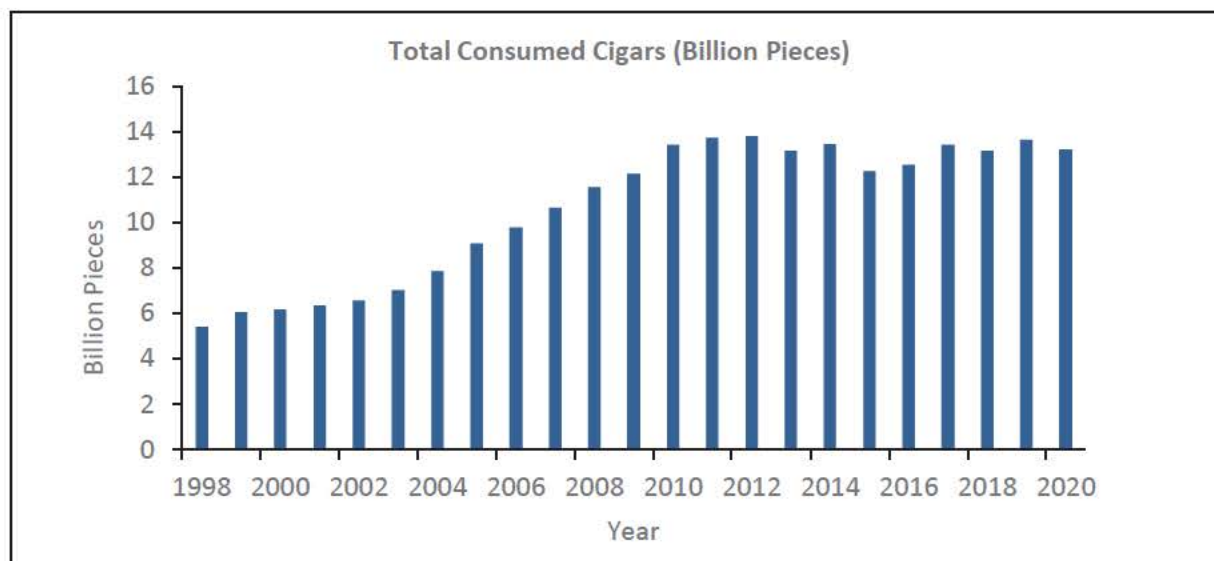
- The U.S. Surgeon General estimates that living with a smoker increases a nonsmoker's chances of developing lung cancer by 20-30%. <sup>11</sup>
- Exposure to SHS increases school children's risk for ear infections, lower respiratory illnesses, more frequent and more severe asthma attacks, and slowed lung growth. Such exposure can cause coughing, wheezing, phlegm, and breathlessness. <sup>9,10</sup>
- SHS causes more than 40,000 deaths a year. <sup>11</sup>

The consumption of cigars in the United States increased significantly from 1997 to 2011. Since 2011 through 2020, the trend of cigar usage has stabilized with a minor decrease overall, per the U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) Statistical Release reports (Figure 1). <sup>12</sup> In combination with declines in use of other tobacco products, it is likely that this is responsible for the decline in SHS exposure observed in several studies that evaluated the levels of SHS exposure in children and nonsmokers living in homes of smokers. <sup>13,14</sup>

Despite the considerable ethnic and racial disparities in SHS exposure in vulnerable populations, data from the National Health and Nutrition Examination Survey showed a decline in SHS exposure from 1999-2000 to 2011-2012 with the highest prevalence of exposure among non-Hispanic subpopulations (46.8%), compared to Mexican Americans (23.9%) and non-Hispanic whites (21.8%) in 2011-2012. <sup>13</sup> There were also significant declines in SHS exposure prevalence noted in 2000 and 2010 National Health Interview Survey Cancer Control Supplements. Exposure to SHS declined in Hispanics from 16.3% in 2000 to 3.1% in 2010, non-Hispanic Asians from 13.4% in 2000 to 3% in 2010, and non-Hispanic blacks from 31.2% in 2000 to 11.5% in 2010, as compared to exposures in non-Hispanic whites, which declined from 25.8% in 2000 to 9.7% in 2010. <sup>14</sup>



Figure 1. Use of Cigars in the United States, 1997 – 2020.



As of December 2020, 28 states and the District of Columbia had implemented comprehensive smoke-free laws.<sup>15</sup> Such laws are expected to reduce the levels of non-users' exposure to SHS and THS.

The Agency does not anticipate new chemicals will be released into the environment as a result of use of the new products, relative to chemicals released into the environment due to use of other cigars already on the market. The applicant states that (1) the combustion products from the new products will be released in the same manner as the combustion products of other marketed cigars; (2) the new products are expected to compete with other currently marketed cigars; and (3) ingredients in the new products are used in other currently marketed tobacco products.

### 6.3 Environmental Justice

No new emissions are expected due to use of the new products. Therefore, there will be no new disproportionate impacts on minority or low-income populations.

### 6.4 Impacts from No-Action Alternative

The environmental impacts of the no-action alternative will not change the existing condition of use of cigars, as many similar tobacco products will continue to be used in the United States.

## 7. Potential Environmental Impacts of the Proposed Actions and Alternatives – Disposal of the New Products

The Agency considered potential impacts of the new products' disposal to resources in the environment. Based on TTB data, which shows relatively stable rates of cigar use in the United States since 2010,<sup>12</sup> and the applicant's submitted information, including market volume projections for the new products (Confidential Appendix 2), the Agency found no significant impacts.

## **7.1 Affected Environment**

The affected environment includes human and natural environments in the United States because the marketing orders will allow for the new products to be sold to consumers and be disposed of in the United States.

## **7.2 Air Quality**

The Agency does not anticipate disposal of the new products or the packaging material will lead to the release of new or increased chemicals into the air.

No changes in air quality are anticipated from disposal of the cigar butts of the new products. The chemicals in the new products' cigar butts are commonly used in other currently marketed cigars. Therefore, the fate and effects of any materials emitted into the air from disposal of the new products are anticipated to be the same as any materials from other cigars disposed of in the United States.

No changes in air quality from disposal of the new products' package materials will be expected because the paper and plastic components of the packages are more likely to be recycled, or at least a portion of the packaging waste is likely to be recycled and the waste generated due to disposal of the new products' packaging is a minuscule portion of the municipal solid waste in the United States<sup>16</sup> per FDA's experience in evaluating the packaging waste generated from cigars.

## **7.3 Water Resources**

The Agency does not anticipate any new impacts on water resources due to disposal of the cigar butts and packaging from the new products because the chemicals in the new products are used in currently marketed cigars. Furthermore, the new products will compete with other cigars currently on the market and will replace the original product.

## **7.4 Biological Resources**

The proposed action is not expected to change the continued existence of any endangered species or result in the destruction or adverse modification of the habitat of any such species, as prohibited under the U.S. Endangered Species Act (ESA) because: (1) disposal of new products will be similar to currently marketed similar products in the United States, and (2) there will be no anticipated increase in cigar disposal because the new products are anticipated to replace and compete with similar products.

## **7.5 Solid Waste**

Environmental impacts from cigar litter are not well studied and potentially pose similar environmental risks as cigarette butts, which can persist in the environment.<sup>17</sup> Like cigarettes, compounds in cigar butts can leach into water, potentially threatening human health and the environment, especially in aquatic and marine ecosystems.<sup>18</sup> The environmental toxicity of air emissions from cigar butts is not well studied, but emissions might resemble those from cigarette butts that are influenced by environmental conditions, chemicals in the butts, brand, length, filter material, types of tobacco, ingredients in the cigarette tobacco filler, number of puffs, and the mass transfer behavior of combustion products along the cigarette.<sup>19</sup>

The Agency does not foresee the introduction of the new products will notably affect current waste generated from all cigars. The applicant stated that the waste generated due to the disposal of the new products will be handled in the same manner as waste generated from other cigars in the United States.

## **7.6 Socioeconomics and Environmental Justice**

The Agency does not anticipate changes in impacts on socioeconomic conditions or environmental justice from disposal of the new products. The waste generated due to disposal of the new products will be handled in the same manner as the waste generated from disposal of other cigars in the United States. No new emissions are expected due to disposal of the new products. Therefore, there will be no disproportionate impacts on minority or low-income populations.

## **7.7 Impacts from No-Action Alternative**

The environmental impacts of the no-action alternative will not change the existing condition of disposal of cigar and cigar packaging, as many other similar products will continue to be disposed of in the United States.

## **8. List of Preparers**

The following individuals were primarily responsible for preparing and reviewing this programmatic environmental assessment:

### ***Preparer:***

Chad Baisden, MS, Center for Tobacco Products

Education: MS in Natural Resources

Experience: Six years in various scientific activities

Expertise: Environmental risk assessment, public risk assessment, regulatory compliance

### ***Reviewer:***

Shannon K. Hanna, Ph.D., Center for Tobacco Products

Education: Ph.D. in Environmental Science and Management

Experience: Six years in environmental science, three years in toxicology

Expertise: Ecotoxicology of new substances and materials, bioaccumulation of chemicals including heavy metals, soil/sediment and water quality

## **9. A Listing of Agencies and Persons Consulted**

Not applicable.

## **10. References**

1. (b) (4)

(b) (4)

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**Confidential Appendix 1: Modifications: New Products as Compared with the Corresponding Original Products**

STN	Modification
EX0001545/PD1	<ul style="list-style-type: none"> <li>• Deletion of the complex purchased ingredient (b) (4) and the addition of a reduced amount of (b) (4) in the cigar binder</li> <li>• Deletion of the tip reinforcing tape and the associated tip reinforcing tape adhesive and the addition of the tip adhesive (b) (4)</li> </ul>
EX0001545/PD3	<ul style="list-style-type: none"> <li>• Deletion of the complex purchased ingredient (b) (4) the addition of a reduced amount of (b) (4) the cigar binder</li> <li>• Deletion of the tip reinforcing tape and the associated tip reinforcing tape adhesive and the addition of the tip adhesive (b) (4)</li> </ul>

**Confidential Appendix 2: Current Market Volume for the Original Products, First- and Fifth-Year Market Volume Projections for the New Products**

First- and fifth-year market volume projections of the new products were compared to the total forecasted use of cigars in the United States.\* The projected use of the new products in the first- and fifth-year of marketing after marketing orders are issued account for about (b) (4) respectively, of the forecasted cigar use in the United States. The applicant stated that the new products will not be commercially marketed simultaneously with the original products.

STN	Projected Market Volume			
	First-Year		Fifth-Year	
	New Product (Number of Cigars)	New Product as a Percent of Total Cigars Used <sup>†</sup>	New Product (Number of Cigars)	New Product as a Percent of Total Cigars Used <sup>†</sup>
EX0001545/PD1	(b) (4)			
EX0001545/PD3				
<b>Total</b>				

\* The Agency used historical data regarding total use of cigars from 1997 to 2020 to mathematically estimate the total number of cigars used in the United States. Using the best-fit trend line with an R<sup>2</sup> value of 0.9287, the forecasted number of cigars that will be used in the United States is estimated at (b) (4) in the fifth year of marketing the new products.

<sup>†</sup> Projected Market Occupation of the New Product in the United States (%) =  $\frac{\text{Projected Market Volume of the New Product (cigar pieces)}}{\text{Projected Use of Cigars in United States (cigar pieces)}} \times 100$