

**Programmatic Environmental Assessment for Marketing  
Orders for New Cigarettes Manufactured by ITG Brands, LLC**

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

November 15, 2019

**Table of Contents**

**1. Applicant and Manufacturer Information .....3**

**2. Product Information .....3**

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

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

**5. Potential Environmental Impacts of the Proposed Actions and Alternatives – Manufacturing the New Products .....4**

    5.1 Affected Environment..... 4

    5.2 Air Quality ..... 5

    5.3 Water Resources..... 6

    5.4 Soil, Land Use, and Zoning ..... 6

    5.5 Biological Resources ..... 6

    5.6 Regulatory Compliance ..... 6

    5.7 Socioeconomics and Environmental Justice ..... 7

    5.8 Solid Waste and Hazardous Materials ..... 7

    5.9 Floodplains, Wetlands, and Coastal Zones ..... 7

    5.10 Cumulative Impacts ..... 7

    5.11 Impacts of the No-Action Alternative ..... 7

**6. Potential Environmental Impacts of the Proposed Actions and Alternatives – Use of the New Products .....8**

    6.1. Affected Environment..... 8

    6.2. Air Quality ..... 8

    6.3. Environmental Justice..... 8

    6.4. Cumulative Impacts ..... 8

    6.5. Impacts of the No-Action Alternative ..... 10

**7. Potential Environmental Impacts of the Proposed Actions and Alternatives – Disposal of the New Products .....10**

    7.1. Affected Environment..... 10

    7.2. Air Quality ..... 10

    7.3. Biological Resources ..... 10

    7.4. Water Resources..... 11

    7.5. Solid Waste ..... 11

    7.6. Socioeconomics and Environmental Justice ..... 11

    7.7. Cumulative Impacts ..... 11

    7.8. Impacts of the No-Action Alternative ..... 12

**8. List of Preparers.....12**

**9. A Listing of Agencies and Persons Consulted .....12**

**10. References.....12**

**CONFIDENTIAL APPENDIX 1. Modifications: New Products as Compared with the Corresponding Original Products .....15**

**CONFIDENTIAL APPENDIX 2. Market Volumes for the New and Corresponding Original Products and Percentage of Cigarette Use in the United States Projected to be Attributed to the New Products .....16**

### 1. Applicant and Manufacturer Information

<b>Applicant Name:</b>	ITG Brands, LLC
<b>Applicant Address:</b>	714 Green Valley Road Greensboro, NC 27408-7018
<b>Manufacturer Name:</b>	ITG Brands, LLC
<b>Product Manufacturing Location:</b>	2525 East Market Street Greensboro, NC 27401

### 2. Product Information

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

New Product Name	STN	Original Product Name
Salem 100's Box	EX0000791	Salem 100's Box
Salem Box	EX0000792	Salem Box
Salem Gold 100's Box	EX0000793	Salem Gold 100's Box
Salem Gold Box	EX0000794	Salem Gold Box
Salem Silver 100's Box	EX0000795	Salem Silver 100's Box
Salem Silver Box	EX0000796	Salem Silver Box
Salem Slim 100's Box	EX0000797	Salem Slim 100's Box

#### Product Identification

<b>Product Category:</b>	Cigarette
<b>Product Subcategory:</b>	Combusted filtered
<b>Product Number per Retail Unit:</b>	Twenty cigarettes per pack with ten packs per carton.
<b>Product Package:</b>	The packaging material consists of a foil inner liner, inner frame, box, film overlap, and carton.

### 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 seven combusted, filtered cigarettes. 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 tobacco 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 original products are previously found exempt from demonstrating substantial equivalence. The new products are made by modifying the corresponding original products. These modifications are to the ingredients in the cigarette paper (Confidential Appendix 1).

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

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

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

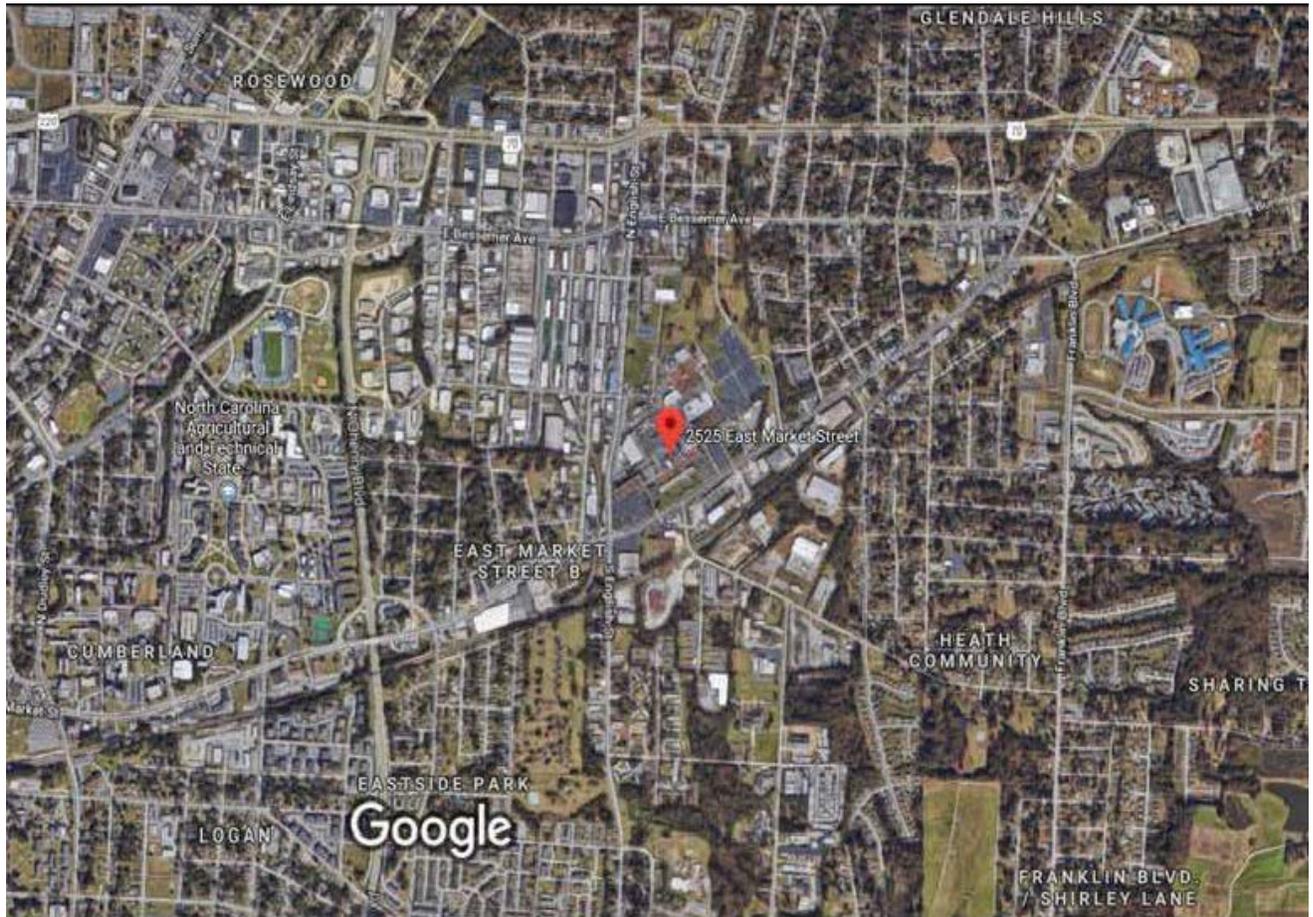
The Agency considered potential impacts to resources in the environment that may be affected by manufacturing the new products and found no significant impacts based on the Agency-gathered information and the following applicant-submitted information:

- Components of the new products are commonly used in other products manufactured at the facility.
- The new products are intended to compete with and eventually replace similar tobacco products currently manufactured at the facility.
- No facility expansion or new construction is expected due to manufacturing the new products.
- The introduction of materials to the environment would not change or exceed the allowed quantities under the facility's air and wastewater permits.

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

The affected environment includes human and natural environments surrounding the facility. The new products would be manufactured at the address listed in section 1 of this document (Figure 1).

**Figure 1. Location of the Manufacturing Facility**



Imagery ©2019 Google, Map data ©2019 Google 1000 ft

The new product would be manufactured at 2525 East Market Street, Greensboro, NC 27401 in Guilford County. The total land area of Guildford county is approximately 650 square miles with a population of around 490,000, and it is located near the eastern coastal region (Figure 1). The manufacturing facility is in a mixed-use area. There is an apartment complex beyond the facility’s parking lot to the east, a county highway patrol and driver’s license office to the southeast, retail and industrial facilities across a five-lane road to the south, a series of industrial operations and a gas station across a four-lane road to the west, and an auto repair facility and a row of single-family homes to the north (Google Maps, 2019).

A riverine wetland (within the Cape Fear River basin, HUC 12-030300020105) runs north to south on the property beyond the parking lot near the eastern edge (EPA, 2019a). Where no foliage obscures the aerial imagery, the channel appears to be one to two feet in width with several segments in culverts under roadways.

## **5.2 Air Quality**

The Agency does not anticipate that manufacturing the new products would cause the release of any new chemicals or new type of emissions into the environment. The applicant stated that manufacturing

the new products is not expected to result in changes in air emissions or require any additional environmental controls for air emissions.

### **5.3 Water Resources**

The Agency does not anticipate that manufacturing the new products would cause the discharge of any new chemicals into water. The new products are intended to 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 would lead to changes in soil, land use, or zoning. The applicant stated that there would be no expected facility expansion or new construction due to manufacturing the new products. Therefore, there would 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 product 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. The applicant stated that there are no plans to expand the facility. The facility is in a developed area with little undisturbed natural habitat identified on aerial imagery (Google Maps, 2019).

The U.S. Fish and Wildlife Service (FWS) identifies the following listed species as being present in Guilford County (FWS, 2018):

- Bald eagle (*Haliaeetus leucocephalus*), protected under the Bald and Golden Eagle Protection Act.
- Cape Fear shiner (*Notropis mekistocholas*), endangered.
- Roanoke logperch (*Percina rex*), endangered.
- Atlantic pigtoe (*Fusconaia masoni*), proposed for listing as threatened.
- Schweinitz's sunflower (*Helianthus schweinitzii*), endangered
- Small whorled pogonia (*Isotria medeoloides*), threatened.

The limited riverine wetland along the eastern boundary of the site may harbor transient migratory birds and provide habitat for non-sensitive species adapted to high levels of human activity.

Because the proposed actions do not require expansion of the manufacturing facility, and the listed species are not found in the immediate vicinity of the facility, there would be no impacts to protected species or their potential habitat.

### **5.6 Regulatory Compliance**

The applicant stated that the manufacturing facility complies with all federal, state, and local environmental regulations. The applicant provided copies of the facility's air, storm water, and wastewater permits and stated that they also comply with applicable solid and hazardous waste regulations.

The Agency's search for the manufacturing facility in the Environmental Protection Agency's Enforcement and Compliance History Online database did not reveal any violations of the environmental laws and regulations in 2018 (EPA, 2019b).

The applicant stated that the proposed action would neither jeopardize the continued existence of any endangered species, nor result in the destruction or adverse modification of the habitat of any such species identified under the Endangered Species Act 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 similar tobacco products currently manufactured at the facility.

No significant environmental impacts have been identified from manufacturing the new product; therefore, there would be no disproportionate impacts to environmental justice (low-income, minority, or other special) populations.

#### **5.8 Solid Waste and Hazardous Materials**

The Agency does not foresee that the introduction of the new products would notably affect the current manufacturing waste generated from the facility production of all combusted, filtered cigarettes. The Agency anticipates the waste generated due to manufacturing the new products would 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 facility. Therefore, no new or revised waste permit or construction of new waste management facility is expected.

#### **5.9 Floodplains, Wetlands, and Coastal Zones**

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

#### **5.10 Cumulative Impacts**

The applicant stated that the introduction of materials to the environment would not change or exceed the allowed quantities under the facility's air and wastewater permits, the new products would be manufactured in a similar manner as the original products, and no facility expansion is required. Therefore, the Agency does not anticipate any cumulative impacts from manufacturing the new products.

#### **5.11 Impacts of the No-Action Alternative**

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

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

The Agency considered potential impacts to resources in the environment that could be affected by use of the new products and found no significant impacts based on Agency-gathered information and the applicant's submitted information. Included in the information the Agency considered were the projected market volumes for the new products and the documented decline in cigarette use in the United States.

### **6.1. Affected Environment**

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

### **6.2. Air Quality**

The Agency does not anticipate that new chemicals would 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 cigarettes already on the market because (1) the combustion products from the new products would be released in the same manner as the combustion products of the original products and any other marketed cigarettes; (2) the new products are expected to compete with, or replace, other currently marketed cigarettes; and (3) the 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 would be no disproportionate impacts on minority or low-income populations.

### **6.4. Cumulative Impacts**

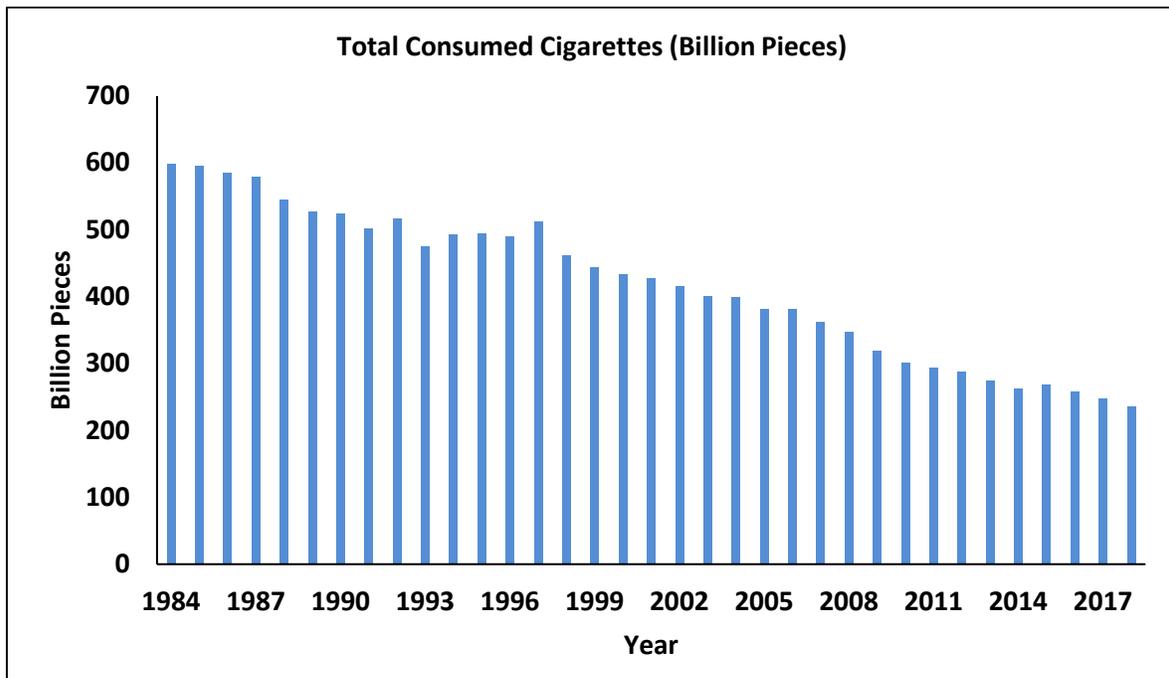
The impacts from use of combusted tobacco products include exposure to secondhand smoke (SHS) produced from burned cigarettes. Particles emitted by smoking may remain on surfaces, be re-emitted back into the gas phase, or react with oxidants and other compounds in the environment to yield secondary pollutants, thirdhand smoke (THS). These pollutants coexist in mixtures in the environment alongside SHS (Burton, 2011; Matt et al., 2011).

There is no safe level of exposure to SHS (U.S. Department of Health and Human Services, 2006a and 2006b). 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 to 30% (U.S. Department of Health and Human Services, 2014).
- 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. It can cause coughing, wheezing, phlegm, and breathlessness (U.S. Department of Health and Human Services, 2006a and 2006b).
- SHS causes more than 40,000 deaths a year (U.S. Department of Health and Human Services, 2014).

However, the use of cigarettes in the United States is declining, per the U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) Statistical Release reports, (Figure 2).<sup>1</sup> This likely 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 (Homa et al., 2015; Yao et al., 2016). 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 (Homa et al., 2015). There were also significant declines in SHS exposure prevalence noted in the 2000 and 2010 National Health Interview Survey Cancer Control Supplements. SHS exposure 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 (Yao et al., 2016).

**Figure 2. Use of Cigarettes in the United States, 1984 – 2018**



As of March 2019, 28 states and the District of Columbia have implemented comprehensive smoke-free laws (American Lung Association, 2019). Such laws are expected to reduce the levels of non-user exposure to SHS and THS.

<sup>1</sup> U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) statistical data available at: <https://www.ttb.gov/tobacco/tobacco-stats.shtml>. Accessed March 7, 2019.

## **6.5. Impacts of the No-Action Alternative**

The environmental impacts of the no-action alternative would not change the existing condition of use of cigarettes, as many similar tobacco products would 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 to resources in the environment that may be affected by disposal of the new products. Based on publicly available information such as the documented continuous decline of cigarette use in the United States, and the applicant's submitted information, including market volume projections for the new products, 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 would allow for the new tobacco products to be sold to consumers in the United States.

### **7.2. Air Quality**

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

No changes in air quality are anticipated from disposal of the cigarette butts of the new products. The chemicals in the new products' cigarette butts are commonly used in other currently marketed cigarettes. Because the new products are anticipated to compete with or replace other currently marketed cigarettes, the butt waste generated from the new products would replace the same type of waste. 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 cigarettes disposed of in the United States.

No changes in air quality from disposal of the new products' package materials would be expected because (1) 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, (2) the packaging materials are commonly used in the United States, and (3) the waste generated due to disposal of the new products' packaging is a minuscule portion of the municipal solid waste per FDA's experience in evaluating the packaging waste generated from cigarettes.

### **7.3. Biological Resources**

The proposed actions are 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. EPA. Although disposal of smoldering cigarettes has been implicated in many fire incidents,<sup>2,3</sup> the new products are not expected to change the fire frequency as (1) the disposal of the new products would be the same as the disposal of cigarettes that are currently marketed in the United States, and (2) there would be no anticipated increase in number of cigarettes being disposed of as the new products are anticipated to replace similar marketed cigarettes.

#### **7.4. Water Resources**

No changes in any impacts on water resources are expected due to disposal of the cigarette butts and packaging from the new products because the chemicals in the new products would be used in currently marketed cigarettes. Furthermore, the new products would compete with or replace other cigarettes currently on the market.

#### **7.5. Solid Waste**

The Agency does not foresee the introduction of the new products would notably affect the current cigarette butt and packaging waste generated from all combusted, filtered cigarettes. The waste generated due to disposal of the new products would be in the same manner as any other waste generated from any other combusted, filtered cigarettes marketed in the United States. The number of cigarette butts generated would be equivalent to the market projections (Confidential Appendix 2) and a portion of those would be littered.

#### **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 would be handled in the same manner as the waste generated from disposal of other cigarettes in the United States. No new emissions are expected due to disposal of the new products; therefore, there would be no disproportionate impacts on minority or low-income populations.

#### **7.7. Cumulative Impacts**

A major existing environmental consequence of the use of the new products, as well as other conventional cigarettes, is littering of discarded cigarette filters or butts (Novotny and Zhao, 1999). Cigarette butts are among the most common forms of litter found on beaches (Claereboudt, 2004; Smith et al., 1997), near streams, night clubs (Becherucci and Pon, 2014), bus stops (Wilson et al., 2014), roads, and streets (Healton et al., 2011; Patel et al., 2013). Cigarette butts have been found at densities averaging more than four cigarette butts per meter squared of urban environments (Seco Pon and Becherucci, 2012).

Compounds in cigarette butts can leach out into water, potentially threatening human health and the environment, especially marine ecosystems (Kadir and Sarani, 2015). The environmental toxicity of cigarette butts due to air emissions is not well studied. The chemicals in cigarette butts can be the

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<sup>2</sup> National Fire Protection Association. The smoking-material fire problem. Available at: <https://www.nfpa.org/News-and-Research/Fire-statistics-and-reports/Fire-statistics/Fire-causes/Smoking-Materials>. Accessed September 16, 2019.

<sup>3</sup> UC Davis Health News. Available at: <https://www.ucdmc.ucdavis.edu/publish/news/newsroom/2763>. Accessed October 7, 2019.

original chemicals in the unsmoked cigarettes or the pyrolysis and distillation products deposited in the cigarette butts. Airborne emissions from cigarette butts after disposal depend on the environmental conditions and the chemicals in the butts. These emissions can be influenced by several factors, such as the cigarette brand, cigarette length, filter material, types of tobacco, ingredients in the cigarette and tobacco filler, number of puffs, and the mass transfer behavior of combustion products along the cigarette.<sup>4</sup>

However, the cumulative impacts from cigarette butts are declining because the use of cigarettes in the United States is declining.

## **7.8. Impacts of the No-Action Alternative**

The environmental impacts of the no-action alternative would not change the existing condition of disposal of cigarettes and cigarette packaging, as many other similar tobacco products would 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:***

William E. Brenner, B.S., Center for Tobacco Products

Education: B.S. in Biology

Experience: Five years in various scientific activities

Expertise: NEPA analysis, environmental risk assessment, air quality analysis, archaeological and archival preservation

### ***Reviewer:***

Hoshing W. Chang, Ph.D., Center for Tobacco Products

Education: M.S. in Environmental Science and Ph.D. in Biochemistry

Experience: Ten years in FDA-related NEPA review

Expertise: NEPA analysis, environmental risk assessment, wastewater treatment

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

Not applicable.

## **10. References**

American Lung Association. 2019. Smokefree Air Laws. Available at: <http://www.lung.org/our-initiatives/tobacco/smokefree-environments/smokefree-air-laws.html> (updated March 8, 2019). Accessed September 16, 2019.

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<sup>4</sup> NIST Technical Report 8147 available at: <http://dx.doi.org/10.6028/NIST.IR.8147>. Accessed October 7, 2019.

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Disease Prevention and Health Promotion, Coordinating Center for Health Promotion, Office on Smoking and Health. Atlanta, GA.

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Wilson N, Oliver J, Thomson G. Smoking close to others and butt littering at stops: Pilot observational study. *PeerJ*. 2014;2.

Yao T, Sun HY, Wang Y, Lightwood J, Max W. Sociodemographic differences among U.S. children and adults exposed to secondhand smoke at home: National Health Interview Surveys 2000 and 2010. *Public Health Reports*. 2016;131:357-366.

**CONFIDENTIAL APPENDIX 1. Modifications: New Products as Compared with the Corresponding Original Products**

STN	Modification
EX0000791- EX0000797	<ul style="list-style-type: none"><li data-bbox="431 369 1338 430">• Deletion of complex banding solution in the fire standard compliant (FSC) cigarette paper and the addition of a different banding solution.</li></ul>

**CONFIDENTIAL APPENDIX 2. Market Volumes for the New and Corresponding Original Products and Percentage of Cigarette Use in the United States Projected to be Attributed to the New Products**

First- and fifth-year market volume projections of the new products were compared to the total forecasted use of cigarettes in the United States.<sup>5</sup> 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) and (b) (4) respectively, of the forecasted cigarette use in the United States. The applicant stated that they will not market the original products and the new products simultaneously after the marketing orders for the new products are issued as the new products will replace the original products.

STN	Projected Market Volume			
	First Year		Fifth Year	
	New Product (Cigarettes)	New Product as a Percent of Total Cigarettes Used <sup>6</sup>	New Product (Cigarettes)	New Product as a Percent of Total Cigarettes Used <sup>7</sup>
EX0000791	(b) (4)			
EX0000792				
EX0000793				
EX0000794				
EX0000795				
EX0000796				
EX0000797				
<b>Total</b>				

<sup>5</sup> The Agency used historical data regarding total use of cigarettes from 2002 to 2018 to mathematically estimate the total number of cigarettes used in the United States. Using the best-fit trend line with an R<sup>2</sup> value of 0.9814, the forecasted number of cigarettes that would be used in the United States is estimated at 228.657 billion cigarettes in the first year and 205.021 billion cigarettes in the fifth year of marketing the new products.

<sup>6</sup> Projected Market Occupation of the New Products in the United States (%) =  $\frac{\text{Projected Market Volume of the New Products (cigarette pieces)}}{\text{Projected Use of Cigarettes in United States (cigarette pieces)}} \times 100$

<sup>7</sup> Ibid.