

**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**

April 15, 2020

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1. Applicant and Manufacturer Information

Applicant Name:	ITG Brands, LLC
Applicant Address:	714 Green Valley Road Greensboro, NC 27408
Manufacturer Name:	ITG Brands, LLC
Product Manufacturing Location:	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
Maverick Box	EX0000997	Maverick Box
Maverick Box 100s	EX0000998	Maverick Box 100s
Maverick Gold Box 100s	EX0001000	Maverick Lights Box 100s
Maverick Menthol Box 100s	EX0001001	Maverick Menthol Box 100s
Maverick Menthol Box	EX0001002	Maverick Menthol Box
Maverick Menthol Gold Box 100s	EX0001003	Maverick Menthol Lights Box 100s

Product Identification

Product Category:	Cigarette
Product Subcategory:	Combusted, filtered
Product Number per Retail Unit:	Twenty cigarettes per pack with ten packs per carton.
Product Package:	The packaging material consists of a foil inner liner, paper label, paper closure, 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 six 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 new products are made by modifying the corresponding original products. These modifications are to the tipping paper base paper and ingredients in the tipping paper ink (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

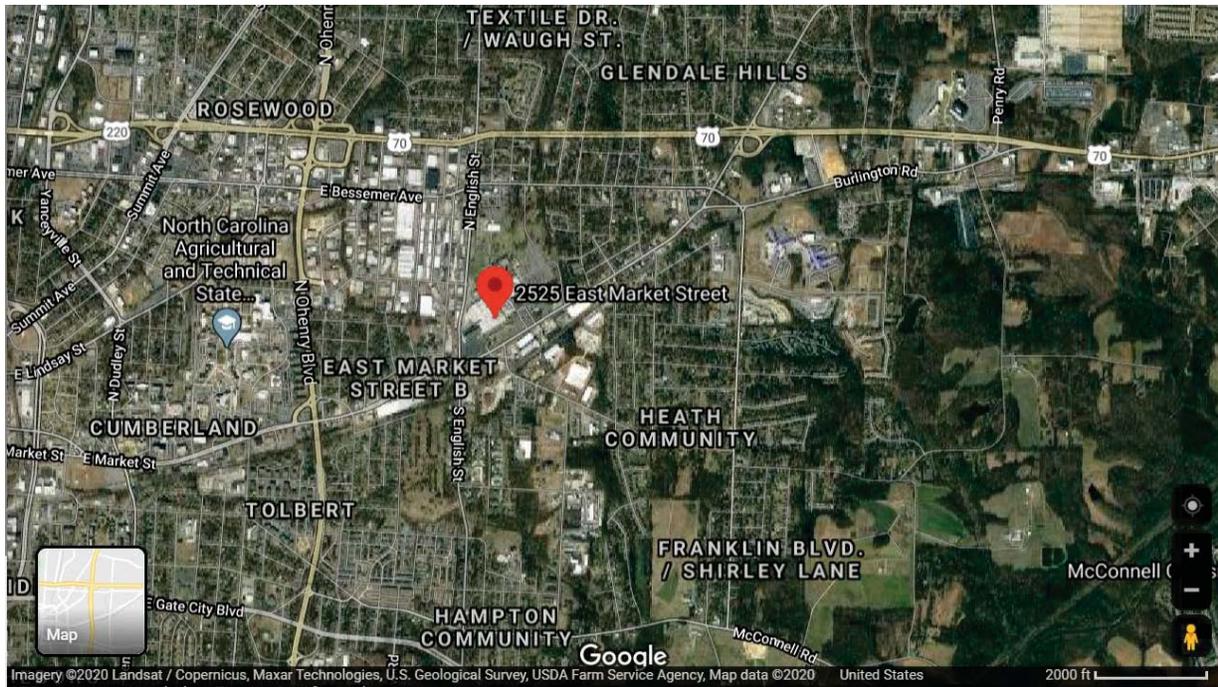
The Agency considered potential impacts to resources in the environment that may be affected by manufacturing the new products and found no significant impacts based on the Agency-gathered information and the following applicant-submitted information:

- The new products would be manufactured in a similar manner as the original products.
- No additional equipment or facility expansion is expected due to manufacturing the new products.
- The new products are intended replace the original 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 Facility¹



The affected environment includes human and natural environments surrounding the facility. The new products would be manufactured by ITG Brands, LLC at 2525 East Market Street, Greensboro, NC 27401 in Guilford County in the North Buffalo Creek Watershed, HUC 12 ID 030300020105. The total land area of Guilford County is approximately 650 square miles with a population of around 535,000 (USCB, 2018). As shown in Figure 1, the manufacturing facility is in a mixed-use industrial and residential area. Surrounding this facility are various shopping centers, apartment complexes, homes, gas stations, grocery stores, and a driver’s license office.

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, 2020a). 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.

¹ Google Maps. 2019. Map of 2525 East Market Street Greensboro, NC 27401. Retrieved from Google Maps. Accessed March 16, 2020.

5.3 Water Resources

The Agency does not anticipate that manufacturing the new products would cause the discharge of any new chemicals into water. Components of the new products reflect existing basic ingredients commonly used in other tobacco products 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 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 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 products would not require expansion of the manufacturing facility. Additionally, U.S. Fish and Wildlife Service (FWS) maps show that the facility is not within or near a critical habitat, or endangered animal and plant species.²

The U.S. FWS identifies the following listed species as being present in Guilford County³ as listed in Table 1:

Table 1. Species Identified by USFWS in Guildford County, North Carolina

Species	Status
Bald eagle (<i>Haliaeetus leucocephalus</i>) ⁴	Protected*
Cape Fear shiner (<i>Notropis mekistocholas</i>)	Endangered
Roanoke logperch (<i>Percina rex</i>)	Endangered
Atlantic pigtoe (<i>Fusconaia masoni</i>)	Proposed threatened
Schweinitz's sunflower (<i>Helianthus schweinitzii</i>)	Endangered
Small whorled pogonia (<i>Isotria medeoloides</i>)	Threatened
*Protected under the Bald and Golden Eagle Protection Act	

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.

² Critical habitat map available at: <https://databasin.org/maps/new#datasets=d579d87eb54f4374a77ea53e7ef66449>. Accessed March 16, 2020.

³ U.S. Fish and Wildlife Services (U.S. FWS) County List, available at: <https://ecos.fws.gov/ecp0/reports/species-by-current-range-county?fips=37081>. Accessed March 16, 2020.

⁴ U.S. Fish and Wildlife Services (U.S. FWS), available at: <https://www.fws.gov/raleigh/species/cntylist/guilford.html> Accessed March 16, 2020.

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 2019 (EPA, 2020b).

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, no disproportionate impacts to environmental justice (low-income, minority, or other special) populations would be expected.

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 Agency does not anticipate any cumulative impacts from manufacturing the new products. The applicant stated that (1) the introduction of materials released into the environment would not change or exceed the allowed quantities under environmental laws and the facility's permits, (2) the new

products would be manufactured in a similar manner as the corresponding original products, and (3) no facility expansion would be required.

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 significant environmental impacts have been identified from use of the new products. Therefore, there would be no disproportionate impacts to environmental justice populations.

6.4. Cumulative Impacts

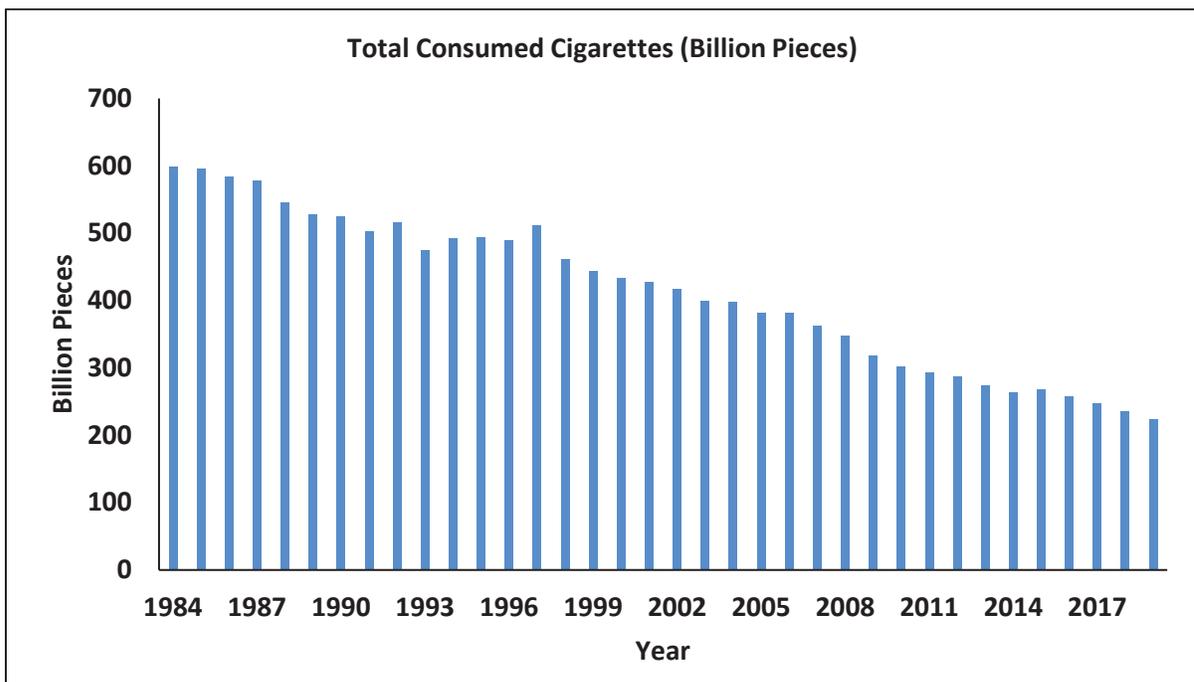
Impacts from use of combusted tobacco products include health effects to both non-users and users. When using cigarettes, the users inhale and exhale smoke. Non-users may also inhale smoke, known as secondhand smoke (SHS). Furthermore, particles emitted by smoking may remain on surfaces, be re-emitted back into the gas phase, or react with oxidants and other compounds in the environment to yield secondary pollutants: referred to as 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 (DHHS, 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% (DHHS, 2006a and 2006b).
- 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 (DHHS, 2006a and 2006b).
- SHS causes more than 40,000 deaths per year (DHHS, 2014).

However, the use of cigarettes in the United States is declining as shown in Figure 2 (U.S. Alcohol and Tobacco Tax and Trade Bureau, 2020). Declining cigarette use is likely 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%) as 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. Additionally, 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 – 2019



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.

6.5. Impacts of the No-Action Alternative

The no-action alternative would not change the existing condition of use of cigarettes in the United States, as many similar 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 material 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. ESA. Although disposal of smoldering cigarettes has been implicated in many fire incidents,^{5,6} 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 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 cigarettes currently on the market. Furthermore, the new products would compete with or replace market share held by similar products.

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 handled 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 square meter in urban environments (Pon and Becherucci, 2012).

The chemicals found in cigarette butts can leach 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 original chemicals in the unsmoked cigarettes or the pyrolysis and distillation products deposited in the

⁵ 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 November 25, 2019.

⁶ UC Davis Health News. Available at: <https://www.ucdmc.ucdavis.edu/publish/news/newsroom/2763>. Accessed November 25, 2019

cigarette butts. Airborne emissions from discarded cigarette butts 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 (NIST, 2016).

The Agency did not identify any actions that would lead to changes in cumulative impacts due to marketing the new products. Additionally, the cumulative impacts from cigarette butts are declining due to declining use of cigarettes in the United States.

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:

Bria J. Martin, B.S., Center for Tobacco Products
Education: B.S. in Biological Sciences
Experience: Three years in various scientific activities
Expertise: NEPA analysis, forestry, ecology and evolutionary studies

Reviewer:

Gregory Gagliano, M.S., Center for Tobacco Products
Education: M.S. in Environmental Science
Experience: Thirty-seven years in environmental compliance and analysis
Expertise: Environmental toxicology, risk assessment, regulatory compliance, NEPA analysis

9. A Listing of Agencies and Persons Consulted

Not applicable.

10. References

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composition of litter in urban areas with different intensity of nightlife use in Mar del Plata, Argentina. *Waste Management*. 2014;34(8):1351-1355.

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Patel V, Thomson GW, Wilson N. Cigarette butt littering in city streets: A new methodology for studying and results. *Tobacco Control*. 2013;22(1):59-62.

Seco Pon JP, Becherucci ME. Spatial and temporal variations of urban litter in Mar del Plata, the major coastal city of Argentina. *Waste Management*. 2012;32(2):343-348.

Smith CJ, Livingston SD, Doolittle DJ. An international literature survey of "IARC Group 1 carcinogens" reported in mainstream cigarette smoke. *Food and Chemical Toxicology*. 1997;35(10-11):1107-1130.

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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
EX0000997 EX0000998 EX0001001 EX0001002 EX0001003	<ul style="list-style-type: none"> • Deletion of tipping paper base paper (b) (4) [REDACTED] and the addition of tipping paper base paper (b) (4) [REDACTED] • Deletion of (b) (4) [REDACTED] and the addition of an equivalent amount of an alternative tipping paper in additive, (b) (4) [REDACTED]
EX0001000	<ul style="list-style-type: none"> • Deletion of tipping paper base paper (b) (4) [REDACTED] and the addition of tipping paper base paper (b) (4) [REDACTED]

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.⁷ 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 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 original products are no longer on the market.

STN	Projected Market Volume			
	First Year		Fifth Year	
	New Product (Cigarettes)	New Product as a Percent of Total Cigarettes Used ⁸	New Product (Cigarettes)	New Product as a Percent of Total Cigarettes Used ⁹
EX0000997	(b) (4)			
EX0000998	(b) (4)			
EX0001000	(b) (4)			
EX0001001	(b) (4)			
EX0001002	(b) (4)			
EX0001003	(b) (4)			
Total	(b) (4)			

⁷ The Agency used historical data regarding total use of cigarettes from 2002 to 2019 to mathematically estimate the total number of cigarettes used in the United States. Using the best-fit trend line with an R² value of 0.9835, the forecasted number of cigarettes that would be used in the United States is estimated at 212.630 billion cigarettes in the first year and 190.636 billion cigarettes in the fifth year of marketing the new products.

⁸ Projected Market Occupation of the New Products in the United States (%) = $\frac{\text{Projected Market Volume of the New Products (cigarette pieces)}}{\text{Projected Use of Cigarettes in United States (cigarette pieces)}} \times 100$

⁹ Ibid.