

**Environmental Assessment for an Exemption Request
by ITG Brands, LLC for 'Kool Soft Pack'**

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

May 2, 2019

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1. Applicant and Manufacturing Facility Information

Applicant Name	ITG Brands, LLC
Applicant Address	714 Green Valley Road Greensboro, NC 27408-7018
Manufacturing Facility	ITG Brands, LLC
Product Manufacturing Address	2525 East Market Street Greensboro, NC 27401

2. Product Information

New and Original Products

New Product Name	New Product STN	Original Product Name	Original Product
Kool Soft Pack	EX0000482	Kool King Soft Pack	GF1501397

Product Identification

Product Category	Cigarettes
Product Subcategory	Combusted filtered
Product Number per Retail Unit	Twenty cigarettes per pack
Product Package	The packaging material consists of a foil inner liner, inner frame, box, film overlap, and carton.

3. The Need for the Proposed Action

The proposed action, requested by the applicant, is for the Food and Drug Administration (FDA) to issue an exemption from substantial equivalence reporting for a marketing order under the provisions of section 905(j)(3) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for the introduction of a combusted, filtered cigarette into interstate commerce for commercial distribution in the United States. 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) a substantial equivalence report under section 905(j) of the FD&C Act is not necessary to ensure that permitting the tobacco product to be marketed would be appropriate for the protection of public health, (4) the new tobacco product is marketed by the same organization as the original product, and (5) an exemption is otherwise appropriate.

The applicant must obtain written notification that the Agency has granted the product an exemption from demonstrating substantial equivalence under section 905(j)(3) before submitting an abbreviated report. Ninety days after the Agency's receipt of the abbreviated report, the applicant may introduce or

deliver for introduction into interstate commerce for commercial distribution the new product for which the applicant has obtained an exemption from demonstrating substantial equivalence.

For this proposed action, the original product is a grandfathered product. The new product differs from the original product due to replacement of a center-line adhesive and an additive (Confidential Appendix 1). The applicant provided first- and fifth-year marketing projections for the new product (Confidential Appendix 2).

4. Alternatives to the Proposed Action

The no-action alternative is the Agency does not issue a marketing order for the new product.

5. Potential Environmental Impacts of the Proposed Action and Alternatives— Manufacturing the New Product

The Agency evaluated potential environmental impacts that may be caused by manufacturing the new product and found no significant impacts based on Agency-gathered information and the following information submitted by the applicant:

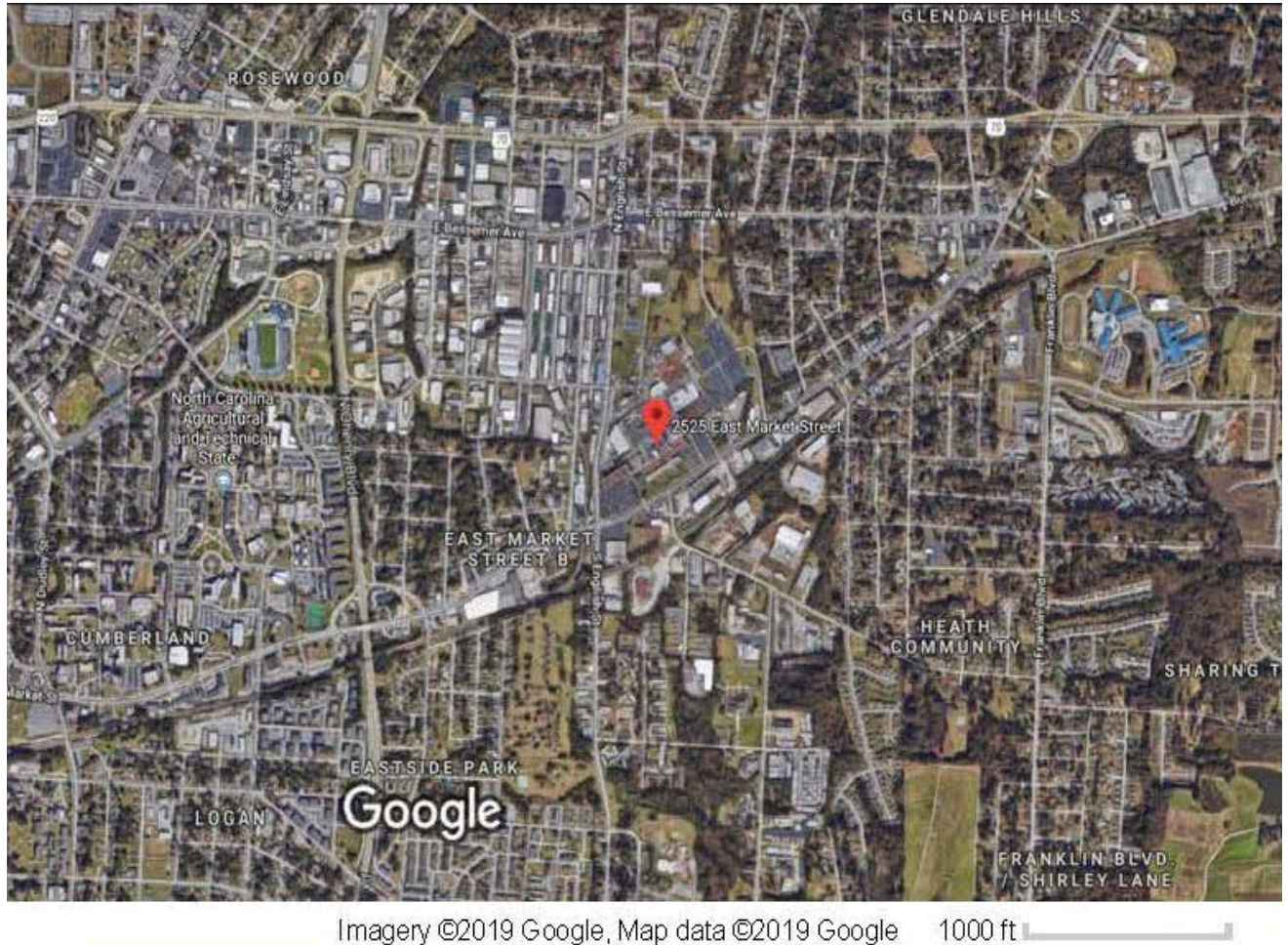
- The new product would be manufactured in the same manner as the original product.
- Endangered species and critical habitats are not expected to be affected by production of the new product.
- No facility expansion is expected due to manufacturing the new product.
- The introduction of materials to the environment would not change or exceed the allowed quantities under the facility's air and wastewater permits.

5.1 Affected Environment

The new product would be manufactured at 2525 East Market Street, Greensboro, NC 27401 in Guilford County. The total land area of Guilford 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 (GoogleMaps, 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.

Figure 1. Location of the Manufacturing Facility



5.2 Air Quality

The Agency does not anticipate that manufacturing the new product would change the release of chemicals into the air. The applicant stated that the modifications compared to the original product would not be expected to release new air emissions.

5.3 Water Resources

The Agency does not anticipate that manufacturing the new product would change the discharge of chemicals in wastewater. The applicant stated that the introduction of materials to the environment would not change or exceed the allowed quantities under the facility's wastewater permit.

5.4 Soil, Land Use, and Zoning

The Agency does not anticipate that manufacturing the new product would lead to changes in soil, land use, or zoning. No facility expansion due to manufacturing the new product would be expected.

Therefore, no zoning change or land conversion of prime farmland, unique farmland, or farmland of statewide importance to non-agricultural use would be anticipated.

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 (GoogleMaps, 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 action does 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 in socioeconomic measures are anticipated due to manufacturing the new product. The Agency does not anticipate any impacts on employment, revenue, or taxes because the new product

would be manufactured within the existing capacity of the manufacturing facility, with no expansion required.

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 manufacturing the new product would notably change the waste generated from the facility's current production of combusted, filtered cigarettes. The waste generated would be handled in the same manner as waste generated from manufacturing other products in the same facility.

5.9 Floodplains, Wetlands, and Coastal Zones

There would be no facility expansion due to manufacturing the new product 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 product would be manufactured in a similar manner as the original product, and no facility expansion is required. Therefore, the Agency does not anticipate any cumulative impacts from manufacturing the new product.

5.11 Impacts of the No-Action Alternative

The no-action alternative would not change the existing manufacturing of other combusted, filtered cigarettes at the applicant's manufacturing facility, as many similar cigarette products would continue to be manufactured at the listed facility.

6. Potential Environmental Impacts of the Proposed Action and Alternatives – Use of the New Product

The Agency evaluated potential environmental impacts that may be caused by use of the new product and found no significant impacts based on Agency-gathered information and the applicant's submitted information.

6.1 Affected Environment

The affected environment includes human and natural environments in the United States because the marketing order would allow for the new product 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 product, 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 product would be released in the same manner as the combustion products from other marketed cigarettes; (2) the new product is expected to compete with or replace other currently marketed cigarettes, so the Agency does not expect that changes in air emissions would be associated with use of the new product (Confidential Appendix 2); and (3) the ingredients in the new product are used in other currently marketed tobacco products.

6.3 Environmental Justice

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

6.4 Cumulative Impacts

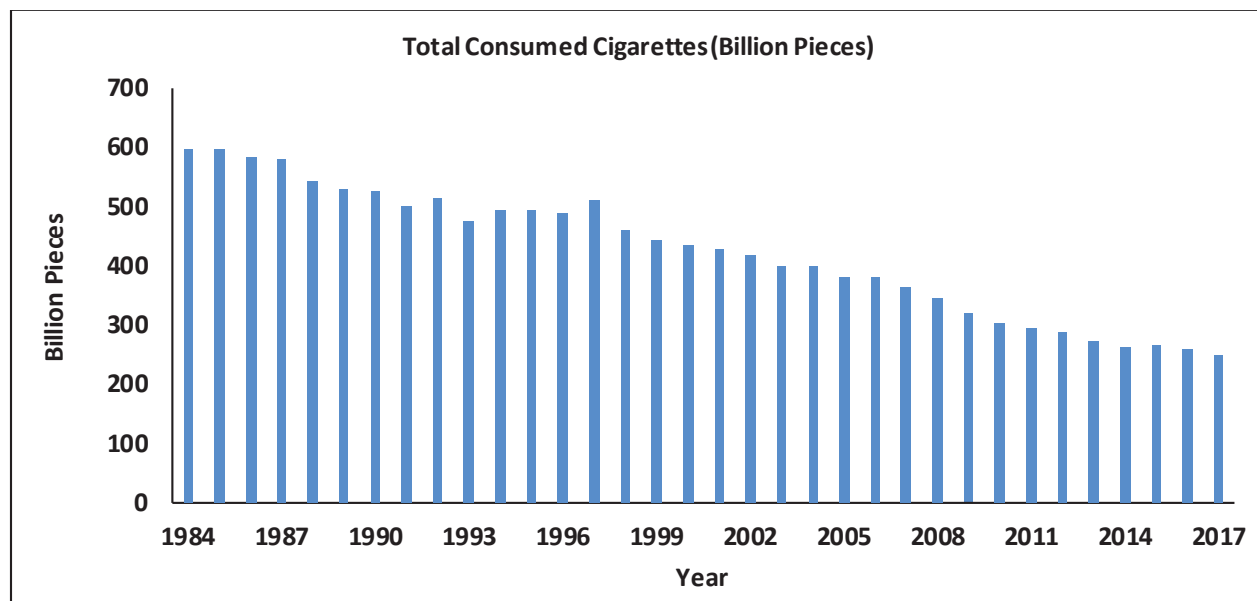
Impacts from use of combusted tobacco products include health effects to non-users as well as users. When using cigarettes, the users inhale the mainstream smoke and exhale secondhand smoke (SHS) to the environment. In addition, particles emitted by smoking may remain on surfaces, be re-emitted back into the gas phase, or react with oxidants and other compounds in the environment to yield secondary pollutants; this is referred to as thirdhand smoke (THS).

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, use of cigarettes in the United States is declining (Figure 2) (U.S. Alcohol and Tobacco Tax and Trade Bureau, 2018). 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%) 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. 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 (Yao et al., 2016).

Figure 2. Use of Cigarettes in the United States, 1984–2017



As of September 2018, 28 states and the District of Columbia had implemented comprehensive smoke-free laws (American Lung Association, 2018). Such laws are also expected to reduce the levels of non-users’ exposure to SHS and THS.

The new product is expected to displace market share from other combusted, filtered cigarette products used in the United States and are not expected to increase the total number of cigarettes smoked nationwide. Therefore, the proposed action would not change existing cumulative impacts, including SHS and THS exposure, from combusted, filtered cigarette use.

6.5 Impacts of the No-Action Alternative

The no-action alternative would not change the existing use of other combusted, filtered cigarettes in the United States, as many similar products would continue to be marketed and therefore used.

7. Potential Environmental Impacts of the Proposed Action and Alternatives – Disposal of the New Product

The Agency evaluated potential environmental impacts that may be caused by disposal of the new product and found no significant impacts based on publicly available information and the applicant’s submitted information.

7.1 Affected Environment

The affected environment includes human and natural environments in the United States because the marketing order would allow the new product to be sold to consumers in the United States.

7.2 Air Quality

The Agency does not anticipate that disposal of the new product or packaging materials would change the release of chemicals into the air.

No changes in air quality are anticipated from either proper disposal or littering of the cigarette butts from the new product. The chemicals in the cigarette butts from the new product would be similar to those commonly found in butts from other currently marketed cigarettes. Because the new product is anticipated to compete with or replace other currently marketed cigarettes, the butt waste generated from the new product would replace the same type of waste. Therefore, the fate and effects of any materials emitted to the air from disposal of the new product are anticipated to be the same as from other cigarettes disposed of in the United States.

7.3 Water Resources

No changes in impacts on water resources are expected due to cigarette butts littered after use of the new product because the chemicals in the new product are the same or similar to those used in cigarettes currently marketed in the United States, and the new product would compete with or replace market share held by currently marketed cigarettes.

7.4 Biological Resources

Disposal of the new product 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. Although disposal of smoldering cigarettes has been implicated in many fire incidents (NFPA, 2013; UC Davis, 2000), disposal of the new product is not expected to change the fire frequency because (1) the disposal of the new product is similar to 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 product is anticipated to replace similar marketed cigarettes.

7.5 Socioeconomics and Environmental Justice

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

7.6 Solid Waste

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

7.7 Cumulative Impacts

A major existing environmental consequence of the use of the new product 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 (Seco Pon and Becherucci, 2012).

The chemicals in cigarette butts can be the original chemicals in the unsmoked cigarettes or the pyrolysis and distillation products deposited in the cigarette butts. The chemicals and their concentrations present in a cigarette butt vary with factors such as the cigarette brand, cigarette length, filter material, varieties of tobacco, ingredients in the cigarette and tobacco fillers, number of puffs, and the mass transfer behavior of combustion products along the cigarette (NIST, 2016). These chemicals can leach into water, potentially threatening human health and the environment, especially marine ecosystems (Kadir and Sarani, 2015). Although not as well-studied, chemicals in discarded cigarette butts can also be emitted to the air, with emissions depending on environmental conditions and the chemicals in the butts.

The Agency did not identify any actions that, when considered with the product's disposal under the proposed action, would lead to changes in cumulative impacts. Additionally, 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 no-action alternative would not change the existing disposal of other combusted, filtered cigarette products in the United States, as many similar products would continue to be marketed and therefore disposed of.

8. List of Preparers

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

Preparer:

Thomas E. Creaven, Center for Tobacco Products

Education: PhD in Biology/Neuroscience, BS in Chemistry/Biology

Experience: Ten years in science education, three years in NEPA review

Expertise: Science education and NEPA reviewer

Reviewer:

Hoshing W. Chang, Center for Tobacco Products

Education: PhD in Biochemistry, MS in Environmental Science

Experience: Ten years in FDA-related NEPA review

Expertise: NEPA analysis, environmental risk assessment, wastewater treatment

9. List of Agencies and Persons Consulted

Not applicable.

10. References

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Confidential Appendix 1: Modifications: The New Product Compared to the Original Product

STN	Modification
EX0000482	Replace a custom filter center line adhesive, (b) (4), with adhesive (b) (4) Replace a complex purchased ingredient, (b) (4), with an equivalent amount of (b) (4).

Confidential Appendix 2: First- and Fifth-Year Market Volume Projections for the New Product and Percentage of Cigarette Use in the United States Projected to be Attributed to the New Product.

First- and fifth-year market volume projections for the new product were compared to the total forecasted use of cigarettes in the United States.¹ The new product accounts for a minor percentage of the total forecasted cigarette use in the United States **(b) (4)** and **(b) (4)**, respectively, for first year and fifth year).

STN	New Product	Projected Market Volume			
		First Year		Fifth Year	
		New Product (# of Cigarettes)	New Product as a Percent of Total Cigarettes Used ²	New Product (# of Cigarettes)	New Product as a Percent of Total Cigarettes Used ³
EX0000482	Kool Soft Pack	(b) (4)	(b) (4)	(b) (4)	(b) (4)

¹ The Agency used historical data regarding total use of cigarettes from 2002 to 2017 to mathematically estimate the total number of cigarettes used in the United States. Using the best-fit trend line with an R² value of 0.9786, the forecasted number of cigarettes that would be used in the United States is estimated at 236.58 billion cigarettes in the first year and 209.83 billion cigarettes in the fifth year of marketing the new product.

² Projected Market Occupation of the New Product in the United States (%) = $\frac{\text{Projected Market Volume of the New Products (cigarette pieces)}}{\text{Projected Use of Cigarettes in United States (cigarette pieces)}} \times 100$

³ Ibid