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

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

July 6, 2022

Table of Contents

1. Applicant and Manufacturer Information

Applicant Name	ITG Brands, LLC
Applicant Address	714 Green Valley Rd, Greensboro, NC 27408
Manufacturer Name	ITG Brands, LLC
Product Manufacturing Address	(b) (4) [redacted]

2. Product Information

New Product Submission Tracking Number (STN), Name, and Original Product Name

New Product Name	STN	Original Product Name
Kool Box	EX0002078.PD1	Kool Box
Kool Blue Box	EX0002078.PD3	Kool Blue Box
Kool 100s Box	EX0002078.PD5	Kool 100s Box

Product Identification

Product Type	Cigarette
Product Subcategory	Combusted, Filtered
Number of Products per Retail Unit	EX0002078.PD1, EX0002078.PD3, EX0002078.PD5: twenty cigarettes per box
Product Package	Packaging is a foil lined box with film overwrap.

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 (SE) reporting for a marketing order under section 905(j)(3) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for 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) 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 product exemption 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 product for which the applicant has obtained an exemption from demonstrating substantial equivalence.

The new products differ from the original products in the deletion of one additive and the addition of another additive (Confidential Appendix 1).

4. Alternative to the Proposed Action

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

5. Potential Environmental Impacts of the Proposed Action and Alternative – New Product Manufacture

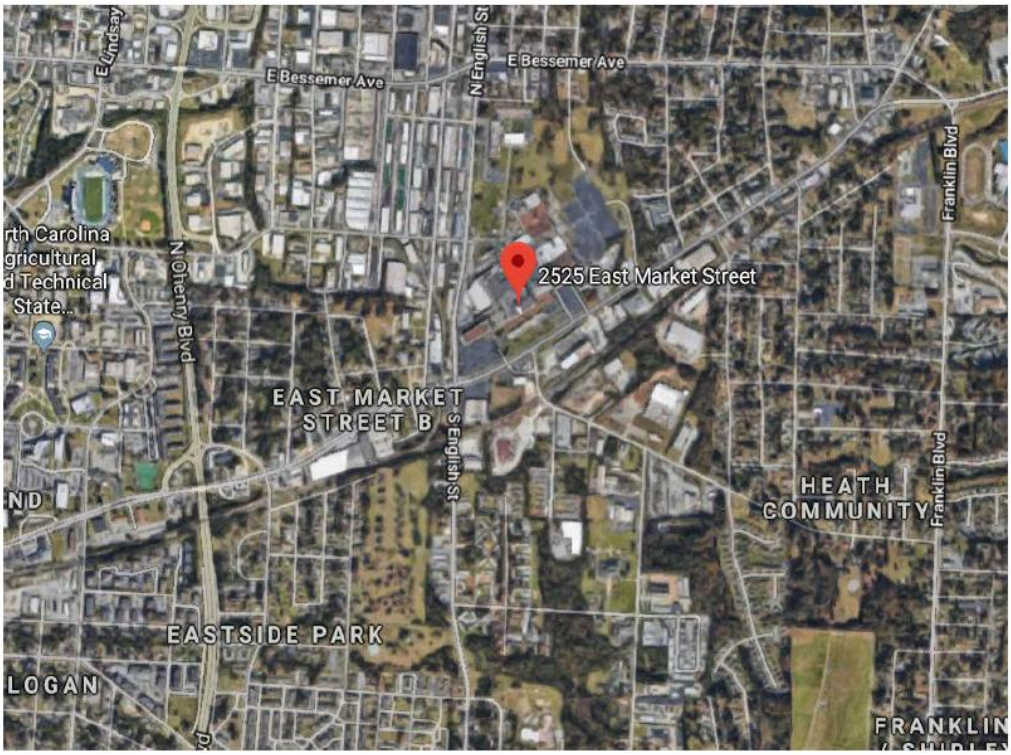
The Agency considered potential impacts to resources in the environment that may be affected by manufacturing the new products and found no significant impacts based on Agency-gathered information and the following applicant-submitted information:

- The new products would be manufactured in a similar manner as the original products.
- The manufacturing facility complies with federal, state, and local regulations.
- No additional equipment or facility expansion is expected due to manufacturing the new products.

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 [1]



The manufacturing facility is located in Guilford County, NC, in the North Buffalo Creek watershed[a], hydrologic unit code 030300020105.[2] The facility is in a mixed-use residential and commercial area and is directly surrounded by commercial property to the north, south, and west. Muddy Creek flows less than one mile to the east/northeast of the manufacturing facility.

[a] A watershed is an area of land where all bodies of water drain to a common outlet such as the outflow of a reservoir, mouth of a bay, or any point along a stream channel. Such bodies of water include the following: surface water from lakes, streams, reservoirs and wetlands; the underlying ground water; and rainfall. See https://water.usgs.gov/edu/watershed.html.

5.2 Air Quality

The Agency does not anticipate that manufacturing the new products would cause the release of any new chemicals into the environment.

EPA's TRI database showed that in 2020, ITG Brands LLC in Greensboro, NC released 2,311 pounds of ammonia and 11,623 pounds of nicotine and nicotine salts to the air (totaling 13,935 pounds) and transferred 9 pounds of ammonia and 126 pounds of nicotine and nicotine salts (totaling 135 pounds) offsite (Table 1) [3]. The TRI database search did not show that the manufacturing facility released into the environment any other reportable toxicants associated with manufacturing tobacco products. In addition, EPA's ECHO database did not show that the facility released the following reportable criteria pollutants: ozone, lead, particulate matter, or sulfur dioxide, at or above the reportable threshold levels to air.

Table 1. Management of Chemical Waste Associated with Manufacturing Tobacco Products at the ITG Brands LLC Manufacturing Facility in 2020

Production-Related Waste Managed or Released		Pounds
Recycled		0
Energy Recovery		0
Treated		0
Subtotal Waste Managed		*0*
On-site Release	Ammonia	2,311
	Nicotine and Nicotine Salts	11,623
Off-site Release	Ammonia	9
	Nicotine and Nicotine Salts	126
Subtotal Waste Released		***14,069***
Total Production-Related Waste		**14,069**

5.3 Water Resources

EPA's TRI database showed that in 2020, ITG Brands LLC, in Greensboro, NC released 5 pounds of ammonia and 5 pounds of nicotine and nicotine salts (totaling 10 pounds) into surface waters.

The Agency does not anticipate that new product manufacture would cause the discharge of any new chemicals into water because the applicant stated that (1) manufacturing the new products would not require any additional environmental controls for water discharges and (2) the manufacturing facility complies with all federal, state and local environmental regulations for water discharges.

5.4 Soil, Land Use, and Zoning

The Agency does not anticipate that new product manufacture would lead to changes in soil, land use, or zoning. The applicant states that there would be no expected facility expansion due to new product manufacture. 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 new product manufacture 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 states that new product

manufacture would not require manufacturing facility expansion. Additionally, U.S. Fish and Wildlife Service (FWS) maps show that the facilities are not within or near a critical habitat, or endangered animal and plant species [4]. Listed in Table 2, the U.S. FWS identifies five endangered or threatened species in Guilford County, NC [5].

Table 2. Species Identified by USFWS in Guilford County, North Carolina [5]

Species	Status
Cape Fear shiner (Notropis mekistocholas)	Endangered
Schweinitz's sunflower (Helianthus schweinitzii)	Endangered
Roanoke logperch (Percina rex)	Endangered
Small whorled pogonia *(Isotria medeoloides)*	Threatened
Atlantic pigtoe (Fusconaia masoni)	Threatened

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

5.6 Regulatory Compliance

The applicant states that the manufacturing facility complies with all local, state, and federal environmental laws. The agency verified the applicant statement, including review of the following permits:

(1) Air Quality permit issued by the State of North Carolina Department of Environmental Quality, Division of Air Quality (Permit #: 04398T26).
(2) Permit for discharge of stormwater at the manufacturing site issued by the State of North Carolina Department of Environmental Quality, Division of Energy, Mineral, and Land Resources (Permit #: NCG060281.
(3) Permit for discharge of wastewater at the manufacturing site issued by the City of Greensboro Water Resources Department, Industrial Waste Section (Permit #: P004).

Additionally, the manufacturing facility submits release data to the EPA under provisions of the Toxic Release Inventory (TRI) program (permit # 27420LRLLR2525E). [3]

The Agency's review of the EPA's Enforcement and Compliance History Online (ECHO) database did not reveal any violations of the environmental laws and regulations by the manufacturing facility. [6]

5.7 Socioeconomics and Environmental Justice

No socioeconomic changes are anticipated due to new product manufacture. The Agency does not anticipate any impacts to employment, revenue, or taxes because the new products are intended to compete with other cigarettes manufactured at the facility and facility expansion is not required. There would be no increase in potential impacts to minorities in the area.

5.8 Solid Waste and Hazardous Materials

The Agency does not foresee that introduction of the new products would notably affect current manufacturing waste generated from facility production of all combusted, filtered cigarettes. The Agency anticipates waste generated due to new product manufacture would be released to the environment and disposed of in landfills in the same manner as any other waste generated from any other tobacco products manufactured in the same facility. The applicant states that new product manufacture would not require additional environmental controls for solid waste disposal. Therefore, no new or revised waste permits or facility construction for new waste management is expected.

5.9 Floodplains, Wetlands, and Coastal Zones

There would be no facility expansion due to new product manufacture and the applicant did not propose any land disturbance. Therefore, there would be no effects to 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 tobacco products at the listed facility, as many similar tobacco products would continue to be manufactured.

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

The Agency evaluated potential impacts to resources in the environment that may 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 first and fifth years of marketing the new products in the United States (Confidential Appendix 2).

6.1 Affected Environment

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

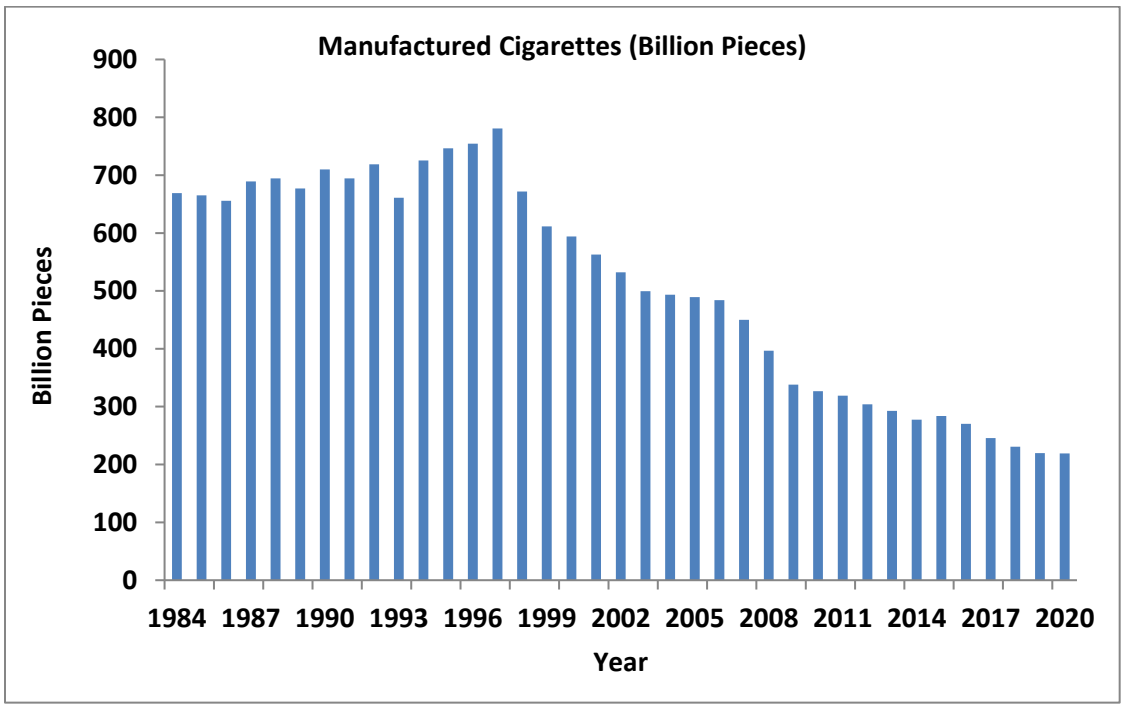
6.2 Air Quality

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. [7, 8]

There is no safe level of exposure to SHS. [9, 10] 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%. [11]
- 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. [9, 10]
- SHS causes more than 40,000 deaths a year. [11]

Figure 2. Use of Cigarettes in the United States, 1984 – 2020

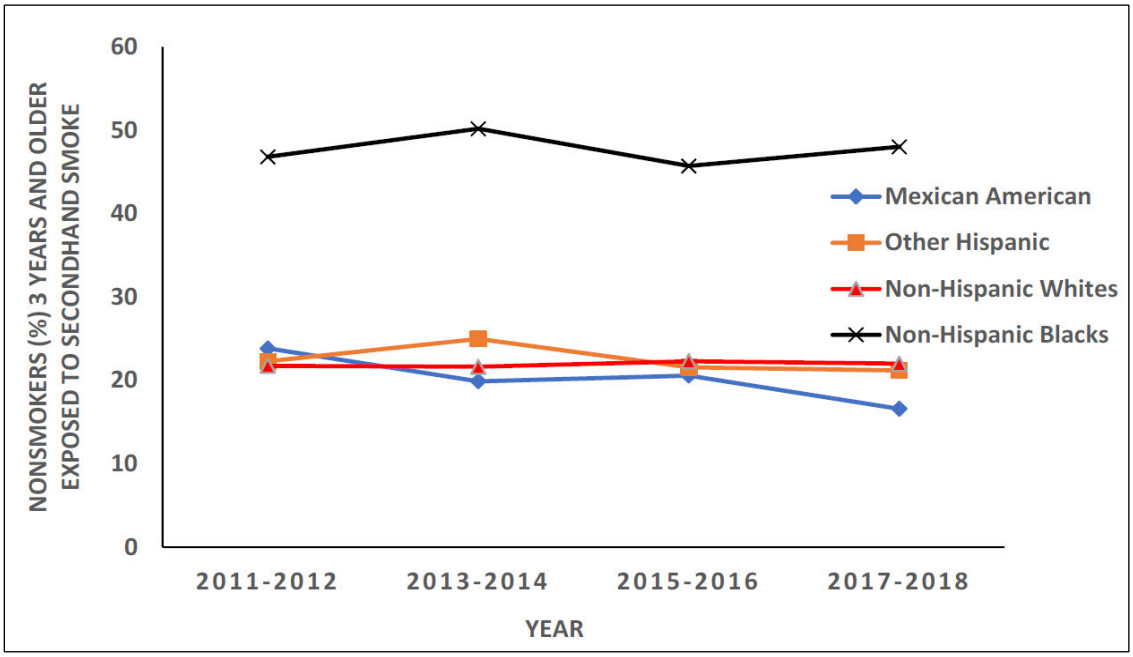


However, cigarette use in the United States is declining, per the U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) Statistical Release reports[b] (Figure 2). [12] This likely is responsible for the decline in SHS exposure observed in several studies that evaluated the levels of SHS exposure in children and nonsmokers living in homes of smokers. [13, 14] Despite 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 among nonsmokers from 87.5% in 1988-1991 to 25.1% in 2013-2014 [15] with the highest prevalence of exposure among non-Hispanic black (50.3%) compared to Mexican Americans (20%) and non-Hispanic whites (21.4%) in 2013-2014. However, no change in exposure occurred between 2011-2012 and 2013-2014. [15]

However, in recent years, a stagnation in the reduction in the rate of SHS exposure has been reported (Figure 3). [16]

[b] TTB sales data are used as proxy for consumption, assuming all products that are sold will be consumed in the United States.

Figure 3. Trends in the Exposure of Nonsmokers to Secondhand Smoke [16]



As of December 2020, 28 states and the District of Columbia had implemented comprehensive smoke-free laws. [17] Such laws are also 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 new product use relative to chemicals released from other cigarettes already on the market because 1) combustion products from the new products would be released in the same manner as combustion products from 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 new product use. Therefore, there will be no new disproportionate impacts to minority or low-income populations.

6.4 Impacts of the No-Action Alternative

The environmental impacts of the no-action alternative will not change the existing condition of cigarette use because many other similar tobacco products will continue to be marketed in the United States.

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

The Agency evaluated potential impacts to resources in the environment that may be affected by new product disposal. The Agency found no significant impacts based on publicly available information such as the decline in cigarette use in the United States [12] and the applicant's submitted information, including the projected market volumes for the new product.

7.1 Affected Environment

The affected environment includes human and natural environments in the United States because the marketing order would allow for the new 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 packaging materials will lead to the release of new or increased chemicals into the air.

No changes in air quality are anticipated from disposal of cigarette butts from the new products. The chemicals in the cigarette butts are commonly found in butts from 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 product 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 new product packaging materials will be expected because, 1) 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) waste generated from packaging disposal [18] is a minuscule portion of the municipal solid waste in the United States per FDA's experience evaluating packaging waste generated from cigarettes.

7.3 Water Resources

No changes in impacts to 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.

7.4 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. ESA. Although disposal of smoldering cigarettes has been implicated in many fire incidents, [19] disposal of the new products is not expected to change fire frequency because 1) disposal of the new products would be the same as disposal of cigarettes currently marketed in the United States, and 2) there would be no anticipated increase in the number of disposed cigarettes because the new products are anticipated to replace similar marketed cigarettes.

7.5 Solid Waste

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. [20] Cigarette butts are among the most common forms of litter found on beaches, [21, 22] near streams, night clubs, [23] bus stops, [24] roads, and streets. [25, 26] Cigarette butts have been found at densities averaging more than four cigarette butts per square meter of urban environments. [27]

Toxic compounds in cigarette butts leach into water, potentially threatening human health and the environment, especially marine ecosystems. [28, 29] The environmental toxicity of cigarette butt air emissions is not well studied. Chemicals in cigarette butts can be the original chemicals in unsmoked cigarettes or constitute associated pyrolysis and distillation products. What constitutes airborne emissions from cigarette butts after disposal depends on environmental conditions and 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. [30]

The Agency does not foresee the introduction of the new products will notably affect the current cigarette butt waste generated from all cigarettes. The waste generated due to disposal of the new products will be handled in the same manner as any other waste generated from any other cigarettes disposed of in the United States. The number of cigarette butts generated is equivalent to the market projections (Confidential Appendix 2) and a portion of those will 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 is expected to be handled in the same manner as waste generated from other cigarettes in the United States. No new emissions are expected due to disposal of the new products. Therefore, there will be no new disproportionate impacts on minority or low-income populations.

7.7 Impacts of the No-Action Alternative

The environmental impacts of the no-action alternative will not change the existing condition of cigarette and cigarette packaging disposal because many other similar tobacco products will continue to be marketed in the United States.

8. List of Preparers

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

Preparer:

Yasmin Termeh-Zonoozi, Center for Tobacco Products
- Education: MPH in Environmental Health
- Experience: Nine years in environmental compliance and analysis
- Expertise: NEPA analysis, regulatory compliance, risk assessment, environmental toxicology

Reviewer:

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

9. A Listing of Agencies and Persons Consulted

None.

10. References

1. Google. Map of 2525 E Market St, Greensboro, NC 27401. *Google Maps*. 2022. Available at: www.google.com/maps Accessesed June 14, 2022.

2. U.S. Environmental Protection Agency. How's My Waterway? Informing the conversation about your waters. 2022. Available at: https://mywaterway.epa.gov/. Accessed June 14, 2022.

3. U.S. Environmental Protection Agency. TRI Facility Report. 2022a. Available at: https://enviro.epa.gov/facts/tri/ef-facilities/#/Release/27420LRLLR2525E . Accessed June 14, 2022.

4. U.S. Fish and Wildlife Service. Critical Habitat for Threatened & Endangered Species [USFWS]. 2022. Available at: https://fws.maps.arcgis.com/home/webmap/viewer.html?webmap=9d8de5e265ad4fe09893cf75b8dbfb77. Accessed June 14 2022.

5. U.S. Fish and Wildlife Service. Listed species believed to or known to occur in Guilford, North Carolina. *ECOS Environmental Conservation Online System*. 2022. Available at: https://ecos.fws.gov/ecp/report/species-listings-by-current-range-county?fips=37081 . Accessed June 14, 2022.

6. U.S. Environmental Protection Agency. Enforcement and Compliance History Online. 2022b. Available at: https://echo.epa.gov/detailed-facility-report?fid=110000346787#. Accessed June 14, 2022.

7. Burton A. Does the smoke ever really clear? Thirdhand smoke exposure raises new concerns. *Environmental Health Perspect*. 2011;119(2):A70-A74.

8. Matt GE, Quintana PJE, Destaillats H, et al. Thirdhand tobacco smoke: emerging evidence and arguments for a multidisciplinary research agenda. *Environ Health Perspect*. 2011;119(9):1218-1226.

9. U.S. Department of Health and Human Services. The Health Consequences of Involuntary Exposure to Tobacco Smoke. A Report of the Surgeon General. *U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion*. 2006a.

10. U.S. Department of Health and Human Services. The Health Consequences of Involuntary Exposure to Tobacco Smoke: A Report of the Surgeon General: What it Means to You. Consumer Booklet. *Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion*. 2006b.

11. U.S. Department of Health and Human Services. The Health Consequences of Smoking—50 Years of Progress. A Report of the Surgeon General. *U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion*. 2014.

12. U.S. Alcohol and Tobacco Tax and Trade Bureau. Tobacco statistics. *U.S. Department of the Treasury*. 2021. Available at: http://www.ttb.gov/tobacco/tobacco-stats.shtml. Accessed May 9, 2022.

13. Homa DM, Neff LJ, King BA, et al. Vital signs: disparities in nonsmokers' exposure to secondhand smoke — United States, 1999–2012. *MMWR Morbidity Mortality Weekly Report*. 2015;64(4):103-108.

14. Yao T, Sung 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(2):357-366.

15. Tsai J, Homa DM, Gentzke AS, et al. Exposure to secondhand smoke among nonsmokers-United States, 1988-2014. *MMWR Morbidity and Mortality Weekly Report*. 2018;67(48):1342-1346.

16. Shastri SS, Talluri R, Shete S. Disparities in secondhand smoke exposure in the United States: national health and nutrition examination survey 2011-1018. *JAMA Interal Mediine*. 2021;181(1):134-137.

17. American Lung Association. Smokefree air laws. 2020. www.lung.org/our-initiatives/tobacco/smokefree-environments/smokefree-air-laws.html. Accessed May 23, 2022.

18. U.S. Environmental Protection Agency. Advancing Sustainable Materials Management: 2018 Fact Sheet. Assessing Trends in Materials Generation and Management in the United States. 2020. https://www.epa.gov/sites/default/files/2021-01/documents/2018_ff_fact_sheet_dec_2020_fnl_508.pdf. Accessed May 24, 2022.

19. Ahrens M. Home fires started by smoking. *National Fire Protection Association*. 2019. Available at: https://www.nfpa.org/News-and-Research/Data-research-and-tools/US-Fire-Problem/Smoking-Materials. Accessed May 23, 2022.

20. Novotny TE, Zhao F. Consumption and production waste: another externality of tobacco use. *Tob Control*. 1999;8(1):75-80.

21. Claereboudt MR. Shore litter along sandy beaches of the Gulf of Oman. *Mar Pollut Bull*. 2004;49(9-10):770-777.

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

23. Becherucci ME, Pon JPS. What is left behind when the lights go off? Comparing the abundance and composition of litter in urban areas with different intensity of nightlife use in Mar del Plata, Argentina. *Waste Manag*. 2014;34(8):1351-1355.

24. Wilson N, Oliver J, Thomson G. Smoking close to others and butt littering at bus stops: pilot observational study. *PeerJ*. 2014;2:e272.

25. Healton CG, Cummings KM, O'Connor RJ, Novotny TE. Butt really? The environmental impact of cigarettes. *Tob Control*. 2011;20(Suppl 1):i1.

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

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

28. Kadir AA, Sarani NA. Cigarette butts pollution and environmental impact - a review. *Applied Mechanics and Materials*. 2015;773-774:1106-1110.

29. Venugopal PD, Hanna SK, Gagliano GG, Chang HW. No butts on the beach: aquatic toxicity of cigarette butt leachate chemicals. *Tob Regul Sci*. 2021;7(1):17-30.

30. Poppendieck D, Khurshid S, Emmerich S. *Measuring Airborne Emissions from Cigarette Butts: Literature Review and Experimental Plan* 2016. NIST technical report 8147.

CONFIDENTIAL APPENDIX 1

Comparison of the New Products to the Original Products

STN	Modification
EX0002078.PD1	• Deletion of a tobacco additive (b) (4) • Addition of a tobacco additive (b) (4)
EX0002078.PD3	• Deletion of a tobacco additive (b) (4) • Addition of a tobacco additive (b) (4)
EX0002078.PD5	• Deletion of a tobacco additive (b) (4) • Addition of a tobacco additive (b) (4)

CONFIDENTIAL APPENDIX 2

Market Volumes of New Products and Projected Percentage of United States Cigarette Use Attributed to the New Products

First and fifth year market projections[c] for the new products were compared to total forecasted cigarette use in the United States.[d]

STN	Projected Market Volume (Number of Cigarettes)			
	First Year		Fifth Year	
	New Product	New Product as a Percent of Total Cigarettes Used[e]	New Product	New Product as a Percent of Total Cigarettes Used[f]
EX0002078.PD1	(b) (4)			
EX0002078.PD3				
EX0002078.PD5				

[c] Market volumes are used as proxy for use, assuming that all produced products will be consumed or used in the United States.

[d] The Agency used historical data regarding cigarette sales from 1997 to 2020 [12] as a proxy for consumption to mathematically estimate the total number of cigarettes used in the United States. Using the best-fit trend line with an R^2 value of 0.9844, the forecasted number of cigarettes that would be used in the United States is estimated at 228.441 billion cigarettes in the first year and 161.201 billion cigarettes in the fifth year of marketing the new product.

[e] Projected Market Occupation of the New Product in the United States (%)=

$$\frac{\text{Projected Market Volume of the New Product (cigarette pieces)}}{\text{Projected Use of Cigarettes in United States (cigarette pieces)}} x\ 100$$

[f] Ibid.