

**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**

December 21, 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, North Carolina 27401

2. Product Information

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

New Tobacco Product		Original Tobacco Product	
Name	STN	Name	STN
Winston Blue Box	EX0001327-PD1	Winston Blue Box	EX0000816
Winston Full Flavor 100's Box	EX0001327-PD3	Winston Full Flavor 100's Box	EX0000817
Winston Gold 100's Box	EX0001327-PD5	Winston Gold 100's Box	EX0000283
Winston Gold Box	EX0001327-PD7	Winston Gold Box	EX0000284
Winston Red 100's Box	EX0001327-PD9	Winston Red 100's Box	EX0000285
Winston Red Box	EX0001327-PD11	Winston Red Box	EX0000286
Winston White 100's Box	EX0001327-PD13	Winston White 100's Box	EX0000287
Winston White Box	EX0001327-PD15	Winston White Box	EX0000288

Product Identification

Product Category:	Cigarette
Product Subcategory:	Combusted filtered
Product Number per Retail Unit:	Twenty cigarettes per box.
Product Package:	The new product's packaging consists of a foil inner liner, inner frame, box, film overlap, and carton. The packaging of the finished new products is identical in materials and composition to those of the original products.

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 eight 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, which previously received marketing orders from FDA through exemption from Substantial Equivalence. The 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 Tobacco 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:

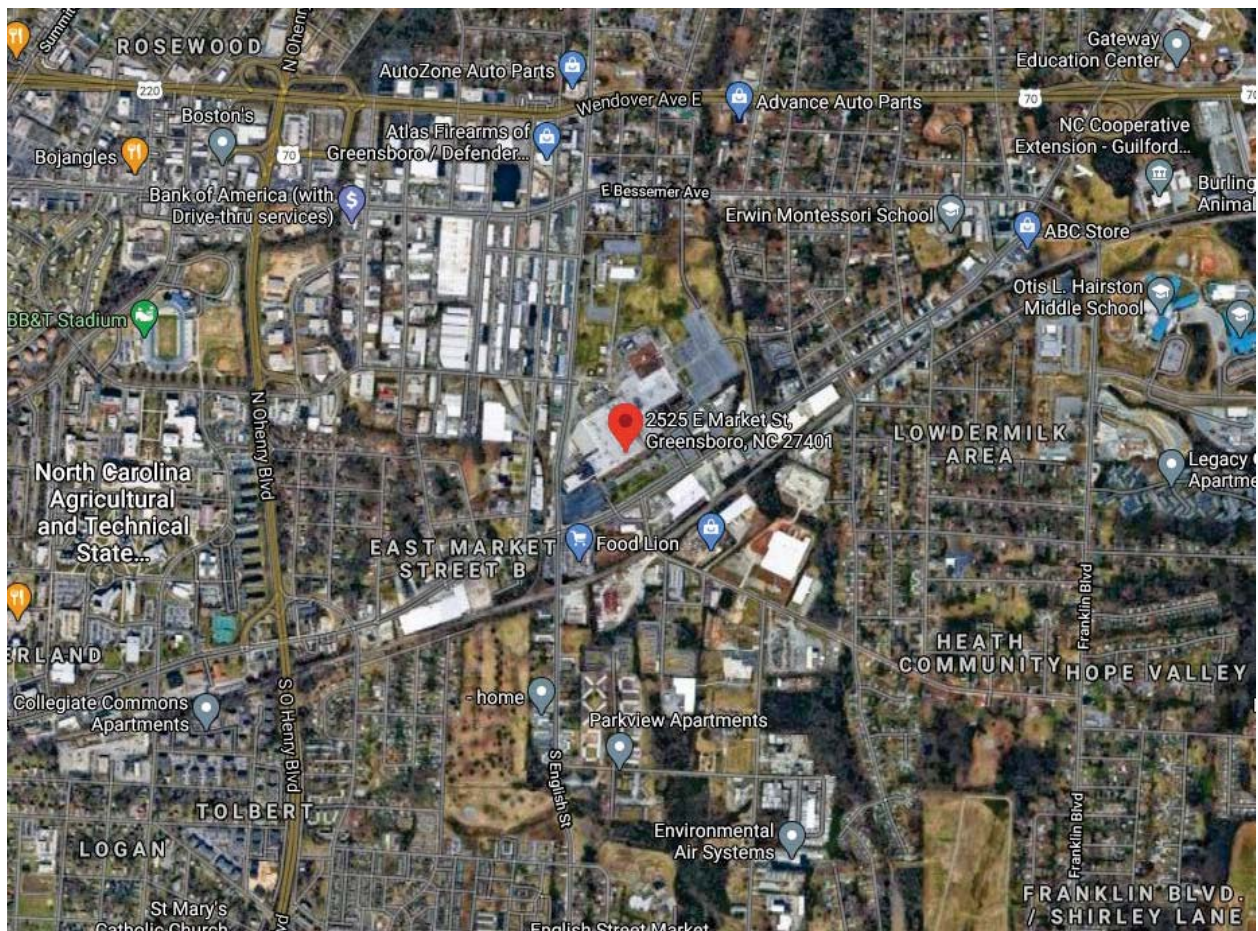
- The new tobacco products will replace the original tobacco products and other currently-marketed tobacco products.
- No facility expansion or new equipment acquisition is expected due to manufacturing the new products.
- The manufacture of the new products is not expected to release new air emissions.

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

¹ Google (2020). Map of 2525 E Market St. Greensboro, NC 27401. Retrieved from Google Maps (www.google.com/maps), December 4, 2020.



The manufacturing facility is located in Guilford County, NC in eastern Greensboro area. The total land area of Guilford county is approximately 650 square miles with a population of around 490,000. The manufacturing facility is surrounded by mixed-use residential and commercial land.

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 any new or additional adverse environmental impacts 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. The applicant stated that manufacturing the new products would not require any additional environmental controls for water discharges.

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 facility is in a developed area with little undisturbed natural habitat identified on aerial imagery (Figure 1). The applicant stated that the requested action will 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 ESA.

The U.S. Fish and Wildlife Service (FWS) identifies the following listed species as being present in Guilford County (FWS, 2020):

- 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*), At risk species. At Risk Species (Petitioned, Candidates or Proposed for Listing under the Endangered Species Act).
- Schweinitz's sunflower (*Helianthus schweinitzii*), Endangered
- Small whorled pogonia (*Isotria medeoloides*), Threatened.

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 and provided the copies of the facility's air, storm water, and waste water permits.

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 for the manufacturing site in 2018 - 2020².

The applicant also stated that the facility complies with the ESA and the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES).

² Enforcement and Compliance History Online. Detailed Facility Report: ITG BRANDS - PRODUCTION OPERATIONS (2525 E. MARKET ST., GREENSBORO, NC 27401). <https://echo.epa.gov/detailed-facility-report?fid=110000346787>
Accessed: December 9, 2020

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 management permit will be required.

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 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 Tobacco 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 (Confidential Appendix 2) 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 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).

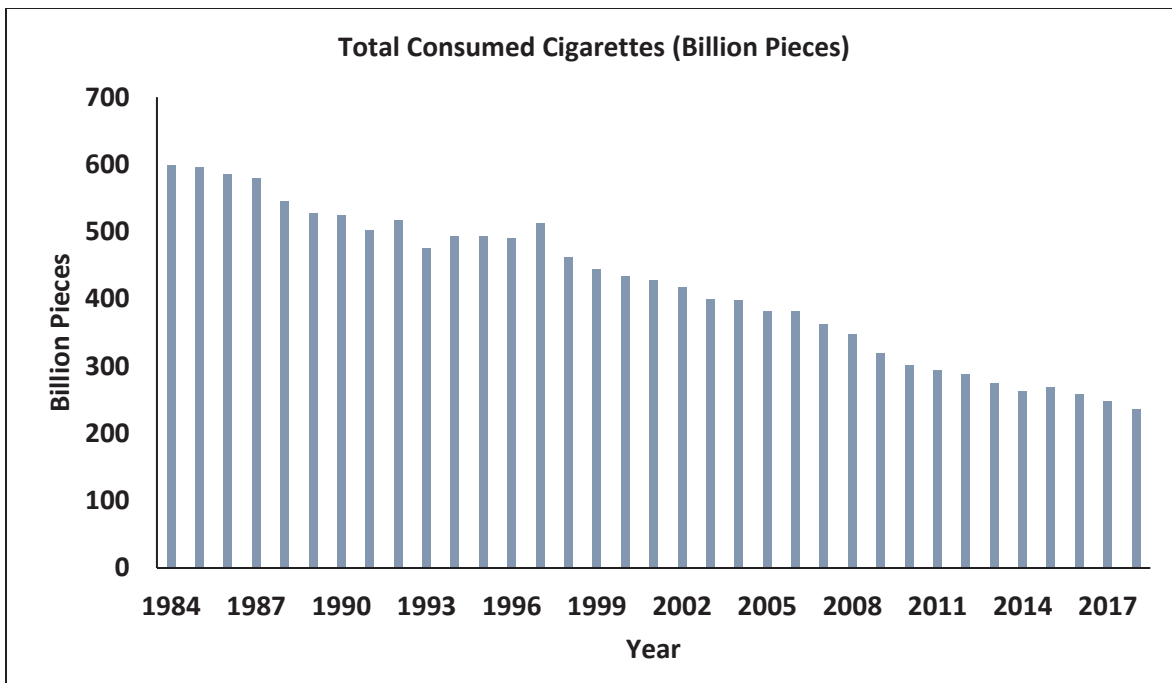
There is no safe level of exposure to SHS (U.S. Department of Health and Human Services, 2006a and 2006b). Even low levels of SHS can harm children and adults in many ways, including the following:

- 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).³ 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

³ U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) statistical data available at: <https://www.ttb.gov/tobacco/tobacco-stats.shtml>. Accessed May 1, 2020



As of March 2020, 28 states and the District of Columbia have implemented comprehensive smoke-free laws (American Lung Association, 2020). Such laws are expected to reduce the levels of non-user exposure to SHS and THS.

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. 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 Tobacco 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 cigarette butts from the new products would be similar to those commonly found in the 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 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 package materials of the new products 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 (U.S. Environmental Protection Agency, 2020) 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 (NFPA, 2013), the new products are not expected to change the fire frequency as (1) the disposal of the new products and packaging materials would be the same as the disposal of other similar tobacco products 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

A major existing environmental consequence of the use of the new products, as well as the original products and 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 (Pon and Becherucci, 2012).

Compounds in littered 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 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.

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. 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:

Sang Ki Park, Ph.D., D.A.B.T., Center for Tobacco Products
Education: M.S. in Biochemistry and Ph.D. in Toxicology
Experience: 12 years in regulatory toxicology review at FDA
Expertise: Chemical risk assessment

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Education: M.S. in Environmental Science and Ph.D. in Biochemistry
Experience: 12 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

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coastal city of Argentina. *Waste Management*. 2012;32(2):343-348.

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

In all EX Requests, the new products are modified from the corresponding original products by deleting the Fire Standard Compliant (FSC) cigarette paper (b)(4) manufactured by (b)(4) and adding an alternate FSC cigarette paper (b)(4) manufactured by (b)(4), which results in changes in the following cigarette paper ingredients.

Component	Modification
Processing aid/ Binder	<ul style="list-style-type: none"> Decrease in (b)(4)
Processing aid	<ul style="list-style-type: none"> Deletion of (b)(4) and (b)(4) Addition of (b)(4)
Fiber	<ul style="list-style-type: none"> Increase in (b)(4)
Combustion modifier	<ul style="list-style-type: none"> Deletion of (b)(4) Addition of (b)(4)
Banding material	<ul style="list-style-type: none"> Deletion of (b)(4) Addition of (b)(4)
Binder	<ul style="list-style-type: none"> Addition of (b)(4)
Processing aid/ Binder	<ul style="list-style-type: none"> Decrease in (b)(4)
Processing aid	<ul style="list-style-type: none"> Deletion of (b)(4) Addition of (b)(4)

CONFIDENTIAL APPENDIX 2. Market Volumes for the Original Tobacco Products and Market Volume Projections for the New Tobacco Products and Percentage of Cigarette Use in the United States Projected to be Attributed to the New Tobacco 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.⁴ The projected use of the new products account for a fraction of a percent of the forecasted cigarette use in the United States. The applicant stated that the new and original products will not be simultaneously marketed, and the new products will replace the original products in the market.

STN	Projected Market Volume of the New Products			
	First-Year		Fifth-Year	
	Number of Cigarettes (Thousands of Cigarettes)	New Product as a Percent of Total Cigarettes Used ⁵	Number of Cigarettes (Thousands of Cigarettes)	New Product as a Percent of Total Cigarettes Used ⁶
EX0001327-PD1	(b)(4)			
EX0001327-PD3				
EX0001327-PD5				
EX0001327-PD7				
EX0001327-PD9				
EX0001327-PD11				
EX0001327-PD13				
EX0001327-PD15				
Total				

⁴ 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 0.9814, the forecasted number of cigarettes that would be used in the United States is estimated at 192.24 billion cigarettes in the first year and 145.78 billion cigarettes in the fifth year of marketing the new products.

⁵ Projected Market Occupation of the New Products in the United States (%) = $\frac{\text{Projected Market Volume of the New Product (cigarette pieces)}}{\text{Projected Use of Cigarettes in United States (cigarette pieces)}} \times 100$

⁶ Ibid