

**Programmatic Environmental Assessment for
Marketing Orders for New Cigarettes Marketed by
Commonwealth Brands, Inc.**

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

December 2, 2019

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1. Applicant and Manufacturing Facility Information

Applicant Name	Commonwealth Brands, Inc.
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

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

STN	New Product Name	Original Product Name
EX0000831	USA Gold Blue 100s Box	USA Gold Ultra Lights 100s Box
EX0000833	USA Gold Blue 100s Soft Pack	USA Gold Ultra Lights 100s Soft Pack
EX0000834	USA Gold Red 100s Box	USA Gold Full Flavor 100s Box
EX0000835	USA Gold Red 100s Soft Pack	USA Gold Full Flavor 100s Soft Pack
EX0000836	USA Gold Red Kings Box	USA Gold Full Flavor Kings Box
EX0000837	USA Gold Red Kings Soft Pack	USA Gold Full Flavor Kings Soft Pack
EX0000838	USA Gold Menthol Green 100s Soft Pack	USA Gold Menthol Lights 100s Soft Pack
EX0000839	USA Gold Non-Filter Kings Soft Pack	USA Gold Non-Filter Kings Soft Pack
EX0000840	USA Gold Menthol Green Kings Soft Pack	USA Gold Menthol Lights Kings Soft Pack
EX0000841	USA Gold Gold Kings Box	USA Gold Lights Kings Box
EX0000842	USA Gold Gold Kings Soft Pack	USA Gold Lights Kings Soft Pack
EX0000843	USA Gold Menthol Dark Green 100s Box	USA Gold Menthol Full Flavor 100s Box
EX0000844	USA Gold Blue Kings Soft Pack	USA Gold Ultra Lights Kings Soft Pack
EX0000845	USA Gold Gold 100s Box	USA Gold Lights 100s Box
EX0000846	USA Gold Gold 100s Soft Pack	USA Gold Lights 100s Soft Pack
EX0000847	USA Gold Menthol Dark Green 100s Soft Pack	USA Gold Full Flavor Menthol 100s Soft Pack
EX0000848	USA Gold Menthol Dark Green Kings Box	USA Gold Full Flavor Menthol Kings Box
EX0000849	USA Gold Menthol Dark Green Kings Soft Pack	USA Gold Full Flavor Menthol Kings Soft Pack
EX0000850	USA Gold Menthol Green 100s Box	USA Gold Menthol Lights 100s Box

Product Identification

Product Category	Cigarettes
Product Subcategory	Combusted filtered and non-filtered ¹
Product Number per Retail Unit	Twenty cigarettes per box/soft pack

¹ The product in Exemption Request EX0000839 is a combusted non-filtered cigarette.

Product Package	<p>The box packaging materials consist of a foil inner liner, inner frame, box, film overlap, and carton.</p> <p>The soft pack packaging materials consist of a foil inner liner, paper label, paper closure, film overlap, and carton.</p>
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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 the provisions of section 905(j)(3) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for eighteen combusted, filtered cigarettes and one combusted non-filtered cigarette. 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 are grandfathered products commercially marketed in the United States as of February 15, 2007. The new products differ from the original products due to the deletion of a side seam adhesive and the addition of a comparable side seam adhesive (Confidential Appendix 1).

4. Alternatives to the Proposed Actions

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

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

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

- The new products would be manufactured in a similar manner as the original products.
- The side seam adhesives for the original and new products contain the same primary ingredients at similar levels
- The new and original products will not be marketed simultaneously as the new products will replace the original products

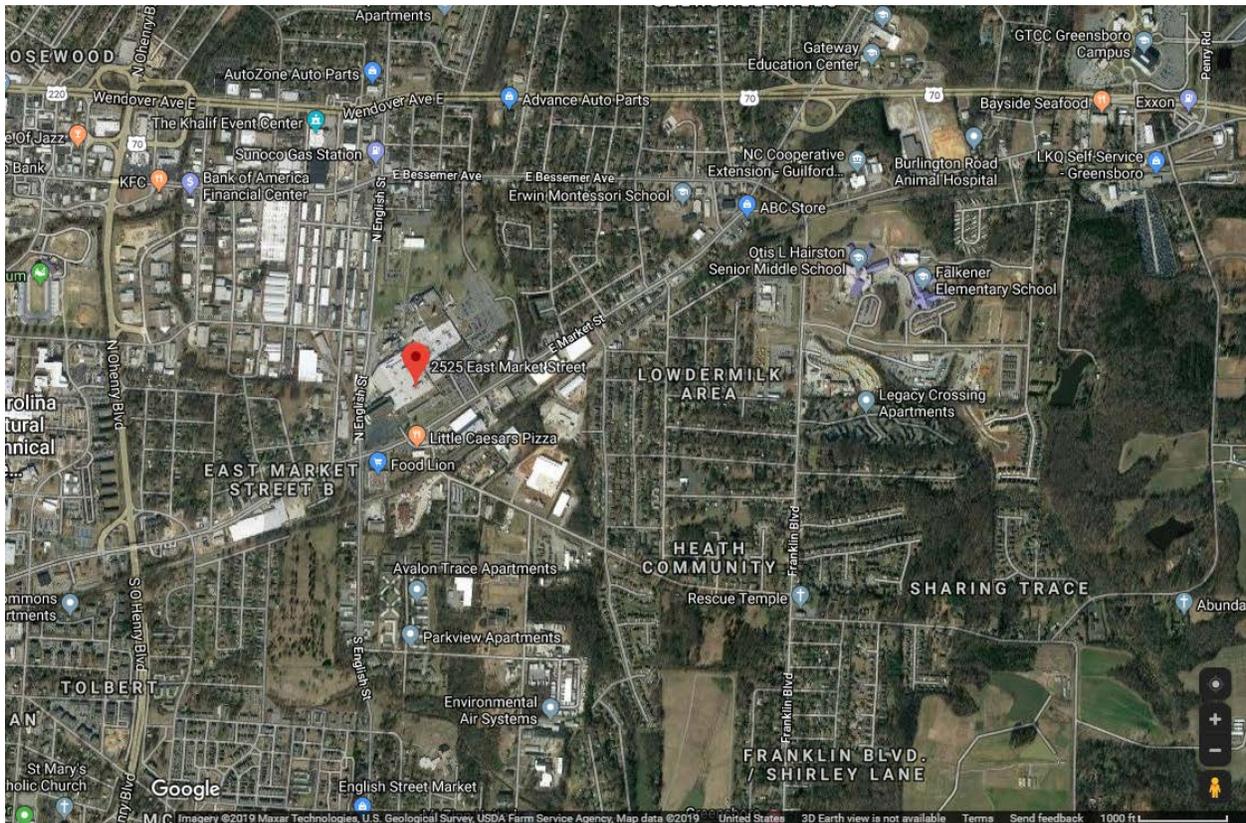
- No facility expansion is expected due to manufacturing the new products.

5.1. Affected Environment

The affected environment includes human and natural environments surrounding the facility. The new products would be manufactured 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 (Google Maps, 2019), 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, 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 products would change the release of chemicals into the air. The applicant stated that the modifications compared to the original products

would not be expected to release new air emissions and would not require any additional environmental controls for air emissions.

5.3. Water Resources

The Agency does not anticipate that manufacturing the new products would change the discharge of chemicals in wastewater. The applicant stated that the new products are intended to replace the original tobacco products currently manufactured at the facility.

5.4. Soil, Land Use, and Zoning

The Agency does not anticipate that manufacturing the new products would lead to changes in soil, land use, or zoning. No facility expansion due to manufacturing the new products 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 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 will not require expansion of the manufacturing facility. The facility is in a developed area with little undisturbed natural habitat as 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 (USFWS, 2018) as listed in Table 1:

Species	Status
Bald eagle (<i>Haliaeetus leucocephalus</i>)	Protected*
Cape Fear shiner (<i>Notropis mekistocholas</i>)	Endangered
Roanoke logperch (<i>Percina rex</i>)	Endangered
Atlantic pigtoe (<i>Fusconaia masoni</i>)	At Risk Species
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.

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 permits for air quality, storm water, and waste water

permits issued for the ITG Brands, LLC manufacturing facility. The applicant also stated that they 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 actions 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 products. The Agency does not anticipate any impacts on employment, revenue, or taxes because the new products would be manufactured within the existing capacity of the manufacturing facility, as no facility expansion would be required.

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

5.8. Solid Waste and Hazardous Materials

The Agency does not foresee that the introduction of the new products would notably affect the current manufacturing waste generated from the facility production of all combusted, filtered cigarettes. The Agency anticipates the waste generated due to manufacturing the new products would be released to the environment and disposed of in landfills in the same manner as any other waste generated from any other products manufactured in the same facility. Therefore, no new or revised waste permit or construction of new waste management facility is expected.

5.9. Floodplains, Wetlands, and Coastal Zones

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

5.10. Cumulative Impacts

The 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, (3) the new products contain the same primary ingredients in the modification of the side adhesive, and (4) no facility expansion would be required.

5.11. Impacts of the No-Action Alternative

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

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

The Agency evaluated potential environmental impacts that may be caused 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 and the decline in cigarette use in the United States over the past three decades.

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 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 from the original products and other marketed cigarettes, (2) the new products are expected to compete with or replace other 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 the mainstream smoke and exhale secondhand smoke (SHS) to the environment. 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).

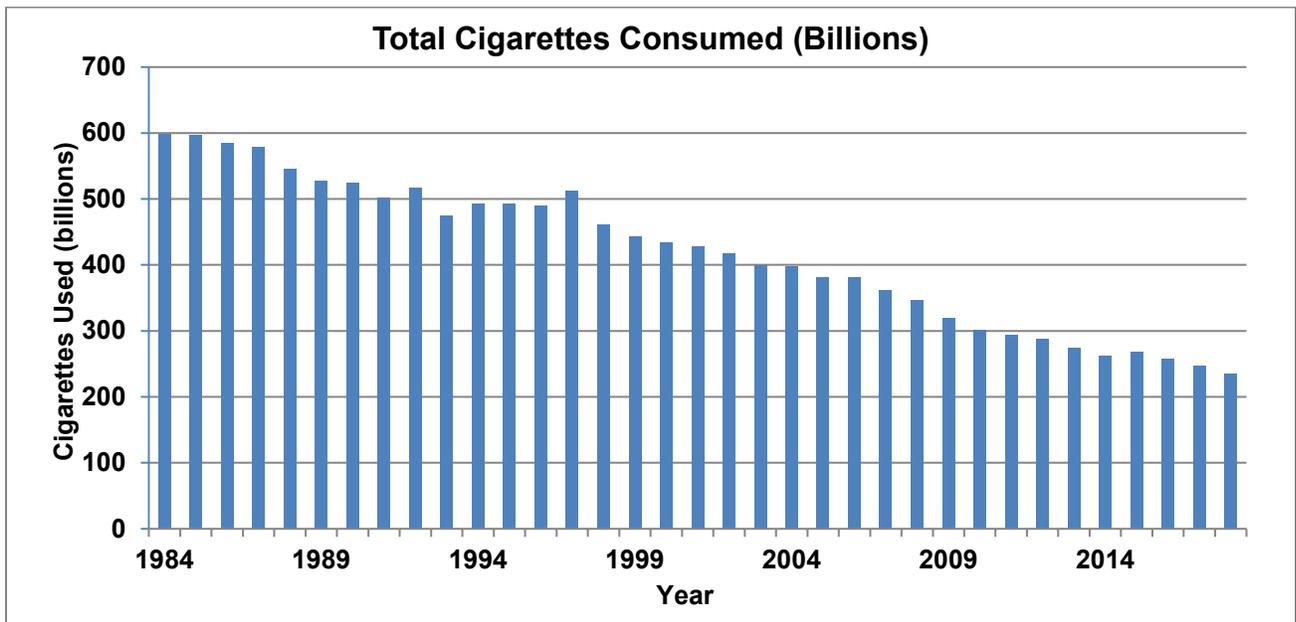
There is no safe level of exposure to SHS (DHHS, 2006a and 2006b). Even low levels of SHS can harm children and adults in many ways, including the following:

- 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, 2018). 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, 1984–2018



As of March 2019, 28 states and the District of Columbia had implemented comprehensive smoke-free laws (American Lung Association, 2019). Such laws are also expected to reduce the levels of non-users' 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 evaluated potential environmental impacts that may be caused by disposal of the new products 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 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 that disposal of the new products 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 products. The chemicals in the cigarette butts from the new products would be similar to those 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 to the air from disposal of the new products are anticipated to be the same as 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 would be a minuscule portion of the municipal solid waste per FDA's experience in evaluating the packaging waste generated from cigarettes.

7.3. Water Resources

No changes in impacts on water resources are expected due to the disposal of cigarette butts and packaging materials following use of the new products because (1) the chemicals in the new products are used in currently marketed cigarettes and (2) the new products are intended to compete with or replace market share held by similar products, and (3) the new products are intended to replace the original products.

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

7.5. Socioeconomics and Environmental Justice

No significant environmental impacts have been identified from disposal of the new products. 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 products 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 products 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 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 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 the new products replacing the original products, and declining use of cigarettes in the United States.

7.8. Impacts of the No-Action Alternative

The no-action alternative would not change the existing disposal of cigarettes and cigarette packaging in the United States, as many other similar products would continue to be marketed.

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 G. 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. List of Agencies and Persons Consulted

Not applicable.

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Confidential Appendix 1: Modifications: The New Products Compared to the Corresponding Original Products

The new products differ from the corresponding original products in the deletion of side seam adhesive (b) (4) and addition of side seam adhesive (b) (4). The side seam replacement resulted in decreased (b) (4) and (b) (4), deletion of (b) (4) and (b) (4), and addition of (b) (4), and (b) (4).

Confidential Appendix 2: First- and Fifth-Year Market Volume Projections for the New Products

First- and fifth-year market volume projections for the new products were compared to the total forecasted use of cigarettes in the United States.² Comparing projected market volumes to forecasted market volumes, the Agency found that the percent share of the projected market volumes is miniscule in comparison to the total forecasted market volumes. Projected use for the new products in the first- and fifth-year account for about (b) (4) respectively.

New Product	Projected Market Volume			
	First Year		Fifth Year	
	New Product (Cigarettes)	New Product as a Percent of Total Cigarettes Used ³	New Product (Cigarettes)	New Product as a Percent of Total Cigarettes Used ³
USA Gold Blue 100s Box	(b) (4)			
USA Gold Blue 100s Soft Pack				
USA Gold Red 100s Box				
USA Gold Red 100s Soft Pack				
USA Gold Red Kings Box				
USA Gold Red Kings Soft Pack				
USA Gold Menthol Green 100s Soft Pack				
USA Gold Non-Filter Kings Soft Pack				
USA Gold Menthol Green Kings Soft Pack				
USA Gold Gold Kings Box				
USA Gold Gold Kings Soft Pack				
USA Gold Menthol Dark Green 100s Box				
USA Gold Blue Kings Soft Pack				
USA Gold Gold 100s Box				
USA Gold Gold 100s Soft Pack				
USA Gold Menthol Dark Green 100s Soft Pack				
USA Gold Menthol Dark Green Kings Box				
USA Gold Menthol Dark Green Kings Soft Pack				
USA Gold Menthol Green 100s Box				
Total				

² The Agency used historical data regarding total use of cigarettes from 2002 to 2018 to mathematically estimate the total number of cigarettes used in the United States. Using the best-fit trend line with an R² value of 0.9814, the forecasted number of cigarettes that would be used in the United States is estimated at 228.657 billion cigarettes in the first year and 205.021 billion cigarettes in the fifth year of marketing the new products.

³ Projected Market Occupation of the New Products in the United States (%) = $\frac{\text{Projected Market Volume of the New Products (cigarette pieces)}}{\text{Projected Use of Cigarettes in United States (cigarette pieces)}} \times 100$