

**Programmatic Environmental Assessment for Nine New  
Cigarettes Manufactured by Sherman's 1400 Broadway, N.Y.C.  
LLC**

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

**January 18, 2019**

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### 1. Applicant and Manufacturer Information

<b>Applicant Name</b>	Altria Client Services LLC
<b>Applicant Address</b>	2325 Bells Road Richmond VA 23234
<b>Manufacturer Name</b>	Sherman's 1400 Broadway, N.Y.C. LLC
<b>Product Manufacturing Address</b>	7615 Boeing Drive Greensboro, NC 27409

### 2. Product Information

#### New and Corresponding Predicate Products

STN	New Product	Predicate Product
SE0014960	Nat's Yellow King / Select Yellow King	Naturals Lights King
SE0014961	Classic	Classic
SE0014962	Originals Menthol	Naturals Mint
SE0014963	Originals Blue	Naturals Lights
SE0014964	Nat's King / Select King	Naturals Originals King
SE0014965	New York Cut Blue	New York Cut Light
SE0014966	New York Cut Original	New York Cut Original
SE0014967	Classic Menthol	Classic Mint
SE0014968	Classic Blue	Classic Light

#### Product Identification

<b>Product Category</b>	Cigarettes
<b>Product Subcategory</b>	Combusted filtered
<b>Product Number per Retail Unit</b>	Twenty cigarettes per pack with five (SE0014961-63, 67-68) or ten (SE0014960, 64-66) packs per paperboard carton
<b>Product Package</b>	The packaging materials differ among the nine new products. Generally, the packages are a paperboard box with a foil (SE0014960, 64-66) or cellophane (SE0014961-63, 67-68) inner liner, a paper label, and polypropylene film overwrap and tear tape. Multiple packs are packaged in a paperboard carton.

### 3. The Need for the Proposed Actions

The proposed actions, requested by the applicant, are for the Food and Drug Administration (FDA) to issue marketing orders under the provisions of sections 910 and 905(j) of the Federal Food, Drug, and Cosmetic Act after finding the new tobacco products substantially equivalent to the corresponding predicate products. The applicant wishes to introduce the new tobacco products into interstate commerce for commercial distribution in the United States and submitted to the Agency nine substantial equivalence reports to obtain marketing orders.

The Agency shall issue marketing orders if the new products are found substantially equivalent to the corresponding predicate products. The predicate products are grandfathered products commercially marketed in the United States as of February 15, 2007.

The new products differ from the corresponding predicate products due to changes in the specification for the banded cigarette paper.

The applicant provided first- and fifth-year marketing projections for the new products (Confidential Appendix 1).

#### **4. Alternatives to the Proposed Actions**

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

#### **5. Potential Environmental Impacts of the Proposed Actions and Alternatives - Manufacturing the New Products**

The Agency 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 the same manner as the predicate products and other products manufactured at the facility.
- Endangered species and critical habitat are not expected to be affected by production of the new products or materials and ingredients used to manufacture the new products.
- No facility expansion is expected due to manufacturing the new products.
- No air or wastewater permits are required for manufacturing the new products.

##### **5.1 Affected Environment**

The new products would be manufactured at 7615 Boeing Drive, Greensboro, NC 27409 (Figure 1).

**Figure 1. Location of the Manufacturing Facility**



A riverine wetland runs southwest to northeast along the southeastern developed section of the property (EPA, 2018). The developed area is adjacent to an irregularly shaped 100- to 1,600-foot-wide undeveloped area with mature trees.

## **5.2 Air Quality**

The Agency does not anticipate that manufacturing the new products would lead to release of new chemicals into the air. The applicant stated that air emissions from manufacturing the new products are expected to be the same as from the corresponding predicate products and would not require a change in the facility's air permit exemption status.

## **5.3 Water Resources**

The Agency does not anticipate that manufacturing the new products would cause any new chemicals to be discharged into water. The applicant stated that aquatic environmental releases from manufacturing the new products are expected to be the same as from the corresponding predicate products and no wastewater permits would be required for manufacturing the new products.

## **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 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. The applicant stated that there are no plans to expand the facility production beyond its current level. According to the U.S. Fish and Wildlife Service's endangered and threatened species maps (FWS 2018), one endangered plant species—Schweinitz's sunflower (*Helianthus schweinitzii*)—and one threatened plant species—small whorled pogonia (*Isotria medeoloides*)—are potentially affected by activities at this location, but there are no critical habitats at this location. The applicant stated that these species are not known to be in the vicinity of the manufacturing facility. The riverine wetland habitat along the southeast of the site may be suitable for two protected migratory bird species, the rusty blackbird (*Euphagus carolinus*) and the wood thrush (*Hylocichla mustelina*), but the applicant reported that no individuals of either species were observed at the site.

## **5.6 Regulatory Compliance**

The applicant stated that the manufacturing facility complies with the requirements of the Clean Air Act, Clean Water Act, and Resource Conservation and Recovery Act (RCRA); and that manufacturing the new products would not change compliance with relevant federal, state, and local environmental regulations. EPA's Enforcement and Compliance History Online database does not list a RCRA registration or emissions or discharge permits for this manufacturing facility.

The applicant stated that no adverse effects are expected to a species or habitat identified under the Endangered Species Act or the Convention on International Trade in Endangered Species of Wild Fauna and Flora.

## **5.7 Socioeconomics and Environmental Justice**

No changes to socioeconomic conditions 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, with no expansion 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 manufacturing the new products would notably affect the amount or types of 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 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 applicant stated that air emissions and water discharges from manufacturing the new products are expected to be the same as from the corresponding predicate products, waste would be handled the same as waste currently generated, and no facility expansion is required. Therefore, the Agency does not anticipate any cumulative impacts from manufacturing the new products.

## **5.11 Impacts of 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 similar cigarette products would continue to be marketed and therefore 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.

### **6.1 Affected Environment**

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

### **6.2 Air Quality**

The Agency does not anticipate 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 other marketed cigarettes, (2) the new products are expected to compete with or replace other currently marketed cigarettes, and (3) the ingredients in the new products are used in other currently marketed tobacco products.

### **6.3 Environmental Justice**

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

### **6.4 Cumulative Impacts**

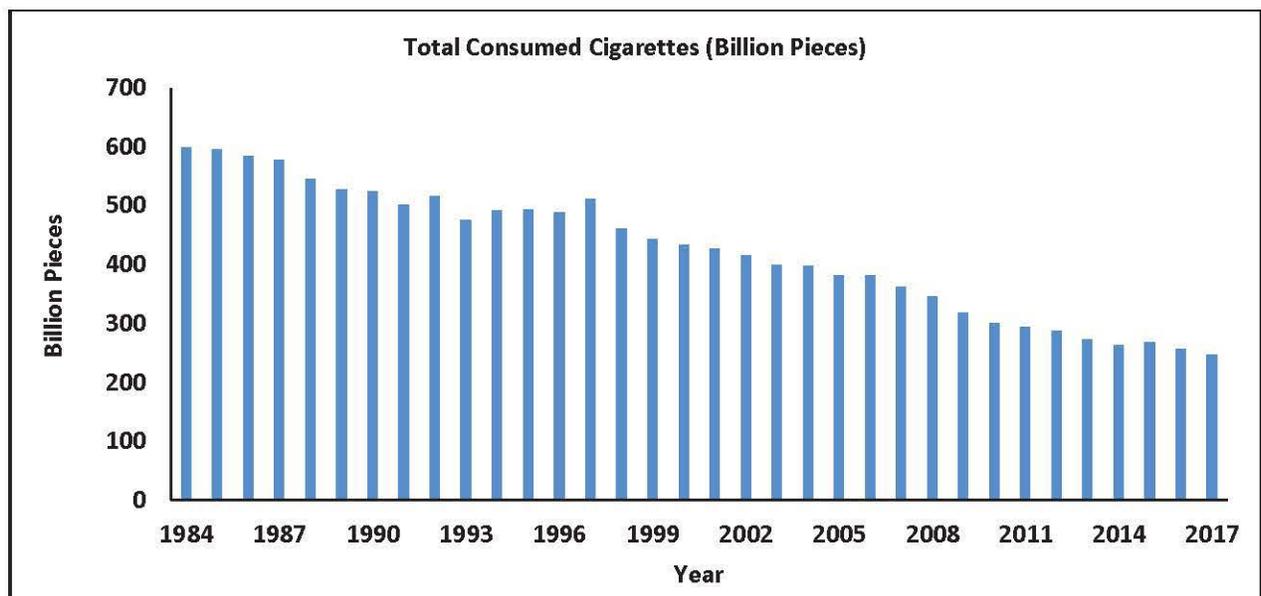
Impacts from use of combusted tobacco products include health effects to non-users as well as users. When using cigarettes, the users inhale the mainstream smoke and exhale secondhand smoke (SHS) to the environment. In addition, particles emitted by smoking may remain on surfaces, be re-emitted back 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 percent (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 products are 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 actions would not change existing cumulative impacts, including SHS and THS exposure, from combusted, filtered cigarette use.

## **6.5 Impacts of No-Action Alternative**

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

## **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 is the entire United States because the marketing orders would allow the new tobacco products to be sold to consumers nationwide.

### **7.2 Air Quality**

The Agency does not anticipate disposal of the new products or packaging materials would release new or increased 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 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.

### **7.3 Water Resources**

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

### **7.4 Biological Resources**

Disposal of the new products 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, 2018), disposal of the new products is not expected to change the fire frequency because (1) the

disposal of the new products is the same as 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 compete with or 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 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 generated is equivalent to the market projections (Confidential Appendix 1) 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, which can persist in the environment for more than 10 years (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. However, the cumulative impacts from cigarette butts is declining because the use of cigarettes in the United States is declining.

The Agency did not identify any actions that, when considered with the products' disposal under the proposed actions, would lead to changes in cumulative impacts.

## **7.8 Impacts of 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:**

Christine M. Modovsky, Center for Tobacco Products (product-specific analyses, primary author)  
Education: M.S. in Environmental Science  
Experience: Twenty-nine years in environmental compliance and analysis  
Expertise: NEPA analysis, regulatory compliance, evaluation of environmental health and ecological effects

### **Reviewer:**

Hoshing W. Chang, Center for Tobacco Products  
Education: Ph.D. in Biochemistry, M.S. 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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Smith, C.J., S.D. Livingston, D.J. Doolittle. 1997. An international literature survey of "IARC Group 1 carcinogens" reported in mainstream cigarette smoke. *Food and Chemical Toxicology* 35(10-11):1107-1130.

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**Confidential Appendix 1: Marketing Projections for the New Products**

STN	Name	Projected Market Volume (cigarettes)	
		First Year	Fifth Year
SE0014960	Nat's Yellow King / Select Yellow King	(b)	(4)
SE0014961	Classic		
SE0014962	Originals Menthol		
SE0014963	Originals Blue		
SE0014964	Nat's King / Select King		
SE0014965	New York Cut Blue		
SE0014966	New York Cut Original		
SE0014967	Classic Menthol		
SE0014968	Classic Blue		

The applicant stated that, after receiving marketing orders for the new products, the new products would replace the corresponding predicate products, which will no longer be marketed.