

**Programmatic Environmental Assessment for Exemption Requests by R.J. Reynolds Tobacco Company for New “True Blue 100, True Menthol Green 100 Soft Pack, True Blue Soft Pack, True Blue, True Blue 100 Soft Pack, True Menthol Green Soft Pack, Kent III Silver 100 Soft Pack”**

Prepared by Center for Tobacco Products

U.S. Food and Drug Administration

November 27, 2017

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This programmatic environmental assessment (PEA) is for Exemption Requests for seven combusted filtered cigarettes manufactured by R.J. Reynold Tobacco Company. Information presented in the PEA is based on the submissions referenced in Appendix 1, unless noted or referenced otherwise. This PEA has been prepared in accordance with 21 CFR 25.40 as part of submissions under section 905(j)(3) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

#### **1. Name of Applicant**

R.J. Reynolds Tobacco Company

#### **2. Address of Applicant**

401 N. Main Street  
Winston-Salem, NC 27101

#### **3. Manufacturer**

R.J. Reynolds Tobacco Company

#### **4. Description of the Proposed Action**

The proposed action is for FDA to issue exemptions from SE Reports for marketing orders under section 905(j)(3) of the FD&C Act for the introduction of combusted filtered cigarettes into interstate commerce for commercial distribution in the United States. These authorizations are based on the finding that the modifications in the new products are minor modifications of a tobacco product that can be sold under the FD&C Act, an SE Report is not necessary to ensure that permitting marketing of the modified tobacco products would be appropriate for the protection of the public health, and an exemption is otherwise applicable. The applicant stated that they intend to discontinue production and marketing of the original products if a marketing order is granted for the new products. The original products for EX0000193, EX0000194, EX0000195, EX0000196, EX0000198, EX0000199, and EX0000200 are grandfathered products GF1501509, GF1501510, GF1501512, GF1501508, GF1501513, GF1501511, and GF1501515, respectively, which received confirmation of grandfathered status on March 29, 2016.

##### **4.1. Requested Action**

The applicant, R.J. Reynolds Tobacco Company, submitted requests to FDA to exempt from SE requirements seven new products, which are combusted filtered cigarettes.

##### **4.2. Need for Action**

R.J. Reynolds Tobacco Company wishes to introduce the new tobacco products, as described, into interstate commerce for commercial distribution in the United States. The applicant claims that the differences in the new products and the corresponding original products are minor modifications. In addition, the applicant claimed that the new and corresponding original products have identical

packaging composition. The applicant must obtain a written notification that FDA has granted the product an 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 products for which the applicant has obtained the exemption from substantial equivalence.

#### 4.3. Identification of the New Tobacco Products that are Subjects of the Proposed Action

##### 4.3.1. Type of Tobacco Products

Combusted filtered cigarettes

##### 4.3.2. Product Names and the Submission Tracking Numbers (STN)

The names of the new products are listed below, along with the submission tracking numbers (STNs) and the name and STN of the original products. See Appendix 1 for additional STNs associated with the new products.

STN	New Product	Original STN	Original Product
EX0000193	True Blue 100	GF1501509	True Box 100s
EX0000194	True Menthol Green 100 Soft Pack	GF1501510	True Menthol 100s
EX0000195	True Blue Soft Pack	GF1501512	True Kings
EX0000196	True Blue	GF1501508	True Box
EX0000198	True Blue 100 Soft Pack	GF1501513	True 100s
EX0000199	True Menthol Green Soft Pack	GF1501511	True Menthol Kings
EX0000200	Kent III Silver 100 Soft Pack	GF1501515	Kent III Ultra Lights 100s

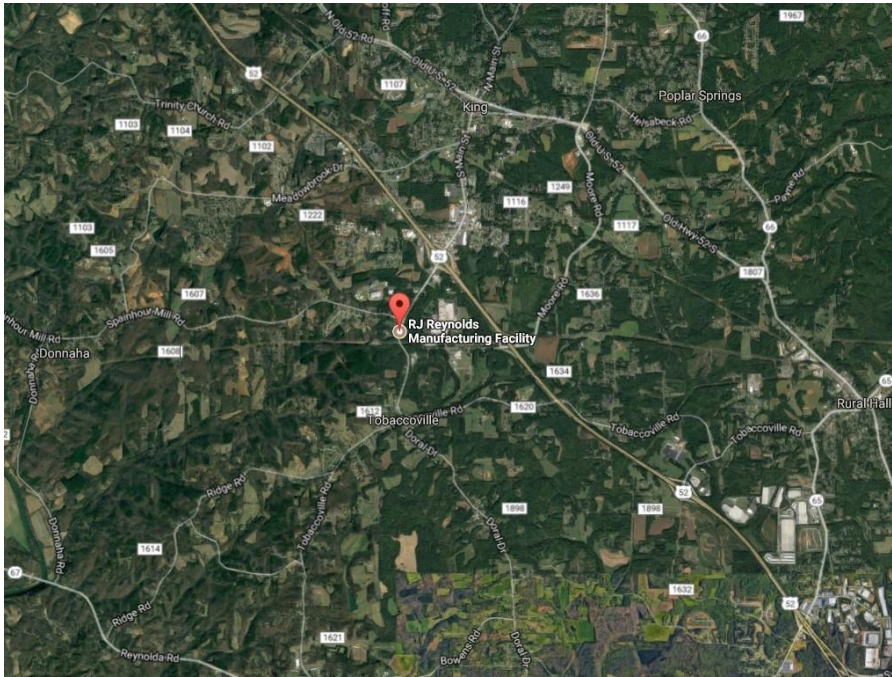
##### 4.3.3. Description of the Products Package

The packaging materials of the finished new products are identical in materials and composition to those of the corresponding original products. The new products' packaging consists of a foil inner liner, inner frame, box, film overlap, and carton.

##### 4.3.4. Location of Manufacturing

The manufacturer, R.J. Reynold Tobacco Company (RJR), is located at 7855 King-Tobacconville Road in Tobacconville, North Carolina in the United States (Figure 1). The facility is surrounded by woodlands, bounded by the city of King, NC to the north, US 52 (a four-lane divided highway) to the east, and mixed use residential, commercial, and agricultural land to the south and west (Figure 1).

**Figure 1. Location of the Manufacturer<sup>1</sup>**



**4.3.5. Location of Use**

R.J. Reynolds Tobacco Company intends to distribute and sell the new tobacco products to consumers in the United States.

**4.3.6. Location of Disposal**

Once used, the new products will be disposed of in landfills as municipal solid waste (MSW) or as litter in the same manner as the original products and any other combusted filtered cigarettes. Disposal of the packaging materials following use will either enter the recycling stream or be disposed of in MSW landfills or as litter. The Agency anticipated the distribution of waste from disposal after use will correspond to the pattern of product use.

**4.4. Modification(s) Identified as Compared to the Original Products**

The applicant stated that the only differences between the new products and the corresponding original products are in the deletion of a complex ingredient tobacco additive and a change in the quantity of existing tobacco additives.

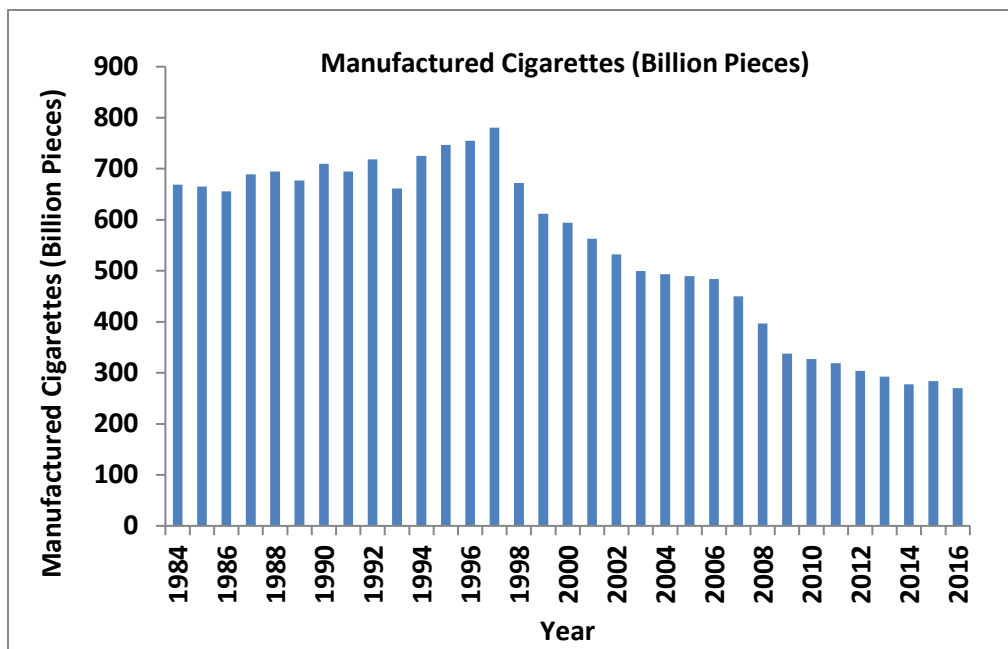
<sup>1</sup> Manufacturer location via Google Map. Accessed October 24, 2017

## 5. Potential Environmental Impacts Due to the Proposed Action

### 5.1. Potential Environmental Impacts Due to Manufacturing the New Products

According to the U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) Statistical Release reports, 270 billion cigarettes (13.5 billion packs of 20 cigarettes each) have been manufactured in 2016 (Figure 2).<sup>2,3</sup> As of June 2017, 29 different tobacco manufacturers were registered as a "non-participating manufacturer" under the Master Settlement Agreement and 128 were registered as a "participating manufacturer" in the State of North Carolina, including R.J. Reynolds Tobacco Company.<sup>4</sup>

Figure 2. Total Cigarettes Manufactured in the United States, 1984-2016



The emission information associated with all tobacco products as reported in the EPA's Toxic Release Inventory (TRI) database is publicly available.<sup>5</sup> In 2016, United States tobacco

<sup>2</sup> U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) statistical data available at: <https://www.ttb.gov/tobacco/tobacco-stats.shtml>. Accessed March 30, 2017.

<sup>3</sup> Million pound of cigarettes value is calculated based on the assumption that approximately 0.9 grams of tobacco is used per cigarette. Million pound cigarettes = 
$$\frac{(X \text{ billion cigarette pieces} \times 10^9) \times \left(\frac{0.9 \text{ g}}{453.59 \text{ g}}\right)}{10^6}$$

<sup>4</sup> North Carolina Department of Justice. Tobacco Lists. 2017. Available at <http://www.ncdoj.gov/getdoc/3b96da5a-6384-4bfc-bd2f-3636a5bb8711/2-6-4-3-6-Tobacco-Lists.aspx>. Accessed October 24, 2017

<sup>5</sup> The estimation is done by using the Toxics Release Inventory (TRI), a dataset (<http://www.epa.gov/tri/>) compiled by the U.S. Environmental Protection Agency (EPA). This database allows users to retrieve information on toxic chemicals handled by many facilities across the United States, including details on quantities of chemicals managed through disposal or other release, recycling, energy recovery or treatment. Data associated with the tobacco manufacturing industry is retrieved by using North American Industry Classification System (NAICS) codes beginning with 3122. Not all toxic release data of tobacco manufacturers

manufacturers released ammonia, nicotine and nicotine salts to the environment and nicotine and nicotine salts were also transferred to publicly owned treatment works (POTWs) or an off-site location (Table 1).<sup>6</sup> The TRI database search also did not show that the Tobaccoville manufacturing facility disposed of, treated, or released into the environment any other toxicants associated with manufacturing tobacco products.

**Table 1 Emissions Associated with Manufacturing Tobacco Products**

<b>Emissions Associated with All Tobacco Product Manufacturers in the United States</b>				
<b>Chemical Name</b>	<b>Air Release (Pound)</b>	<b>Land Release (Pound)</b>	<b>Water Release (Pound)</b>	<b>POTW Transfer (Pound)</b>
<b>Ammonia</b>	406,454	1	186	18,056
<b>Nicotine &amp; Nicotine Salts</b>	253,436	74,322	30	108,051
<b>Emissions Associated with Tobacco Product Manufacturing at RJR Facility in Tobaccoville, NC</b>				
<b>Ammonia</b>	20,003	1	0	4,785
<b>Nicotine &amp; Nicotine Salts</b>	18,909	3	0	277

The Agency anticipates the waste generated due to manufacturing the new products will be released to the environment, transferred to POTW, and disposed of in landfills in the same manner as any other waste generated from any other products manufactured in the same facility and in a similar manner to other combusted filtered cigarettes manufactured in the United States. The applicant stated that the new products will compete with other currently marketed combusted filtered cigarettes. The applicant also stated that production and marketing of the original products will cease if a marketing order is granted for the new products. No expansion of the manufacturing facility is anticipated for manufacturing the new products. Therefore, the Agency does not foresee the introduction of the new products to notably affect the current manufacturing waste generated from the production of all combusted filtered cigarettes.

Based on the information in the Exemption Requests, the new products and the corresponding original products are manufactured in a similar manner and the changes related to the deletion of one tobacco additive and the change in the quantity of existing tobacco additives are minor changes that would not be expected to release new air emissions. Consequently, the Agency does not anticipate any new substances or new type of emissions to be released into the environment as a result of manufacturing the new products.

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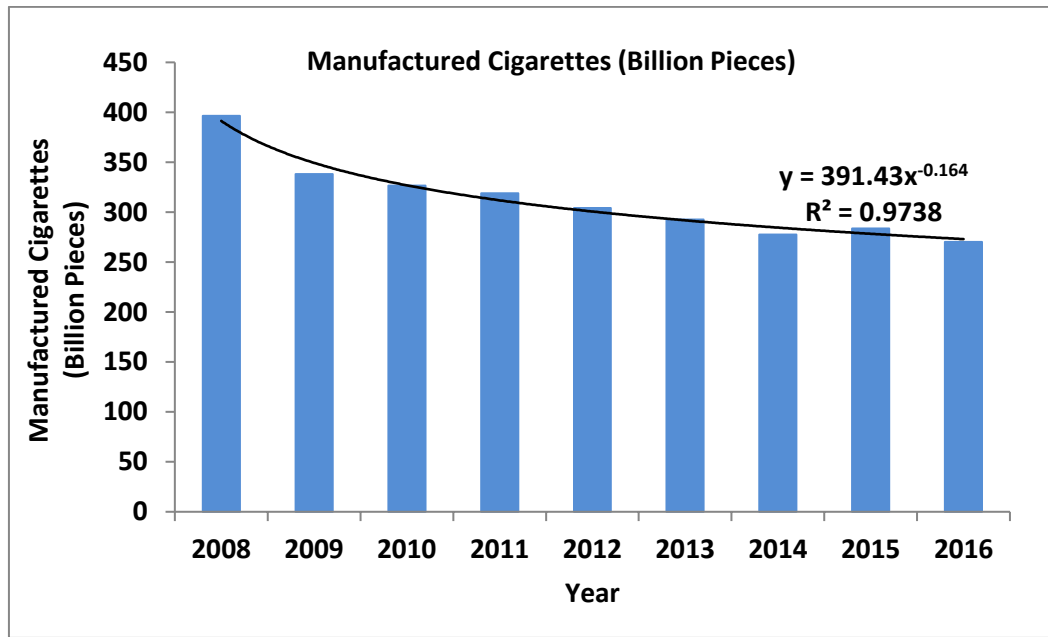
are included in the database. The database includes information from any facility that (1) falls within a TRI-reportable industry sector or is federally-owned or operated; (2) has 10 or more full-time (or equivalent) employees; and (3) manufactures, processes or otherwise uses (MPOU) a TRI-listed chemical <https://www.epa.gov/sites/production/files/documents/TRIListChangesUpdate11282011.pdf>) in an amount above the TRI reporting threshold during a calendar year.

<sup>6</sup> U.S. Environmental Protection Agency (EPA). *TRI Data Form R & A Download*. Available at: [https://www3.epa.gov/enviro/facts/tri/form\\_ra\\_download.html](https://www3.epa.gov/enviro/facts/tri/form_ra_download.html). Searched on September 18, 2017



The applicant provided the first- and fifth-year market volumes for the new products (Confidential Appendix 1). To evaluate the environmental impact of the proposed actions due to manufacturing of the new products, historical data regarding the manufacture of cigarettes in the United States from 2008 to 2016 was used to forecast the manufacture of cigarettes. This was achieved by using one best-fit power trend line with the  $R^2$  value of 0.9738. Accordingly, the forecasted number of all cigarettes to be manufactured in the United States is estimated to be 264.16 billion pieces in 2018 and 251.06 billion pieces in 2022 (Figure 3). The number of all cigarettes manufactured in the United States is estimated to be 268.32 billion pieces in 2017.<sup>7</sup>

Figure 3. Forecast of Cigarettes' Manufacturing in the United States, 2008-2016



The cumulative projected market volumes of the new products are a fraction of the forecasted manufacture of all cigarettes in the United States in 2018 and 2022 (Confidential Appendix 1). Additionally, the applicant stated that manufacturing the new products will not require any new equipment or expansion of the current manufacturing.

The applicant stated that the manufacturing facility complies with all federal, state, and local environmental regulations and provided information on the facility's air, storm water and wastewater permits. The applicant's air permit expired in November 2012 but they reapplied in 2012 and are waiting for the renewed permit. The applicant also stated that their facility complies with other environmental regulations including maintaining EPA Spill Prevention Control and Countermeasure plans, reporting greenhouse gas (GHG) emissions to EPA under the GHG reporting rule 40 CFR 98, submitting EPA Tier 2, EPA TRI, and North Carolina Right-to-Know reports, complying

<sup>7</sup> Projected first-year and fifth-year billion pieces of cigarettes =  $391.3 \times (\text{year} - 2008)^{-0.164}$

with the DHS Chemical Antiterrorism Standards, and complying with applicable solid and hazardous waste regulations. Therefore, cumulative introduction of materials released into the environment is not expected to exceed the allowed amount to be released to the environment under relevant environmental laws.

The applicant noted that the facility complies with the endangered Species Act (ESA) and the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES). The applicant consulted with the U.S. Fish and Wildlife Services and confirmed that the location of the manufacturing facility is not within or near a habitat, critical or otherwise, of a threatened or endangered species, per habitat maps.<sup>8</sup> According to the Exemption Requests, the requested actions 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 applicant also stated that their facility complies with other environmental regulations including maintaining EPA Spill Prevention Control and Countermeasure plans, reporting GHG emissions to EPA under the GHG reporting rule 40 CFR 98, submitting EPA Tier 2, EPA TRI, and North Carolina Right-to-Know reports, complying with the DHS Chemical Antiterrorism Standards, and complying with applicable solid and hazardous waste regulations. Therefore, cumulative introduction of materials released into the environment is not expected to exceed the allowed amount to be introduced to the environment under relevant environmental laws.

## 5.2. Potential Environmental Impacts Due to Use of the New Products

According to the U.S. TTB statistical data, the use of cigarettes in the United States decreased from 512 billion cigarettes (1,1013.81 million pounds) in 1997 to 257 billion cigarettes (509.83 million pounds) in 2016 (Figure 4).<sup>9</sup>

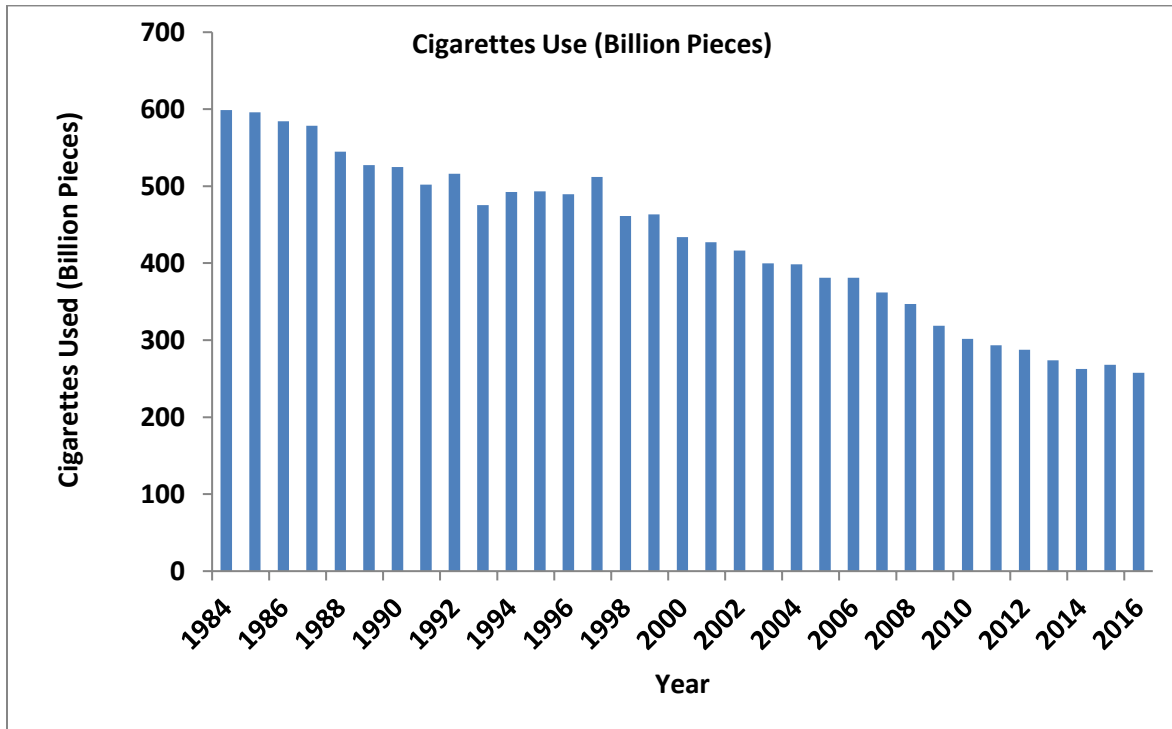
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<sup>8</sup> Habitat maps are located at:

<http://fws.maps.arcgis.com/home/webmap/viewer.html?webmap=9d8de5e265ad4fe09893cf75b8dbfb77>. Accessed on October 31, 2017.

<sup>9</sup> Million pound of cigarettes value is calculated based on the assumption that approximately 0.9 grams of tobacco is used per cigarette. Million pound cigarettes =  $\frac{(X \text{ billion cigarette pieces} \times 10^9) \times \left(\frac{0.9 \text{ g}}{453.59 \text{ g}}\right)}{10^6}$

Figure 4. Use of Cigarettes in the United States, 1984 – 2016



The Agency does not anticipate new substances to be released into the environment as a result of use of the new cigarettes, relative to the substances released by the original products, and other cigarettes already on the market. As noted, the only differences between the new and corresponding original products are deletion of a tobacco additive and an increase in existing tobacco additives. The combustion products from the new products are released in a similar manner to the combustion products of the corresponding original products and other marketed cigarettes.

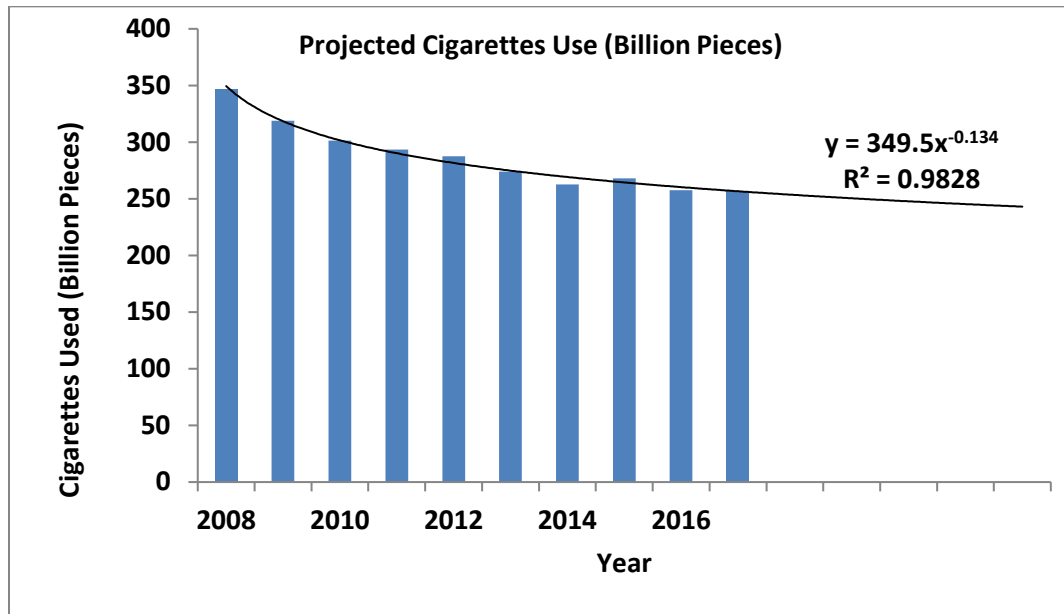
When using cigarettes, the users inhale the mainstream smoke and release tobacco smoke to the environment, referred to as secondhand smoke. There is no safe level of exposure to secondhand smoke [1, 2]. Even low levels of secondhand smoke can harm children and adults in many ways, including the following:

- 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 [3].
- Exposure to secondhand smoke increases school children's risk for ear infections, lower respiratory illnesses, more frequent and more severe asthma attacks, and slowed lung growth, and it can cause coughing, wheezing, phlegm, and breathlessness [1, 2].
- Secondhand smoke causes more than 40,000 deaths a year [3].

To evaluate the environmental impact of the proposed actions due to use of the new products, historical data regarding total use of cigarettes from 2008 to 2016 was employed to mathematically

estimate the forecast of the total amount of these products used in the United States.<sup>10</sup> Using the best-fit trend line with an  $R^2$  value of 0.9828, the forecasted number of cigarettes that will be used in the United States is estimated to be 256.73 billion cigarettes in 2017; 253.47 billion cigarettes and 243.15 billion cigarettes are forecasted to be used in the first year and fifth year of marketing the new products, respectively (Figure 5).<sup>11</sup>

Figure 5. Forecasted Use of Cigarettes in the United States, 2008-2016



The Agency does not anticipate new substances to be released into the environment as a result of use of the new cigarettes, relative to the substances released by the original products, and other cigarettes already on the market. As noted, the difference between the new products and the original products is minor changes in ingredients; the weight of packaging material is the same. Additionally, because (1) the new products will replace the original products and compete with other currently marketed cigarettes; and (2) the projected market volumes of the new products in the first and fifth year of marketing the new products occupy a negligible fraction of the total projected estimate of use of cigarette in the United States (Confidential Appendix 2), no net addition of GHG emissions is anticipated.

<sup>10</sup> The forecast trend line is extrapolated from TTB data. Available from <http://www.ttb.gov/tobacco/tobacco-stats.shtml>. Accessed October 30, 2017.

<sup>11</sup> Projected first-year and fifth-year billion pieces of cigarettes =  $349.5 \times (\text{year} - 2007)^{-0.134}$

### 5.3. Potential Environmental Impacts Due to Disposal of the New Products

#### 5.3.1 Disposal of Packaging Material

Disposal of the packaging materials following use would either enter the recycling stream or be disposed of in MSW landfills or as litter. Information about trash generation in the United States, including details about disposal of materials comparable to those used in cigarette products, can be informative about the disposal of cigarette packing materials. Specifically, according to the U.S. Environmental Protection Agency (U.S. EPA), approximately 258.46 million tons of waste was generated in the United States in 2014, and approximately 89.4 million tons of this material was recycled and composted, equivalent to a 34.6% recycling rate (Figures 6 and 7).<sup>12</sup> Paper and paperboard accounted for 68.61 million tons (26.5%) of the total MSW generated in 2014. Containers and packaging comprised the largest portion of total MSW generated at 76.67 million tons (29.7%), of which 39.13 million tons was made of paper and paperboard. Of the total paper and paperboard MSW, 44.4 million tons (64.7%) was recycled, 19.47 million tons (28.4%) was disposed of in landfills, and 4.74 million tons (6.9%) was combusted with energy recovery. On average, 4.4 pounds of waste was generated per person in the United States, of which 2.1 pounds was recycled, composted, or combusted for energy recovery [4].

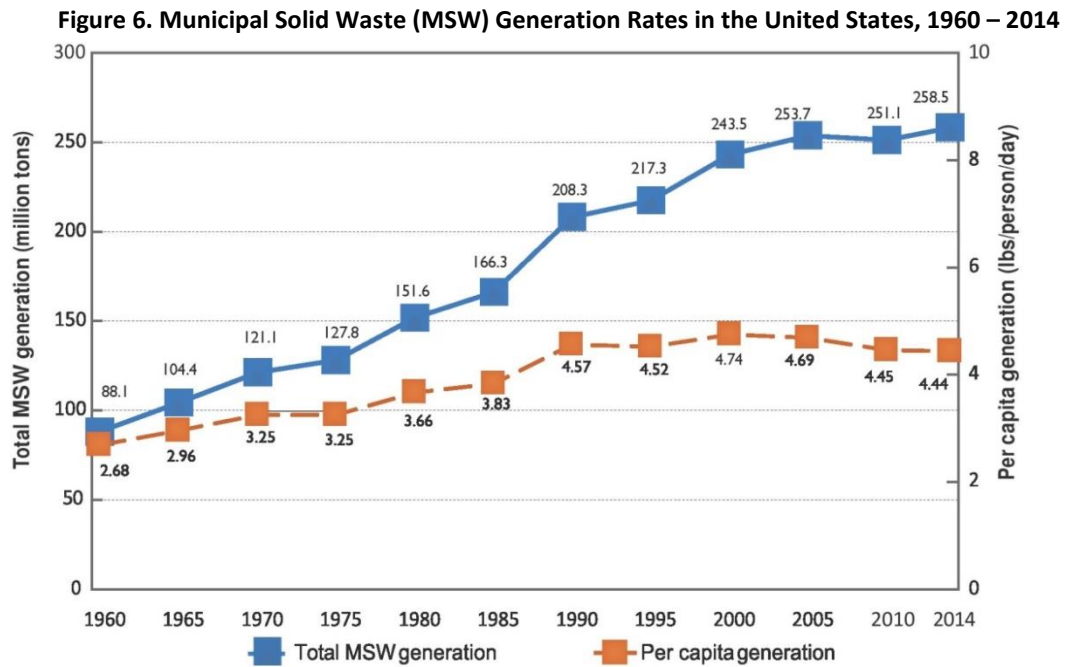


Figure excerpted from the U.S. EPA's "Advancing Sustainable Materials Management: 2014 Fact Sheet"

<sup>12</sup> The "ton" unit in section 5.3.1 is U.S. short ton, unless specified otherwise

**Figure 7. MSW Recycling Rates in the U.S., 1960 – 2014**

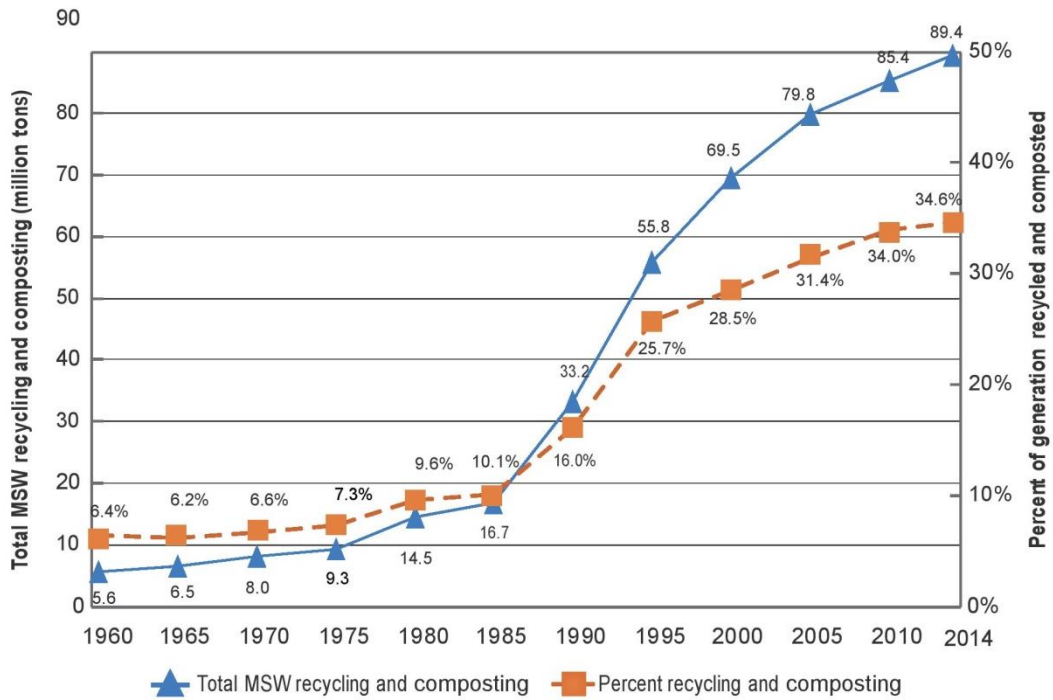


Figure excerpted from the U.S. EPA's "Advancing Sustainable Materials Management: 2014 Fact Sheet"

The Agency believes that the disposal of the new products will be similar to the disposal conditions of other cigarettes that are currently being marketed. After using the new products, the users may dispose of or recycle the packaging material. Users may also discard the combusted cigarettes and filters, as discussed above, as MSW or litter.

To calculate the amount of waste from disposal of the packaging material and product material, the Agency used the first- and fifth-year projected volumes of marketing the new products after issuance of the marketing orders for the new products (Confidential Appendix 1 and 3). The calculated cumulative waste of the packaging material is a miniscule fraction of the forecasted MSW that would be generated in the United States. In addition, because paper components and plastic wrap are more likely to be recycled, at least a portion of the packaging waste is likely to be recycled.

As previously discussed, because (1) the applicant stated that the new products will compete with other similar products on the market, (2) the original products will be discontinued, and (3) based on the above-mentioned information regarding waste, construction of new POTWs or landfills is not anticipated due to the proposed actions.

The Agency does not anticipate the proposed actions to lead to the release of new chemicals into the environment due to use of the products. Therefore, the fate of any materials emitted is anticipated to be the same as any materials from other cigarettes manufactured in the facility.

### 5.3.2 Disposal of Cigarettes Following Use

Used cigarettes are usually disposed of in MSW landfills or as litter. When discarded as litter, the spent products are likely to move by run-off to the ocean. When discarded as MSW, the products would enter landfills. The Agency utilized the historical data for use of cigarettes in the United States to forecast the future use and calculate the projected tobacco waste accordingly (Section 5.2). Assuming that the entire cigarette product is disposed of as MSW, the estimated waste from the forecasted use of all cigarettes in 2018 and 2022 is a fraction of a percent of the total 234.47 million metric tons of the estimated MSW generated in the United States in 2014, as shown in the Table 2 [5].

**Table 2 Forecast of Waste of Used Cigarette Products as Compared to Total MSW in the United States**

Year	Cigarettes (Billion Pieces) <sup>a</sup>	Cigarettes (Metric Tons) <sup>b</sup>	Waste of Cigarettes (Percent of Total MSW in the United States) <sup>c</sup>
Current Year (2017)	256.73	256,730	0.109 %
First Year (2018)	253.47	253,470	0.108 %
Fifth Year (2022)	243.15	243,150	0.104 %

a = Projected billion cigarettes pieces (See Section 5.2)

b =  $\frac{(X \text{ billion pieces} \times 10^9) \times (1 \text{ gram per cigarette})}{10^6}$  (Typically, a cigarette weighs approximately 1 gram.)

c = Percentage =  $\frac{\text{Cigarette metric tons}}{\text{EPA, 2014 Waste metric tons: } (234.47 \times 10^6)} \times 100\%$

A major existing environmental consequence of the use of combusted filtered cigarettes is the waste disposal of the cigarette butts. Evidence has shown that cigarette butts are the most prevalent items discarded into roads and streets in urban areas. Once dumped onto city streets, they move through the storm drains to streams, into the ocean, and back onto the beaches, while leaching toxicants, including arsenic, lead, nicotine and ethyl phenol, into the aquatic environment and soil along the way. Discarded filters are found to be the most collected item in beach clean-ups and litter surveys. An estimated 30 percent of the total waste (by count) on U.S. shorelines, waterways, and land is cigarette butt waste [6].

### 5.3.3 Air Emissions

The used tobacco products and packaging materials that are disposed of in MSW landfills or incinerated will produce GHGs. The Clean Air Act requires that all landfills constructed or modified after July 17, 2014 to install landfill gas collection-and-control systems if they will have a waste capacity of 2.5 million metric tons or more. Additionally, all landfills must report GHG emissions to the U.S. EPA under 40 CFR 98.

Methane (CH<sub>4</sub>) is a potent GHG that has a global warming potential of 28-36 times greater than carbon dioxide (CO<sub>2</sub>), and has an atmospheric life of about 12 years. Landfills are the third largest source of human-related CH<sub>4</sub> emissions in the United States, releasing an estimated

133.1 million metric tons of CO<sub>2</sub>-equivalent, accounting for approximately 15.4% of these emissions in 2015 [7]. The decomposition of landfill waste produces approximately 50% biogenic CO<sub>2</sub> and 50% CH<sub>4</sub>, by volume, as well as trace amounts of non-CH<sub>4</sub> organic compounds and volatile organic compounds. However, only CH<sub>4</sub> generation and emissions are estimated and reported for landfills, a convention set forth by the 2006 Intergovernmental Panel on Climate Change (IPCC) Guidelines [8].

Because the waste generated from the new products comprises a negligible fraction of the total MSW, the GHG emitted from waste associated with the new products is negligible according to quantified GHG emissions from disposal of the new products (Confidential Appendix 4) in this PEA. No additional control of GHG emissions is anticipated in the landfills.

The Agency does not anticipate that the proposed actions will lead to the release of new chemicals into the environment due to disposal of the new products. Therefore, the fate of any materials emitted is anticipated to be the same as any materials from other cigarettes. No new types of material are anticipated to be emitted to the environment due to disposal after use.

## **6. Use of Resources and Energy**

The applicant stated that there will be no change in how the new products are manufactured compared to the corresponding original products. The same raw materials and energy will be used to manufacture the new products compared to the corresponding original products and the applicant does not anticipate any increased energy or resource needs to manufacture the new products. The applicant stated that the proposed actions will not require an expansion of the manufacturing facility. When comparing the market volume projections with the forecasted total cigarette volumes in the United States, the Agency found that the projected market volumes of the new products are a small portion of the total forecasted cigarette market volume in 2018 and 2022. Because the applicant stated that the new products will compete with other similar cigarettes and that the original products will be discontinued, no increase of overall cigarette market volume and no net increase of energy use will be expected from the proposed actions. The applicant stated that no adverse effects to endangered or threatened species or critical habitat are expected from manufacturing the new products. Additionally, the applicant stated that the manufacturing facility has a goal to minimize GHG emissions by 20%, reduce energy use by 25%, reduce water use by 30%, and increase recycling to at least 60% of the waste at the facility by 2020.

## **7. Mitigation**

During the review of the available data and information, the Agency did not identify adverse environmental effects for the new products. Therefore, no mitigation measures were developed.



## **8. Alternatives to the Proposed Action**

*Alternative A (No-action alternative):* The no-action alternative is to not authorize the marketing of the new tobacco products in the United States. The environmental impact of the no-action alternative would not change the existing condition of the manufacturing, use, and disposal following use of tobacco products, as many similar tobacco products would continue to be marketed.

*Alternative B (Proposed actions):* There is no substantial environmental effect due to the proposed actions of authorizing the new products and associated manufacture, use, and disposal following use of the new tobacco products.

## **9. List of Preparers:**

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

### Preparer:

Rudaina Alrefai-Kirkpatrick, Ph.D., Center for Tobacco Products

Education: Ph.D. in Plant Molecular Biology and Virology

Experience: 25 years in various scientific activities

Expertise: NEPA analysis, environmental risk assessment, evidence-based assessment of health technologies, NEPA Implementation

### Reviewer:

Hoshing Chang, PhD, Center for Tobacco Products

Education: PhD in Biochemistry and MS in Environmental Science

Experience: 9 years in NEPA practice

Expertise: Waste water treatment, environmental impact analysis

## **10. List of Agencies and Persons Consulted**

Not applicable.

## **11. Appendix List**

Appendix 1: Submission Tracking Numbers for the EX Requests for the New Products and Related Amendments Covered Under this Programmatic Environmental Assessment (PEA)

## **12. Confidential Appendix**

Confidential Appendix 1: The First-, and Fifth-Year Market Volume Projections of the New Products

Confidential Appendix 2: Comparison of the First- and Fifth-Year Market Volume Projections for the New Products with Total Cigarettes Used in the United States

Confidential Appendix 3: Projected Waste of Packaging Material and Cigarette Butts in the First and Fifth Year of Marketing the New Products

Confidential Appendix 4: The Agency's Estimated GHG Emissions in the First and Fifth Year of Marketing the New Products

### 13. References

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**APPENDIX 1**

**Submission Tracking Numbers for the EX Requests for the New Products and Related Amendments Covered Under this Programmatic Environmental Assessment (PEA)**

<b>STN</b>	<b>New Product</b>	<b>Amendments</b>
EX0000193	True Blue 100	No Amendments
EX0000194	True Menthol Green 100 Soft Pack	
EX0000195	True Blue Soft Pack	
EX0000196	True Blue	
EX0000198	True Blue 100 Soft Pack	
EX0000199	True Menthol Green Soft Pack	
EX0000200	Kent III Silver 100 Soft Pack	

**CONFIDENTIAL APPENDIX 1**

**First- and Fifth-Year Market Volume Projections of the New Products**

STN	First-Year Projected Market Volume (Pieces)	Fifth-Year Projected Market Volume (Pieces)
EX0000193	(b) (4)	(b) (4)
EX0000194	(b) (4)	(b) (4)
EX0000195	(b) (4)	(b) (4)
EX0000196	(b) (4)	(b) (4)
EX0000198	(b) (4)	(b) (4)
EX0000199	(b) (4)	(b) (4)
EX0000200	(b) (4)	(b) (4)
Cumulative Volume <sup>13</sup>	(b) (4)	(b) (4)
Projected Manufacture of Cigarettes in United States <sup>14</sup>	264.16 Billion	251.06 Billion
Projected Market Occupation of New Product in the United States (%) <sup>15</sup>	(b) (4)	(b) (4)

The cumulative projected market volumes of the new products in the first and fifth year of marketing comprise a fraction of a percent of the estimated future cigarette manufacturing in the United States.

<sup>13</sup> Summation of Market Volumes

<sup>14</sup> See section 5.1

<sup>15</sup> *Projected Market Occupation of New Product in the United States (%) =*  

$$\frac{\text{Cumulative volume (cigarette pieces)}}{\text{Projected Manufacture of Cigarettes in United States (cigarette pieces)}} \times 100\%$$

**CONFIDENTIAL APPENDIX 2**

**Comparison of the First- and Fifth-Year Market Volume Projections for the New Products with Total Cigarettes Used in the United States**

STN	First-Year Projected Volume (Pieces)	Fifth-Year Projected Volume (Pieces)
EX0000193	(b) (4)	
EX0000194		
EX0000195		
EX0000196		
EX0000198		
EX0000199		
EX0000200		
Cumulative Volume <sup>16</sup>		
Projected Use of Cigarettes in United States <sup>17</sup>	253.47 billion	243.15 billion
Projected Market Volume of Use of New Product in the United States (%) <sup>18</sup>	(b) (4)	

The cumulative projected market volumes of the new products in the first and fifth year of marketing comprise a fraction of a percent of the estimated future use of cigarettes in the United States.

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<sup>16</sup> Summation of Market Volumes

<sup>17</sup> See section 5.2

<sup>18</sup> *Projected Market Volume of Use of New Product in the United States (%) =*  

$$\frac{\text{Cumulative volume (cigarette pieces)}}{\text{Projected Use of Cigarettes in United States (cigarette pieces)}} \times 100\%$$

**CONFIDENTIAL APPENDIX 3**

**Projected Waste of Packaging Material and Cigarette Butts in the First and Fifth Year of Marketing the New Products**

To analyze the environmental effects from total waste due to the proposed actions, the Agency estimated the first- and fifth-year projected weight of the packaging and product materials waste (in metric tons) that would be generated from disposal after use of the new products in 2018 and 2022. Projected waste generation is a summation of the projected waste of cardboard retail boxes, cardboard of the cartons, foil inner liner, plastic wrap of retail boxes, and cigarettes butts of the new products:

$\sum_{i=1}^7 A_i = \sum_{i=1}^7 (B_i + C_i + D_i + E_i + F_i)$ $B_i = \frac{G_i}{H_i} \times I_i \times S$ $C_i = \frac{G_i}{H_i \times J_i} \times K_i \times S$ $D_i = \frac{G_i}{H_i} \times L_i \times S$ $E_i = \frac{G_i}{H_i} \times M_i \times S$ $F_i = \frac{G_i \times O_i \times P_i}{100} \times S$	<p><i>A<sub>i</sub></i>: Projected total waste generation of the product (metric tons)</p> <p><i>B<sub>i</sub></i>: Projected waste generation of retail cardboard boxes of the new products (metric tons)</p> <p><i>C<sub>i</sub></i>: Projected waste generation of the retail cardboard cartons of the new products (metric tons)</p> <p><i>D<sub>i</sub></i>: Projected waste generation of the foil inner liner (metric tons)</p> <p><i>E<sub>i</sub></i>: Projected waste generation of retail box plastic of the new products (metric tons)</p> <p><i>F<sub>i</sub></i>: Projected waste generation of cigarette butts of the new products (metric tons)</p> <p><i>G<sub>i</sub></i>: Total Projected market volume of the new products (total number of individual cigarettes; also see Confidential Appendix 2)</p> <p><i>H<sub>i</sub></i>: Number of cigarettes per retail box</p> <p><i>I<sub>i</sub></i>: Weight of empty retail cardboard box (grams)</p> <p><i>J<sub>i</sub></i>: Number of retail boxes per carton</p> <p><i>K<sub>i</sub></i>: Weight of empty retail carton (grams)</p> <p><i>L<sub>i</sub></i>: Weight of foil inner liner (grams)</p> <p><i>M<sub>i</sub></i>: Weight of plastic wrap per retail box (grams)</p> <p><i>O<sub>i</sub></i>: Weight of cigarette (gram)</p> <p><i>P<sub>i</sub></i>: Cigarette butt ratio</p> <p><i>Q<sub>i</sub></i>: Cigarette butt length<sup>19</sup></p> <p><i>R<sub>i</sub></i>: Length of cigarette (millimeter)</p>
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<sup>19</sup> ISO 15592-3 (Section 9.3) prescribes a standard termination line for machine smoking (cigarette butt length) of 27 mm. This value is an estimate of the cigarette butt length that is disposed of as solid waste following use.

$P_i = \frac{Q_i}{R_i}$	$S: 1.0 \times 10^{-6}$ metric tons/gram
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**a) Projected Waste of Packaging Material**

Projected packaging waste is calculated as below:

Projected Year	STN	Market volume $G_i$	# of Cigarettes per box $H_i$	Weight of retail box $l_i$	Retail box waste $B_i$	# of boxes per carton $J_i$	Weight of carton $K_i$	Carton Waste $C_i$	Weight of foil $L_i$	Foil waste $D_i$	Weight of Plastic $M_i$	Plastic waste $E_i$
First-Year Projected Volume	EX0000193	(b) (4)										
	EX0000194											
	EX0000195											
	EX0000196											
	EX0000198											
	EX0000199											
	EX0000200											
	Total											
Fifth-Year Projected Volume	EX0000193											
	EX0000194											
	EX0000195											
	EX0000196											
	EX0000198											
	EX0000199											
	EX0000200											
	Total											

If all the projected packaging waste generated from use of the new products is disposed of in landfills, the projected cumulative cardboard waste generated in the first and fifth years of marketing the new products would be (b) (4) (b) (4) ) metric tons in 2018 and (b) (4) (b) (4) ) metric tons in 2022. This is a negligible fraction of the 258.46 million tons (equivalent to 234.47 million metric tons) of total

waste reported in the United States in 2014.<sup>20</sup> Likewise, the projected plastic waste of (b) (4) metric tons in 2018 and (b) (4) metric tons in 2022 is a negligible fraction of the 234.47 million metric tons of total waste reported in the United States in 2014.

A portion of the generated cardboard waste is likely to be recycled, with an overall recycling rate for paper and paperboard products of 64.7% in the United States. If 64.7% of the cardboard boxes is recycled and the rest (35.3%) is disposed of as waste, the estimated cardboard waste disposed of in landfills (variable B and C above) would be decreased to (b) (4) metric tons (b) (4) metric tons) in the first year and (b) (4) metric tons (b) (4) metric tons) in the fifth year of marketing the new products.

**b) Projected Waste of Cigarette Butts**

Projected waste of disposed cigarette butts is calculated as below:

Market Volume	STN	Market volume $G_i$	Length of Cigarette $R_i$	Weight of Cigarette $O_i$	Waste of Cigarette Butt $F_i$
First-Year Market Volume	EX0000193	(b) (4)			
	EX0000194				
	EX0000195				
	EX0000196				
	EX0000198				
	EX0000199				
	EX0000200				
	Total				
Fifth-Year Market Volume	EX0000193				
	EX0000194				
	EX0000195				
	EX0000196				
	EX0000198				
	EX0000199				
	EX0000200				

<sup>20</sup> EPA. Advancing Sustainable Materials Management: Facts and Figures Report. Available at: <https://www.epa.gov/smm/advancing-sustainable-materials-management-facts-and-figures-report> (accessed October 24, 2017).



	<b>Total</b>	(b) (4)
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If all the projected filter waste generated from use of the new products is disposed of in landfills, the projected waste of (b) (4) metric tons in 2018 and (b) (4) metric tons in 2022 will be a negligible fraction of the 234.47 million metric tons of total waste reported in the United States in 2014.

**CONFIDENTIAL APPENDIX 4**

**The Agency’s Estimated GHG Emissions in the First and Fifth Year of Marketing the New Products**

**a) GHG Emissions from Use of Products:**

The amount of CO<sub>2</sub>-equivalent (CO<sub>2</sub>-eq) gases emitted from the use of one cigarette is estimated at 45-65 mg [9]. As a conservative approach, the Agency used the upper limit of CO<sub>2</sub> emitted per cigarette to calculate the GHG emissions from use of the new products.

GHG Emissions from Use of Product (metric tons of CO<sub>2</sub>-eq) =

$$\text{Projected Market Volume of Product (cigarette)} \times 0.065 \text{gCO}_2 \text{ - eq/cigarette} \times 0.000001 \text{ metric tons/g}$$

Metric Tons of CO <sub>2</sub> -eq		
STN	First-Year	Fifth-Year
EX0000193	(b) (4)	
EX0000194		
EX0000195		
EX0000196		
EX0000198		
EX0000199		
EX0000200		
<b>Cumulative</b>		

Cumulative estimated total GHG emissions associated with marketing the new products are (b) (4) metric tons CO<sub>2</sub>-eq in the first year and (b) (4) metric tons CO<sub>2</sub>-eq in the fifth year after marketing the new products. This is a negligible fraction of the 6.87 billion metric tons of CO<sub>2</sub>-eq reported in the United States in 2014 [7].

**b) GHG Emissions from Disposal of New Products Following Use:**

GHG emissions from the disposal of packaging and spent new products following use of the new products were calculated using the Waste Reduction Model (WARM), version 14 [10]. WARM is a calculation tool that estimates GHG emissions across different material types commonly found in municipal solid waste (MSW).

Metric Tons of CO <sub>2</sub> -eq		
STN	First-Year	Fifth-Year
EX0000193	(b) (4)	
EX0000194		
EX0000195		
EX0000196		
EX0000198		
EX0000199		
EX0000200		
Cumulative		

Taking into account the rates for recycling and landfill disposal of various material types, the cumulative total amount of GHG emissions from the disposal of packaging and products for the new products following use is a negligible fraction of the 115.7 million metric tons of CO<sub>2</sub>-eq reported in the United States in 2015 [7].