

**Programmatic Environmental Assessment for Exemption Requests by R.J.
Reynolds Tobacco Company for New “Camel Crush, Camel Crush Filter, and
Camel Crush”**

Prepared by Center for Tobacco Products

U.S. Food and Drug Administration

December 21, 2017

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This programmatic environmental assessment (PEA) is for Exemption Requests for three 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 three 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 product for EX0000202, EX0000203, and EX0000204 is grandfathered product GF1200548, which received confirmation of grandfathered status on May 24, 2013.

4.1. Requested Action

The applicant, R.J. Reynolds Tobacco Company, submitted requests to FDA to exempt from SE requirements three 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 original product are minor modifications. In addition, the applicant claimed that the new products and the original product have identical packaging composition. For each new product, 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 product 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 product. See Appendix 1 for additional STNs associated with the new products.

STN	New Product	Original STN	Original Product
EX0000202	Camel Crush	GF1200548	Camel Light Box with Menthol Capsule
EX0000203	Camel Crush Filter	GF1200548	Camel Light Box with Menthol Capsule
EX0000204	Camel Crush	GF1200548	Camel Light Box with Menthol Capsule

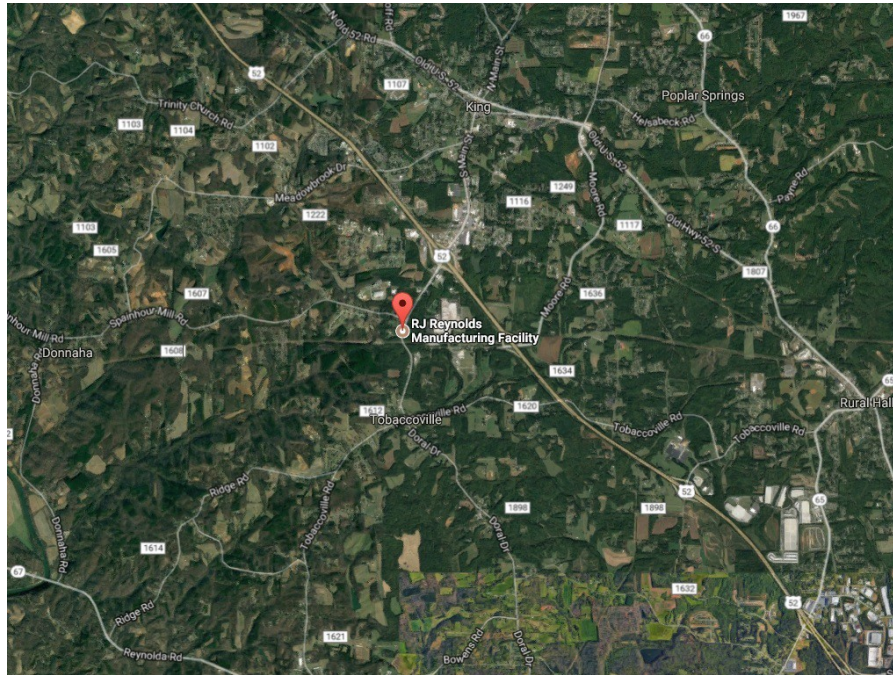
4.3.3. Description of the Products Package

The packaging materials of the finished new products are identical in materials and composition to those of the original product. 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-Tobaccoville Road in Tobaccoville, 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 Manufacturer¹



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 differences between the new products and the original product in all three STNs are the replacement of a non-fire standards compliant (FSC) cigarette paper with an FSC cigarette paper and removal of the printed monogram ink on the barrel. In addition, EX0000203 also replaces the cork-on-white tipping paper with an alternate cork-on-white tipping paper and EX0000204 also replaces the cork-on-white tipping paper with a white tipping paper.

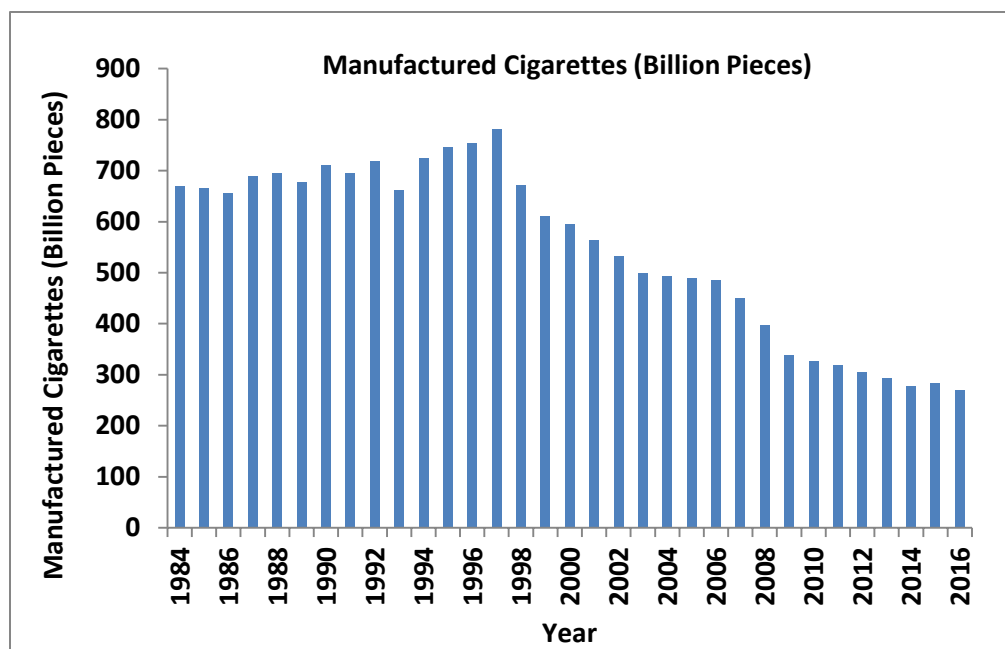
¹ Manufacturer location via Google Map. Accessed October 24, 2017

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).^{2 3} 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.⁴

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



² 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.

³ 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 =
$$\frac{(X \text{ billion cigarette pieces} \times 10^9) \times \left(\frac{0.9 \text{ g}}{453.59 \text{ g}}\right)}{10^6}$$

⁴ 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

The emission information associated with all tobacco products as reported in the EPA's Toxic Release Inventory (TRI) database is publicly available.⁵ In 2016, United States tobacco manufacturers, including RJR in Tobaccoville, NC, 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).⁶ The TRI database search did not show that the Tobaccoville manufacturing facility disposed of, treated, or released into the environment any other reportable toxicants associated with manufacturing tobacco products.

Table 1 Emissions Associated with Manufacturing Tobacco Products

Emissions Associated with All Tobacco Product Manufacturers in the United States				
Chemical Name	Air Release (Pound)	Land Release (Pound)	Water Release (Pound)	POTW Transfer (Pound)
Ammonia	406,454	1	186	18,056
Nicotine & Nicotine Salts	253,436	74,322	30	108,051
Emissions Associated with Tobacco Product Manufacturing at RJR Facility in Tobaccoville, NC				
Ammonia	10,003	1	0	493
Nicotine & Nicotine Salts	18,909	3	0	4,409

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 product 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 original product are manufactured in a similar manner. The changes, detailed in section 4.4 of this document, would not

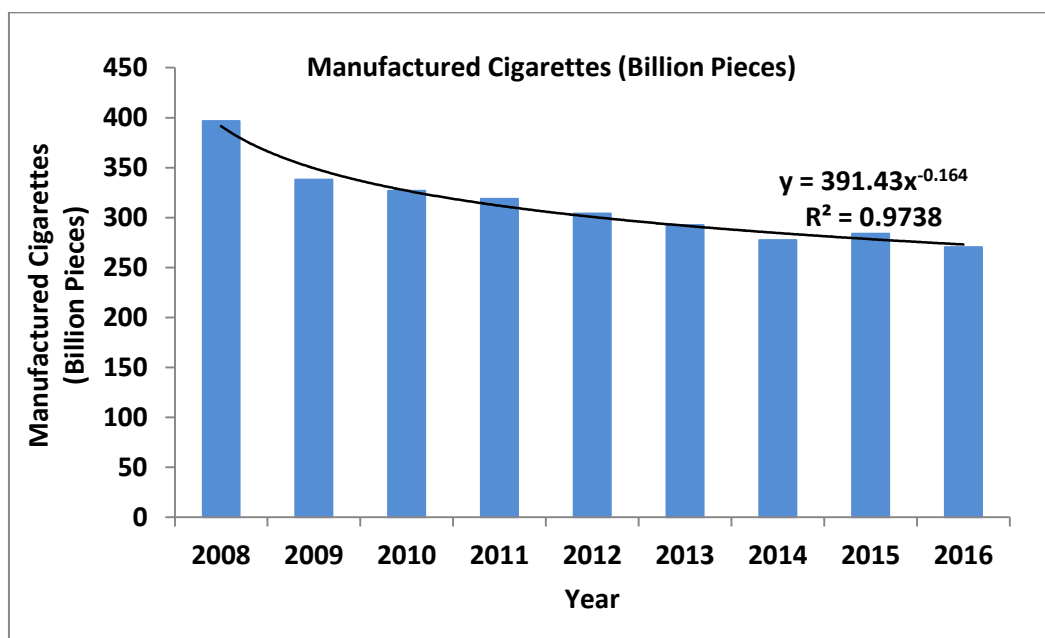
⁵ The estimation is done by using the Toxics Release Inventory (TRI), a dataset (<http://www.epa.gov/tri/>) compiled by the U.S. Environmental Protection Agency (EPA). This database allows users to retrieve information on toxic chemicals handled by many facilities across the United States, including 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 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.

⁶ 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. Searched on September 18, 2017

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.

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 2017.⁷

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

⁷ Projected first-year and fifth-year billion pieces of cigarettes = $391.43 \times (\text{year} - 2008)^{-0.164}$

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 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.⁸ 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

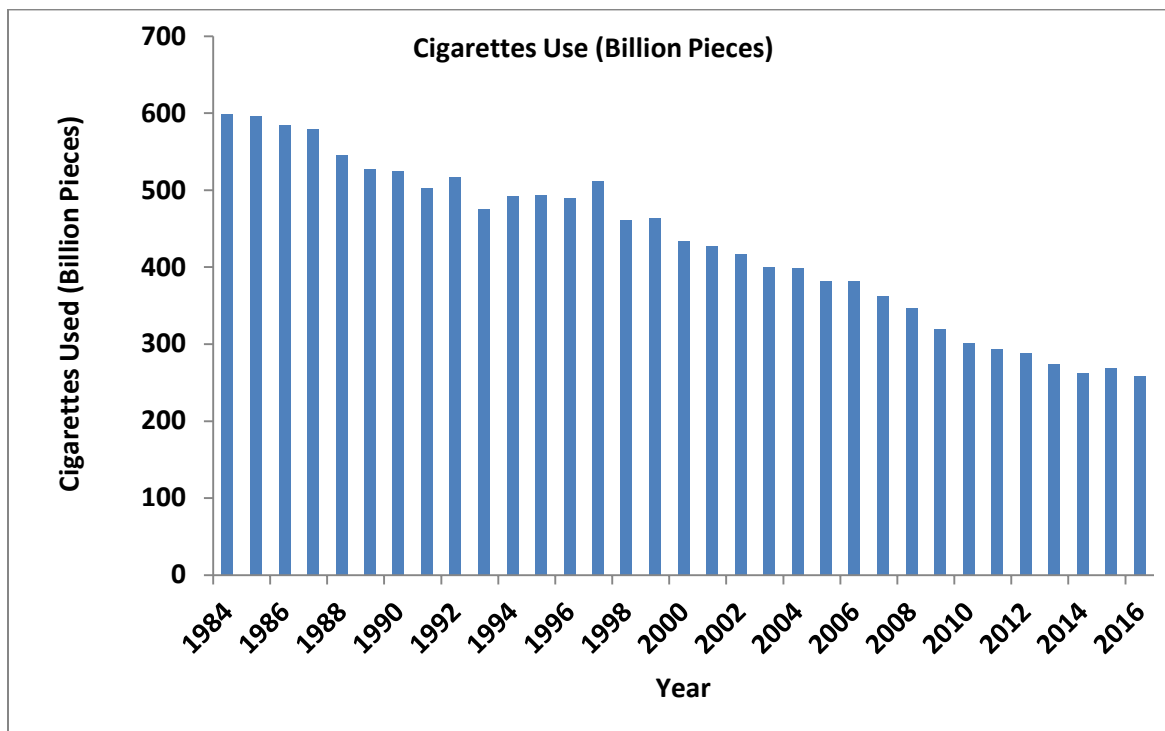
According to the U.S. TTB statistical data, the use of cigarettes in the United States decreased from 512 billion cigarettes (1,1013.81 million pounds) in 1997 to 257 billion cigarettes (509.83 million pounds) in 2016 (Figure 4).⁹

⁸ Habitat maps are located at:

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

⁹ 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 product, and other cigarettes already on the market. The combustion products from the new products will be released in the same manner as the combustion products of the original product and other marketed cigarettes.

When burned, cigarettes produce environmental smoke (ETS) or 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:

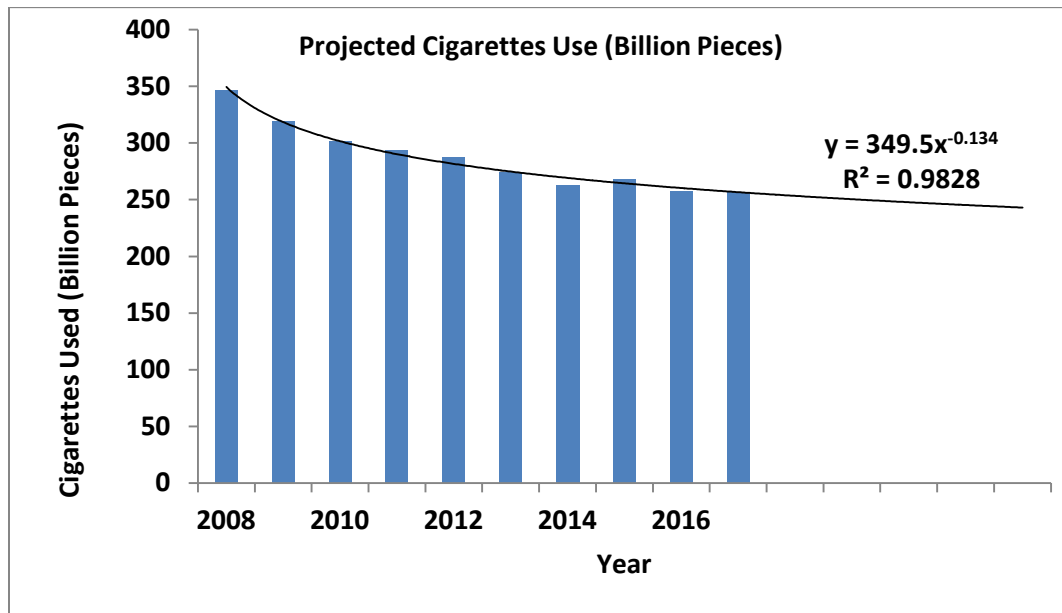
- The U.S. Surgeon General estimates that living with a smoker increases a nonsmoker's chances of developing lung cancer by 20 to 30% [3].
- Exposure to secondhand smoke increases school children's risk for ear infections, lower respiratory illnesses, more frequent and more severe asthma attacks, and 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.¹⁰ Using the

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

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).¹¹

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 product, and other cigarettes already on the market. As noted, the difference between the new products and the original product are minor changes; the weight of packaging material is the same. Additionally, because (1) the new products will replace the original product 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 cigarettes in the United States (Confidential Appendix 2), no net addition of GHG emissions is anticipated.

Accessed October 30, 2017.

¹¹ 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 packaging 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).¹² 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].

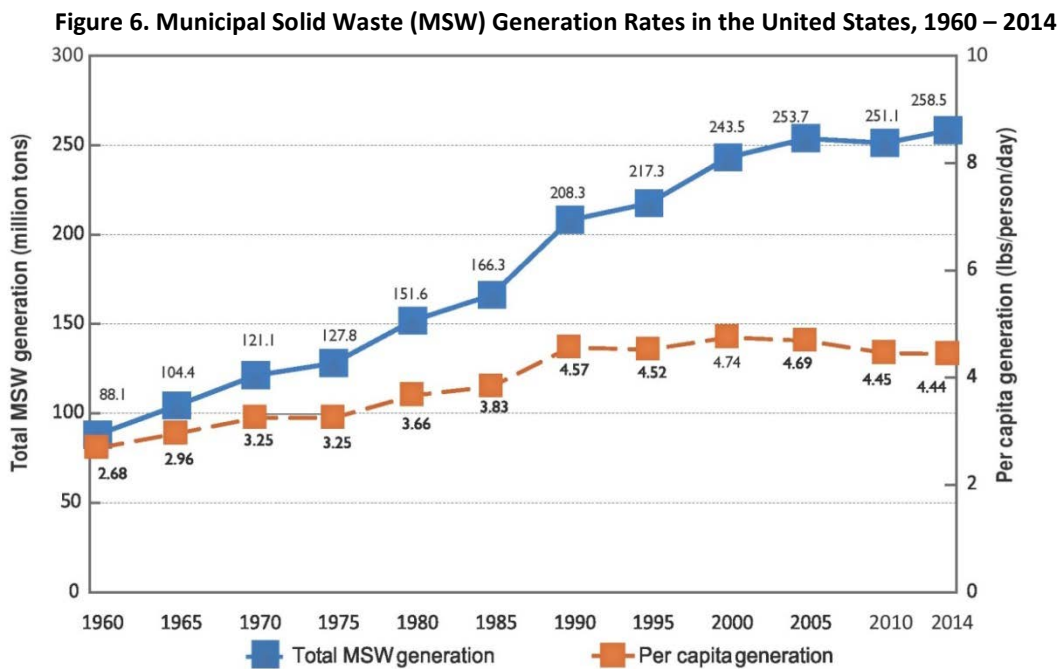


Figure excerpted from the U.S. EPA's "Advancing Sustainable Materials Management: 2014 Fact Sheet"

¹² 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

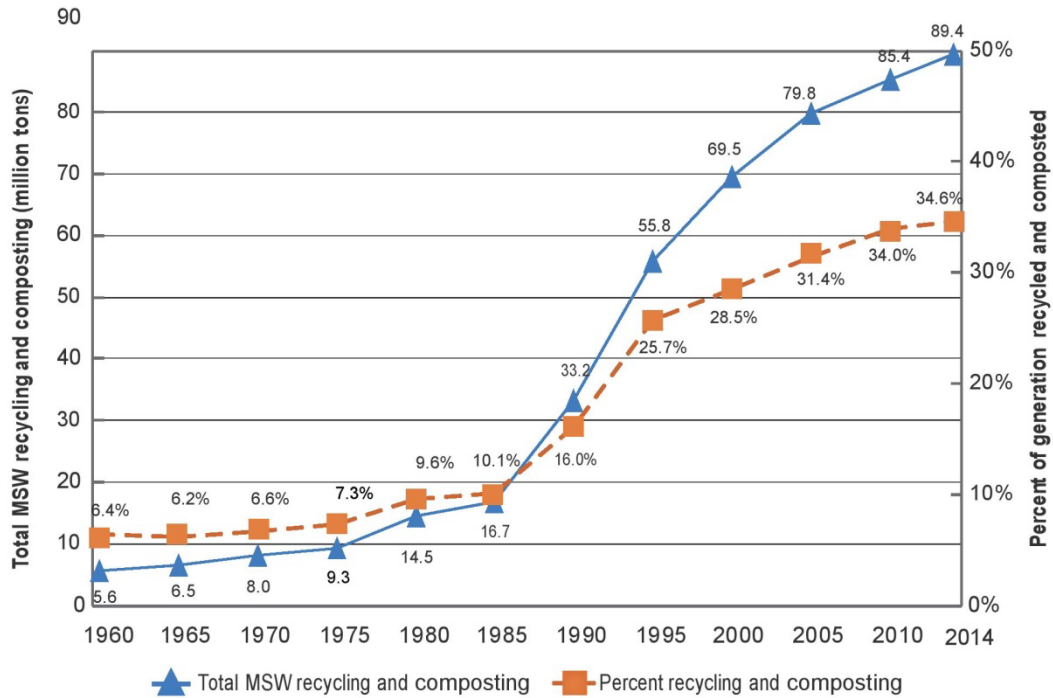


Figure excerpted from the U.S. EPA's "Advancing Sustainable Materials Management: 2014 Fact Sheet"

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.

Construction of new POTWs or landfills is not anticipated due to the proposed actions. The Agency has reached this determination because, as previously discussed, (1) the new products will compete with other similar products on the market, (2) the original product will be discontinued, and (3) the waste generated will be a miniscule fraction of the total MSW generated in the United States.

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) ^a	Cigarettes (Metric Tons) ^b	Waste of Cigarettes (Percent of Total MSW in the United States) ^c
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% 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 (CH₄) is a potent GHG that has a global warming potential of 28-36 times greater than carbon dioxide (CO₂), and has an atmospheric life of about 12 years. Landfills are the third largest source of human-related CH₄ emissions in the United States, releasing an estimated

133.1 million metric tons of CO₂-equivalent, accounting for approximately 15.4% of these emissions in 2015 [7]. The decomposition of landfill waste produces approximately 50% biogenic CO₂ and 50% CH₄, by volume, as well as trace amounts of non-CH₄ organic compounds and volatile organic compounds. However, only CH₄ 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 original product. The same raw materials and energy will be used to manufacture the new products compared to the original product 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 product 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:

William E. Brenner, B.S., Center for Tobacco Products

Education: B.S. in Biology

Experience: 3 years in various scientific activities

Expertise: NEPA analysis, environmental risk assessment, air quality analysis, archaeological and archival preservation

Reviewer:

Hoshing Chang, Ph.D., Center for Tobacco Products

Education: Ph.D. in Biochemistry and M.S. 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

1. U.S. Department of Health and Human Services (HHS). 2006. The Health Consequences of Involuntary Exposure to Tobacco Smoke: A Report of the Surgeon General. Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Coordinating Center for Health Promotion, Office on Smoking and Health. Atlanta, GA.
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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)

STN	New Product	Amendments
EX0000202	Camel Crush	No Amendments
EX0000203	Camel Crush Filter	
EX0000204	Camel Crush	

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)
EX0000202	(b) (4)	
EX0000203		
EX0000204		
Cumulative Volume ¹³		
Projected Manufacture of Cigarettes in United States ¹⁴	264.16 Billion	251.06 Billion
Projected Market Occupation of New Products in the United States (%) ¹⁵	(b) (4)	

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

¹³ Summation of Market Volumes

¹⁴ See section 5.1

¹⁵

$$\text{Projected Market Occupation of New Product in the United States (\%)} = \frac{\text{Cumulative volume (cigarette pieces)}}{\text{Projected Manufacture of Cigarettes in United States (cigarette pieces)}} \times 100\%$$

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)
EX0000202	(b) (4)	
EX0000203		
EX0000204		
Cumulative Volume ¹⁶		
Projected Use of Cigarettes in United States ¹⁷	253.47 billion	243.15 billion
Projected Market Volume of Use of New Product in the United States (%) ¹⁸	(b) (4)	

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

¹⁶ Summation of Market Volumes

¹⁷ See section 5.2

¹⁸ *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:

$\sum_{i=1}^7 A_i = \sum_{i=1}^7 (B_i + C_i + D_i + E_i + F_i)$ $B_i = \frac{G_i}{H_i} \times I_i \times S$ $C_i = \frac{G_i}{H_i \times J_i} \times K_i \times S$ $D_i = \frac{G_i}{H_i} \times L_i \times S$ $E_i = \frac{G_i}{H_i} \times M_i \times S$ $F_i = \frac{G_i \times O_i \times P_i}{100} \times S$	A_i: Projected total waste generation of the product (metric tons) B_i: Projected waste generation of retail cardboard boxes of the new products (metric tons) C_i: Projected waste generation of the retail cardboard cartons of the new products (metric tons) D_i: Projected waste generation of the foil inner liner (metric tons) E_i: Projected waste generation of retail box plastic of the new products (metric tons) F_i: Projected waste generation of cigarette butts of the new products (metric tons) G_i: Total Projected market volume of the new products (total number of individual cigarettes; also see Confidential Appendix 2) H_i: Number of cigarettes per retail box I_i: Weight of empty retail cardboard box (grams) J_i: Number of retail boxes per carton K_i: Weight of empty retail carton (grams) L_i: Weight of foil inner liner (grams) M_i: Weight of plastic wrap per retail box (grams) O_i: Weight of cigarette (gram) P_i: Cigarette butt ratio Q_i: Cigarette butt length¹⁹ R_i: Length of cigarette (millimeter)
---	--

¹⁹ 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.

$P_i = \frac{Q_i}{R_i} \times 100$	$S: 1.0 \times 10^{-6}$ metric tons/gram
------------------------------------	--

a) Projected Waste of Packaging Material

Projected packaging waste is calculated as below:

Projected Year	STN	Market Volume (Billion) G_i	# of Cigarettes per box H_i	Weight of retail box I_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	EX0000202	(b) (4)	20	4.84	(b) (4)	10	18.80	(b) (4)	1.07	(b) (4)	0.37	(b) (4)
	EX0000203		20	4.84		10	18.80		1.07		0.37	
	EX0000204		20	4.84		10	18.80		1.07		0.37	
	Total											
Fifth-Year Projected Volume	EX0000202		20	4.84		10	18.80		1.07		0.37	
	EX0000203		20	4.84		10	18.80		1.07		0.37	
	EX0000204		20	4.84		10	18.80		1.07		0.37	
	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) metric tons in 2018 and (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 2014.²⁰ 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.

²⁰ 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) Projected Waste of Cigarette Butts

Projected waste of disposed cigarette butts is calculated as below:

Market Volume	STN	Market Volume (Billion) G_i	Length of Cigarette R_i	Weight of Cigarette O_i	Waste of Cigarette Butt F_i
First-Year Market Volume	EX0000202	(b) (4)	83	0.9591	(b) (4)
	EX0000203		83	0.9574	
	EX0000204		83	0.9574	
	Total				
Fifth-Year Market Volume	EX0000202		83	0.9591	
	EX0000203		83	0.9574	
	EX0000204		83	0.9574	
	Total				

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 CO₂-equivalent (CO₂-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 CO₂ emitted per cigarette to calculate the GHG emissions from use of the new products.

GHG Emissions from Use of Product (metric tons of CO₂-eq) =

$$\text{Projected Market Volume of Product (cigarette)} \times 0.065gCO_2 - eq/cigarette \\ \times 0.000001 \text{ metric tons/g}$$

Metric Tons of CO ₂ -eq		
STN	First-Year	Fifth-Year
EX0000202	(b) (4)	
EX0000203		
EX0000204		
Cumulative		

The cumulative estimated total GHG emissions associated with marketing the new products is (b) (4) metric tons CO₂-eq in the first year and (b) (4) metric tons CO₂-eq in the fifth year after marketing the new products. This is a negligible fraction of the 6.87 billion metric tons of CO₂-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 ₂ -eq		
STN	First-Year	Fifth-Year
EX0000202	(b) (4)	
EX0000203		
EX0000204		
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 CO₂-eq reported in the United States in 2015 [7].

**Environmental Assessment for Exemption Request by R.J. Reynolds
Tobacco Company for New “Old Gold Blue Filter 100 Soft Pack”**

Prepared by Center for Tobacco Products

U.S. Food and Drug Administration

December 21, 2017

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This environmental assessment (EA) is for an Exemption Request for one combusted filtered cigarette manufactured by R.J. Reynold Tobacco Company. Information presented in the EA is based on the submission referenced in Appendix 1, unless noted or referenced otherwise. This EA 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 an exemption from SE Report for a marketing order under section 905(j)(3) of the FD&C Act for the introduction of one combusted filtered cigarette into interstate commerce for commercial distribution in the United States. This authorization is based on the finding that the modifications in the new product 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 product 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 product if a marketing order is granted for the new product. The original product for EX0000206 is a grandfathered product GF1200339, which received confirmation of grandfathered status on April 2, 2013.

4.1. Requested Action

The applicant, R.J. Reynolds Tobacco Company, submitted a request to FDA to exempt from SE requirements for one new product, which is a combusted filtered cigarette.

4.2. Need for Action

R.J. Reynolds Tobacco Company wishes to introduce the new tobacco product, as described, into interstate commerce for commercial distribution in the United States. The applicant claims that the differences in the new product and the original product are minor modifications. In addition, the applicant claimed that the new and 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 product for which the applicant has obtained the exemption from substantial equivalence.

4.3. Identification of the New Tobacco Product that are Subject of the Proposed Action

4.3.1. Type of Tobacco Product

Combusted filtered cigarette

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

The name of the new product is listed below, along with the submission tracking number (STNs) and the name and STN of the original product. See Appendix 1 for additional STNs associated with the new product.

STN	New Product	Original STN	Original Product
EX0000206	Old Gold Blue Filter 100 Soft Pack	GF1200339	Old Gold Ultra Lights 100

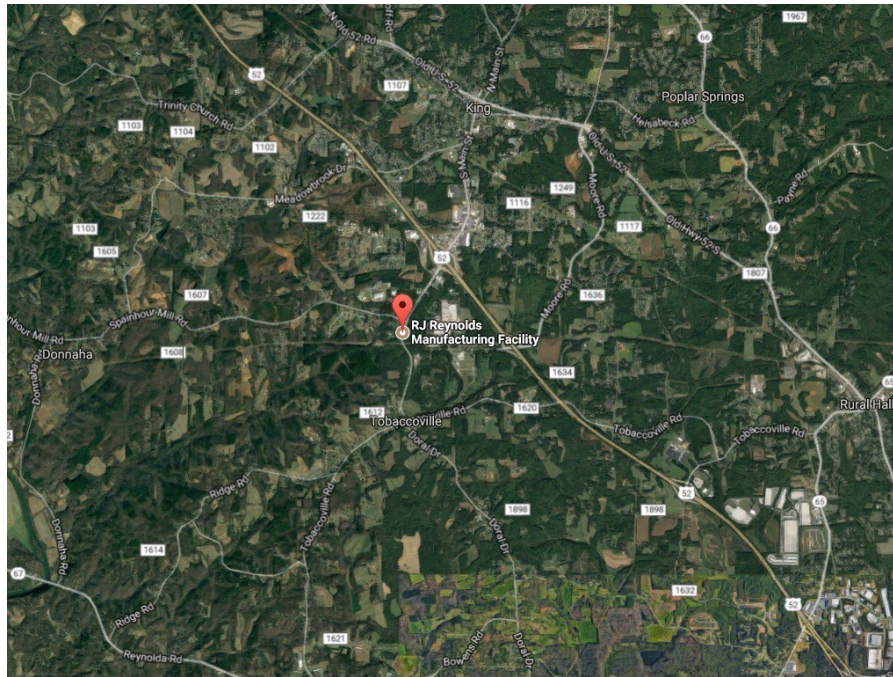
4.3.3. Description of the Product Package

The packaging materials of the finished new product are identical in materials and composition to those of the original product. 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-Tobaccoville Road in Tobaccoville, 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 Manufacturer¹



4.3.5. Location of Use

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

4.3.6. Location of Disposal

Once used, the new product will be disposed of in landfills as municipal solid waste (MSW) or as litter in the same manner as the original product 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 Product

The applicant stated that the only differences between the new product and the original product are the replacement of a non-fire standards compliant (FSC) cigarette paper with an FSC cigarette paper, removal of the printed monogram ink on the barrel, removal of a tobacco ingredient, and an increase of existing ingredients (Confidential Appendix 1).

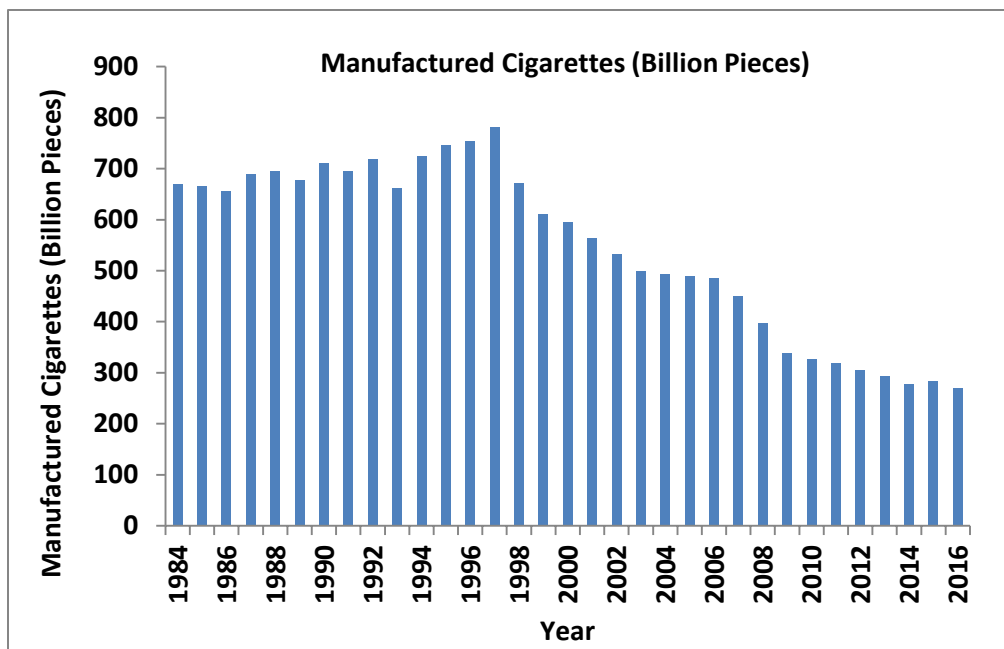
¹ Manufacturer location via Google Map. Accessed October 24, 2017

5. Potential Environmental Impacts Due to the Proposed Action

5.1. Potential Environmental Impacts Due to Manufacturing the New Product

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).² 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.³

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.⁴ In 2016, United States tobacco

² 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.

³ 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

⁴ 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 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

manufacturers including RJR in Tobaccoville, NC released ammonia, nicotine and nicotine salts into the environment and nicotine and nicotine salts were also transferred to publicly owned treatment works (POTWs) or an off-site location (Table 1).⁵ The TRI database search also did not show that the Tobaccoville manufacturing facility disposed of, treated, or released into the environment any other reportable toxicants associated with manufacturing tobacco products.

Table 1 Emissions Associated with Manufacturing Tobacco Products in 2016

Emissions Associated with All Tobacco Product Manufacturers in the United States				
Chemical Name	Air Release (Pound)	Land Release (Pound)	Water Release (Pound)	POTW Transfer (Pound)
Ammonia	406,454	1	186	18,056
Nicotine & Nicotine Salts	253,436	74,322	30	108,051
Emissions Associated with Tobacco Product Manufacturing at RJR Facility in Tobaccoville, NC				
Ammonia	10,003	1	0	493
Nicotine & Nicotine Salts	18,909	3	0	4,409

The Agency anticipates the waste generated due to manufacturing the new product 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 product will compete with other currently marketed combusted filtered cigarettes. The applicant also stated that production and marketing of the original product will cease if a marketing order is granted for the new product. No expansion of the manufacturing facility is anticipated for manufacturing the new product. Therefore, the Agency does not foresee the introduction of the new product to notably affect the current manufacturing waste generated from the production of all combusted filtered cigarettes.

Based on the information in the Exemption Request, the new product and the original product are manufactured in a similar manner. The changes, detailed in section 4.4 of this document, 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 product.

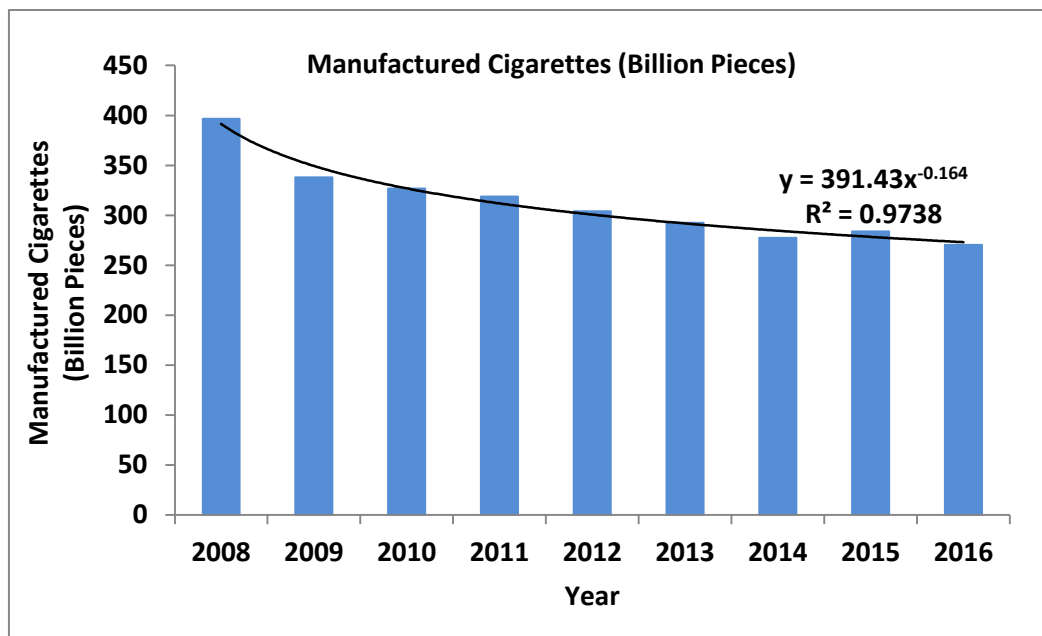
The applicant provided the first- and fifth-year market volumes for the new product (Confidential Appendix 2). To evaluate the environmental impact of the proposed action due to manufacturing of the new product, historical data regarding the manufacture of cigarettes in the United States from 2008 to 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

reporting threshold during a calendar year.

⁵ 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. Searched on September 18, 2017

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 2017.⁶

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



The cumulative projected market volumes of the new product are a fraction of the forecasted manufacture of all cigarettes in the United States in 2018 and 2022 (Confidential Appendix 2). Additionally, the applicant stated that manufacturing the new product 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 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

⁶ Projected first-year and fifth-year billion pieces of cigarettes = $391.43 \times (\text{year} - 2008)^{-0.164}$

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.⁷ According to the Exemption Request, 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 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

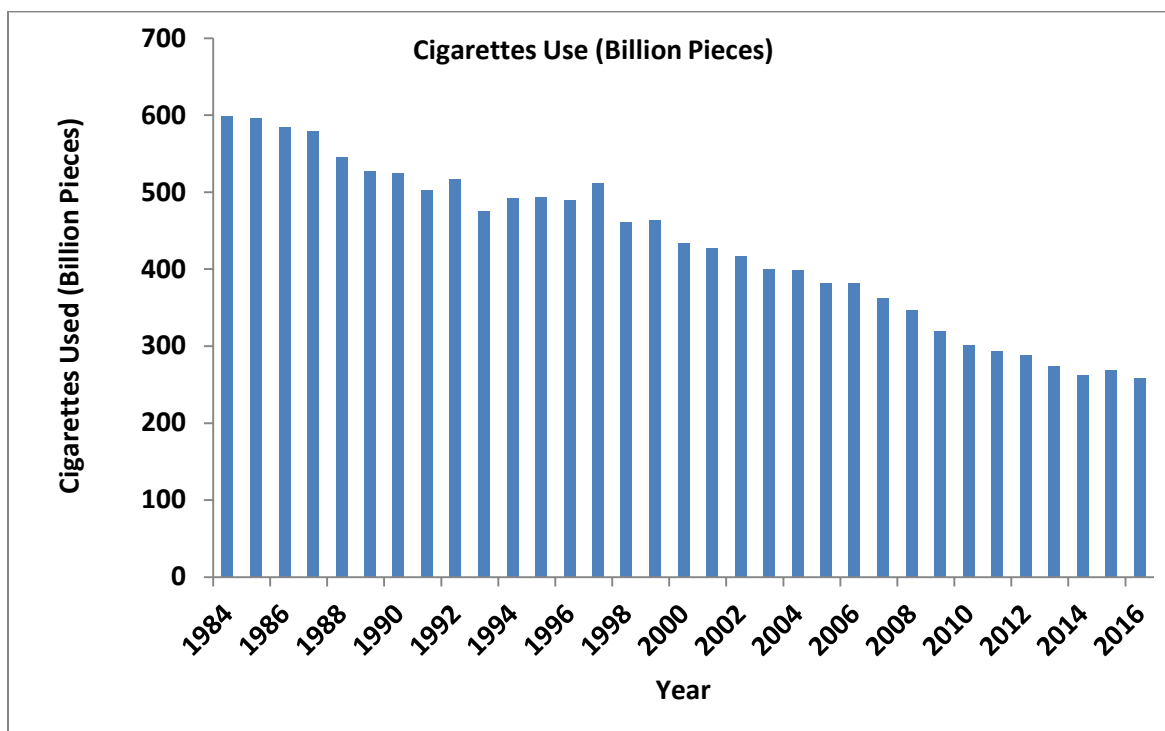
According to the U.S. TTB statistical data, the use of cigarettes in the United States decreased from 512 billion cigarettes (1,1013.81 million pounds) in 1997 to 257 billion cigarettes (509.83 million pounds) in 2016 (Figure 4).⁸

⁷ Habitat maps are located at:

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

⁸ 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 cigarette, relative to the substances released by the original product, and other cigarettes already on the market. The combustion products from the new product will be released in the same as the combustion products of the original product and other marketed cigarettes.

When burned, cigarettes produce environmental smoke (ETS) or 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:

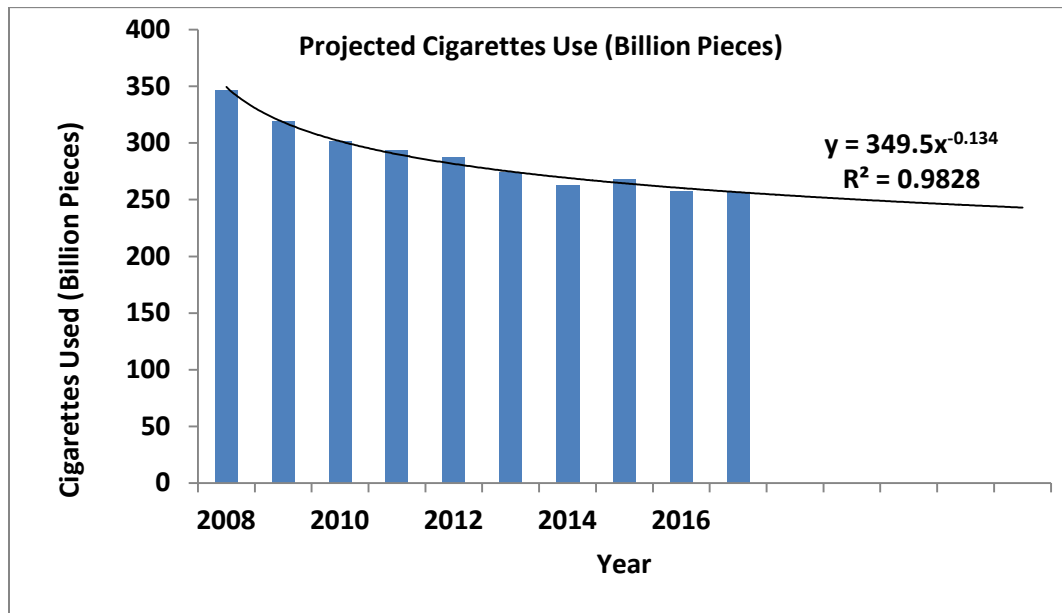
- The U.S. Surgeon General estimates that living with a smoker increases a nonsmoker's chances of developing lung cancer by 20 to 30% [3].
- Exposure to secondhand smoke increases school children's risk for ear infections, lower respiratory illnesses, more frequent and more severe asthma attacks, and 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 action due to use of the new product, 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.⁹ Using the

⁹ The forecast trend line is extrapolated from TTB data. Available from <http://www.ttb.gov/tobacco/tobacco-stats.shtml>. Accessed October 30, 2017.

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 product, respectively (Figure 5).¹⁰

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 cigarette, relative to the substances released by the original product, and other cigarettes already on the market. As noted, the difference between the new product and the original product are minor changes. Additionally, because (1) the new product will replace the original product and compete with other currently marketed cigarettes; and (2) the projected market volumes of the new product in the first and fifth year of marketing the new product occupy a negligible fraction of the total projected estimate of use of cigarettes in the United States (Confidential Appendix 3), no net addition of GHG emissions is anticipated.

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 packaging materials. Specifically,

¹⁰ Projected first-year and fifth-year billion pieces of cigarettes = $349.5 \times (\text{year} - 2007)^{-0.134}$

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).¹¹ 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].

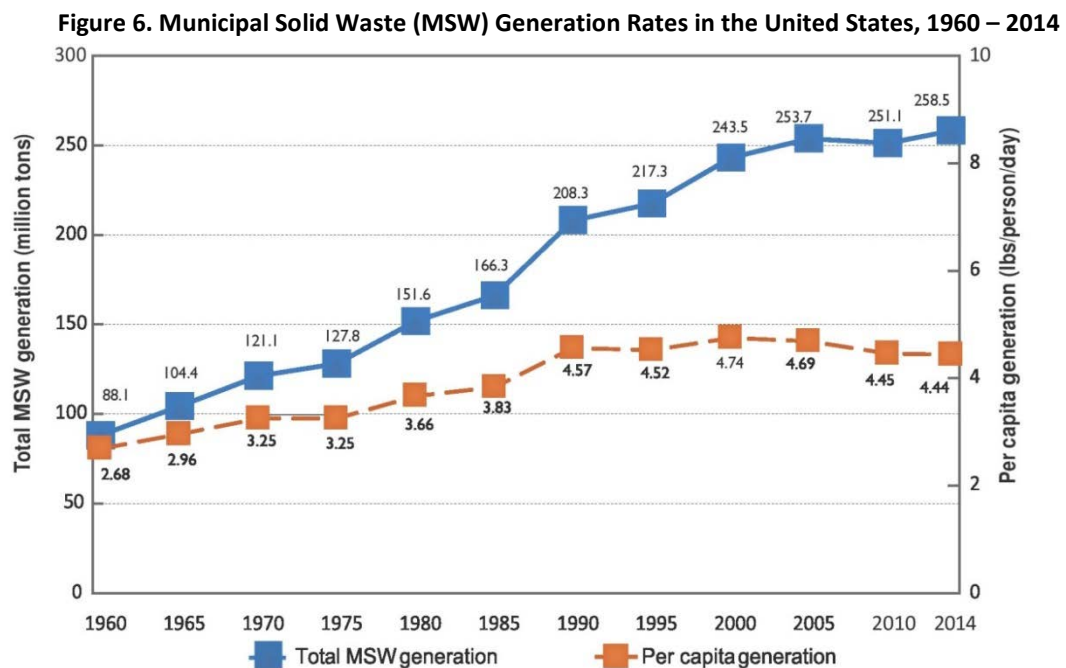


Figure excerpted from the U.S. EPA's "Advancing Sustainable Materials Management: 2014 Fact Sheet"

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

¹¹ The "ton" unit in section 5.3.1 is U.S. short ton, unless specified otherwise

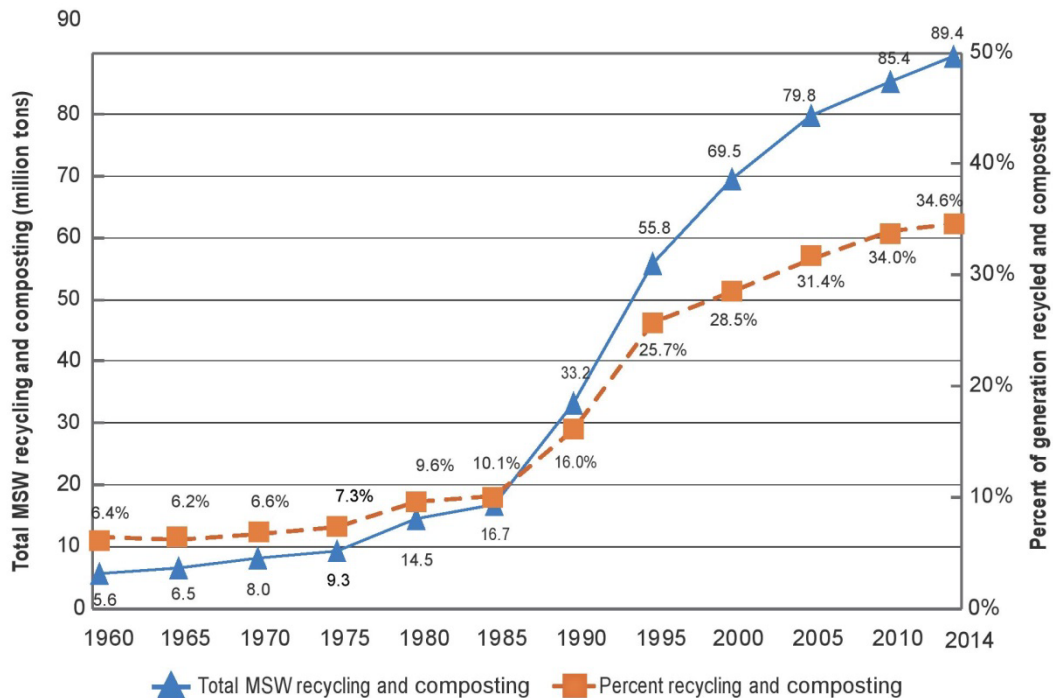


Figure excerpted from the U.S. EPA's "Advancing Sustainable Materials Management: 2014 Fact Sheet"

The Agency believes that the disposal of the new product will be similar to the disposal conditions of other cigarettes that are currently being marketed. After using the new product, the users may dispose of or recycle the packaging material. Users may also discard the combusted cigarette and filter, 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 product after issuance of the marketing order for the new product (Confidential Appendix 2 and 4). 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.

Construction of new POTWs or landfills is not anticipated due to the proposed action. The Agency has reached this determination because, as previously discussed, (1) the new product will compete with other similar products on the market, (2) the original product will be discontinued, and (3) the waste generated will be a miniscule fraction of the total MSW generated in the United States.

The Agency does not anticipate the proposed action to lead to the release of new chemicals into the environment due to use of the product. 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) ^a	Cigarettes (Metric Tons) ^b	Waste of Cigarettes (Percent of Total MSW in the United States) ^c
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% 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 (CH₄) is a potent GHG that has a global warming potential of 28-36 times greater than carbon dioxide (CO₂), and has an atmospheric life of about 12 years. Landfills are the third largest source of human-related CH₄ emissions in the United States, releasing an estimated

133.1 million metric tons of CO₂-equivalent, accounting for approximately 15.4% of these emissions in 2015 [7]. The decomposition of landfill waste produces approximately 50% biogenic CO₂ and 50% CH₄, by volume, as well as trace amounts of non-CH₄ organic compounds and volatile organic compounds. However, only CH₄ 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 product comprises a negligible fraction of the total MSW, the GHG emitted from waste associated with the new product is negligible according to quantified GHG emissions from disposal of the new product (Confidential Appendix 5) in this PEA. No additional control of GHG emissions is anticipated in the landfills.

The Agency does not anticipate that the proposed action will lead to the release of new chemicals into the environment due to disposal of the new product. 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 product are manufactured compared to the original product. The same raw materials and energy will be used to manufacture the new product compared to the original product and the applicant does not anticipate any increased energy or resource needs to manufacture the new product. The applicant stated that the proposed action 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 product are a small portion of the total forecasted cigarette market volume in 2018 and 2022. Because the applicant stated that the new product will compete with other similar cigarettes and that the original product will be discontinued, no increase of overall cigarette market volume and no net increase of energy use will be expected from the proposed action. The applicant stated that no adverse effects to endangered or threatened species or critical habitat are expected from manufacturing the new product. 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 product. 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 product 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 action): There is no substantial environmental effect due to the proposed action of authorizing the new product and associated manufacture, use, and disposal following use of the new tobacco product.

9. List of Preparers:

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

Preparer:

William E. Brenner, B.S., Center for Tobacco Products

Education: B.S. in Biology

Experience: 3 years in various scientific activities

Expertise: NEPA analysis, environmental risk assessment, air quality analysis, archaeological and archival preservation

Reviewer:

Hoshing Chang, Ph.D., Center for Tobacco Products

Education: Ph.D. in Biochemistry and M.S. 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 Number for the EX Request for the New Product and Related Amendments Covered Under this Environmental Assessment (EA)

12. Confidential Appendix

Confidential Appendix 1: Proposed Minor Modification to the Original Product

Confidential Appendix 2: The First-, and Fifth-Year Market Volume Projections of the New Product

Confidential Appendix 3: Comparison of the First- and Fifth-Year Market Volume Projections for the New Product with Total Cigarettes Used in the United States

Confidential Appendix 4: Projected Waste of Packaging Material and Cigarette Butts in the First and Fifth Year of Marketing the New Product

Confidential Appendix 5: The Agency's Estimated GHG Emissions in the First and Fifth Year of Marketing the New Product

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APPENDIX 1

Submission Tracking Number for the EX Request for the New Product and Related Amendments Covered Under this Environmental Assessment (EA)

STN	New Product	Amendments
EX0000206	Old Gold Blue Filter 100 Soft Pack	No Amendments

CONFIDENTIAL APPENDIX 1

Proposed Minor Modifications to the Original Product

STN	Modification
EX0000206	Deletion of a non-FSC Cigarette Paper
	Addition of FSC Cigarette Paper
	Deletion of Tobacco Additive (b) (4)
	Increase of water to (b) (4) mg/cigarette in the new product from (b) (4) mg/cigarette in the original product
	Increase of glycerin to (b) (4) mg/cigarette in the new product from (b) (4) mg/cigarette in the original product
	Deletion of Printed Monogram Ink on Barrel

CONFIDENTIAL APPENDIX 2

First- and Fifth-Year Market Volume Projections of the New Product

STN	First-Year Projected Market Volume (Pieces)	Fifth-Year Projected Market Volume (Pieces)
EX0000206	(b) (4)	(b) (4)
Projected Manufacture of Cigarettes in United States ¹²	264.16 Billion	251.06 Billion
Projected Market Occupation of New Product in the United States (%) ¹³	(b) (4)	(b) (4)

The cumulative projected market volumes of the new product in the first and fifth year of marketing comprise a negligible percentage of the estimated future cigarette manufacturing in the United States.

¹² See section 5.1

¹³

$$\text{Projected Market Occupation of New Product in the United States (\%)} = \frac{\text{Cumulative volume (cigarette pieces)}}{\text{Projected Manufacture of Cigarettes in United States (cigarette pieces)}} \times 100\%$$

CONFIDENTIAL APPENDIX 3

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

STN	First-Year Projected Volume (Pieces)	Fifth-Year Projected Volume (Pieces)
EX0000206	(b) (4)	
Projected Use of Cigarettes in United States ¹⁴	253.47 billion	243.15 billion
Projected Market Volume of Use of New Product in the United States (%) ¹⁵	(b) (4)	

The cumulative projected market volumes of the new product in the first and fifth year of marketing comprise a negligible percentage of the estimated future use of cigarettes in the United States.

¹⁴ See section 5.2

¹⁵ *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 4

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 action, 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 product 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 product:

$\sum_{i=1}^7 A_i = \sum_{i=1}^7 (B_i + C_i + D_i + E_i + F_i)$ $B_i = \frac{G_i}{H_i} \times I_i \times S$ $C_i = \frac{G_i}{H_i \times J_i} \times K_i \times S$ $D_i = \frac{G_i}{H_i} \times L_i \times S$ $E_i = \frac{G_i}{H_i} \times M_i \times S$ $F_i = \frac{G_i \times O_i \times P_i}{100} \times S$	A_i: Projected total waste generation of the product (metric tons) B_i: Projected waste generation of retail cardboard boxes of the new product (metric tons) C_i: Projected waste generation of the retail cardboard cartons of the new product (metric tons) D_i: Projected waste generation of the foil inner liner (metric tons) E_i: Projected waste generation of retail box plastic of the new product (metric tons) F_i: Projected waste generation of cigarette butts of the new product (metric tons) G_i: Total Projected market volume of the new product (total number of individual cigarettes; also see Confidential Appendix 2) H_i: Number of cigarettes per retail box I_i: Weight of empty retail cardboard box (grams) J_i: Number of retail boxes per carton K_i: Weight of empty retail carton (grams) L_i: Weight of foil inner liner (grams) M_i: Weight of plastic wrap per retail box (grams) O_i: Weight of cigarette (gram) P_i: Cigarette butt ratio Q_i: Cigarette butt length¹⁶ R_i: Length of cigarette (millimeter)
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¹⁶ 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.

$P_i = \frac{Q_i}{R_i} \times 100$	S: 1.0×10^{-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 (# of cigarettes) G_i	# of Cigarettes per box H_i	Weight of retail box I_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	EX0000206	(b) (4)	20	1.60	(b) (4)	10	21.63	(b) (4)	1.18	(b) (4)	0.42	(b) (4)
	Total	(b) (4)										
Fifth-Year Projected Volume	EX0000206	(b) (4)	20	1.60	(b) (4)	10	21.63	(b) (4)	1.18	(b) (4)	0.42	(b) (4)
	Total	(b) (4)										

If all the projected packaging waste generated from use of the new product is disposed of in landfills, the projected cumulative cardboard waste generated in the first and fifth years of marketing the new product 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 2014.¹⁷ 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 product.

¹⁷ 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) Projected Waste of Cigarette Butts

Projected waste of disposed cigarette butts is calculated as below:

Market Volume	STN	Market Volume (# of Cigarettes) G_i	Length of Cigarette R_i	Weight of Cigarette O_i	Waste of Cigarette Butt F_i
First-Year Market Volume	EX0000206	(b) (4)	99	1.0727	(b) (4)
	Total				
Fifth-Year Market Volume	EX0000206	(b) (4)	99	1.0727	(b) (4)
	Total				

If all the projected filter waste generated from use of the new product 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 5

The Agency's Estimated GHG Emissions in the First and Fifth Year of Marketing the New Product

a) GHG Emissions from Use of Product:

The amount of CO₂-equivalent (CO₂-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 CO₂ emitted per cigarette to calculate the GHG emissions from use of the new product.

GHG Emissions from Use of Product (metric tons of CO₂-eq) =

$$\text{Projected Market Volume of Product (cigarette)} \times 0.065gCO_2 - eq/cigarette \\ \times 0.000001 \text{ metric tons/g}$$

Metric Tons of CO ₂ -eq		
STN	First-Year	Fifth-Year
EX0000206	(b) (4)	(b) (4)

The estimated total GHG emissions associated with marketing the new product is (b) (4) metric tons CO₂-eq in the first year and (b) (4) metric tons CO₂-eq in the fifth year after marketing the new product. This is a negligible fraction of the 6.87 billion metric tons of CO₂-eq reported in the United States in 2014 [7].

b) GHG Emissions from Disposal of New Product Following Use:

GHG emissions from the disposal of packaging and spent new products following use of the new product 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 ₂ -eq		
STN	First-Year	Fifth-Year
EX0000202	(b) (4)	

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 product for the new product following use is a negligible fraction of the 115.7 million metric tons of CO₂-eq reported in the United States in 2015 [7].