

**Programmatic Environmental Assessment for  
Exemption Requests by R.J. Reynolds Tobacco  
Company for “Monarch Red 100’s Soft Pack, Monarch  
Gold 100’s Soft Pack, Monarch Blue 100’s Soft Pack,  
Monarch Red Box, Monarch Gold Box, and GPC Non-  
Filter Soft Pack”**

Prepared by Center for Tobacco Products

U.S. Food and Drug Administration

August 29, 2017

## Table of Contents

1.	Name of Applicant.....	4
2.	Address.....	4
3.	Manufacturer.....	4
4.	Description of Proposed Actions.....	4
4.1	Requested Action.....	4
4.2	Need for Action.....	4
4.3	Identification of the New Tobacco Products that is the Subject of the Proposed Actions.....	5
4.3.1	Type of Tobacco Products.....	5
4.3.2	Product Names and Their Original STNs.....	5
4.3.3	Description of the Product Package.....	5
4.3.4	Location of Manufacturing.....	5
4.3.5	Location of Use.....	6
4.3.6	Location of Disposal.....	6
4.4	Modification(s) Identified as Compared to the Original Product.....	6
5.	Environmental Introduction Due to the Proposed Actions.....	6
5.1.	Introduction as a Result of Manufacturing the New Tobacco Products.....	6
5.1.1.	Tobacco Manufacture in the U.S. and Pollution Emission by R.J. Reynolds’ Tobacoville Facility.....	7
5.1.2.	Environmental Introduction from Manufacturing the New Tobacco Products.....	8
5.2.	Environmental Introduction as a Result of Use of the New Tobacco Products.....	9
5.3.	Environmental Introduction as a Result of Disposal Following Use of the New Tobacco Products.....	10
5.3.1.	Disposal Following Use of Cigarettes.....	10
a)	Disposal of Packaging Material.....	10
b)	Disposal of Used Cigarettes Following Use.....	11
c)	Air Emissions.....	12
5.3.2.	Environmental Introduction from Disposal Following Use of the New Products.....	12
6.	Fate of Materials Released into the Environment Due to the Proposed Actions.....	13

7. Environmental Effects of New Materials Released into the Environment due to the Proposed Actions .....	13
8. Use of Resources and Energy .....	14
9. Mitigation.....	14
10. Alternatives to the Proposed Actions .....	14
11. List of Preparers.....	14
12. List of Agencies and Persons Consulted.....	15
13. Appendix List.....	15
14. Confidential Appendix List.....	15
15. References.....	15
APPENDIX 1 .....	17
Submission Tracking Numbers for the EX Requests of the New Products and Related Amendments Covered Under this Programmatic Environmental Assessment (PEA).....	17
APPENDIX 2.....	18
Forecast of Cigarettes Manufactured in the U.S. ....	18
APPENDIX 3.....	19
Projected Use of Cigarettes in the U.S. in the First and Fifth Year of Marketing the New Products .....	19
CONFIDENTIAL APPENDIX 1 .....	20
Changes Between New and Original Products .....	20
CONFIDENTIAL APPENDIX 2.....	21
Projected Waste of Packaging Material and Cigarette Butts in the First and Fifth Year of Marketing the New Products.....	21
CONFIDENTIAL APPENDIX 3.....	24
The First- and Fifth-Year Market Volume Projections of the New Products .....	24
CONFIDENTIAL APPENDIX 4.....	25
Comparison of the First- and Fifth-Year Market Volume Projections for the New Products with Total Cigarettes Used in the U.S.....	25
CONFIDENTIAL APPENDIX 5.....	26
The Agency's Estimated GHG in the First and Fifth Year of Marketing the New Products .....	26

This programmatic environmental assessment (PEA) is for the Exemption Requests for multiple combusted, filtered cigarettes manufactured by “R.J. Reynolds 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 to 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**

RAI Services Company on behalf of R.J. Reynolds Tobacco Company

## **2. Address**

401 N. Main Street  
Winston-Salem, NC 27101

## **3. Manufacturer**

R.J. Reynolds Tobacco Company  
7855 King-Tobaccoville Road  
Tobaccoville, NC 27050

## **4. Description of Proposed Actions**

These proposed actions are for FDA to issue exemptions from SE Reports for the market authorization under section 905(j)(3) of the FD&C Act for the introduction of combusted, filtered cigarettes into interstate commercial distribution in the U.S. This authorization is based on the finding that the modifications would be minor modifications of a tobacco product that can be sold under the FD&C Act, a 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 original products for EX0000167, EX0000168, and EX0000170-EX0000173 are grandfathered products, GF1501275, GF1501279, GF1501256, GF1501276, GF1501280, and GF1501209. GF1501209 received confirmation of grandfathered status on December 23, 2015; the rest, March 31, 2016.

### **4.1 Requested Action**

The applicant, RAI Services on behalf of R.J. Reynolds Tobacco Company, submitted requests to FDA to exempt from SE requirements the new “Monarch Red 100’s Soft Pack, Monarch Gold 100’s Soft Pack, Monarch Blue 100’s Soft Pack, Monarch Red Box, Monarch Gold Box, and GPC Non-Filter Soft Pack” combusted, filtered cigarettes.

### **4.2 Need for Action**

RAI Services Company on behalf of R.J. Reynolds Tobacco Company wishes to introduce the new tobacco products as described into interstate commerce for commercial distribution in the U.S. The applicant states that the differences between the new and original products are the deletion of a complex tobacco additive and increase of an existing tobacco additive (Confidential Appendix 1). In addition, the applicant claimed that there are no other differences in the characteristics between the new and original products. 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 is the Subject of the Proposed Actions

#### 4.3.1 Type of Tobacco Products

Combusted, filtered cigarettes

#### 4.3.2 Product Names and Their Original STNs

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

New Product		Original Product	
STN	Name	STN	Name
EX0000167	Monarch Red 100's Soft Pack	GF1501275	Monarch Full Flavor 100's Soft Pack
EX0000168	Monarch Gold 100's Soft Pack	GF1501279	Monarch Light 100's Soft Pack
EX0000170	Monarch Blue 100's Soft Pack	GF1501256	Monarch Ultra Light 100's Soft Pack
EX0000171	Monarch Red Box	GF1501276	Monarch Full Flavor Box
EX0000172	Monarch Gold Box	GF1501280	Monarch Light Box
EX0000173	GPC Non-Filter Soft Pack	GF1501209	GPC Non-Filter King Soft Pack

#### 4.3.3 Description of the Product Package

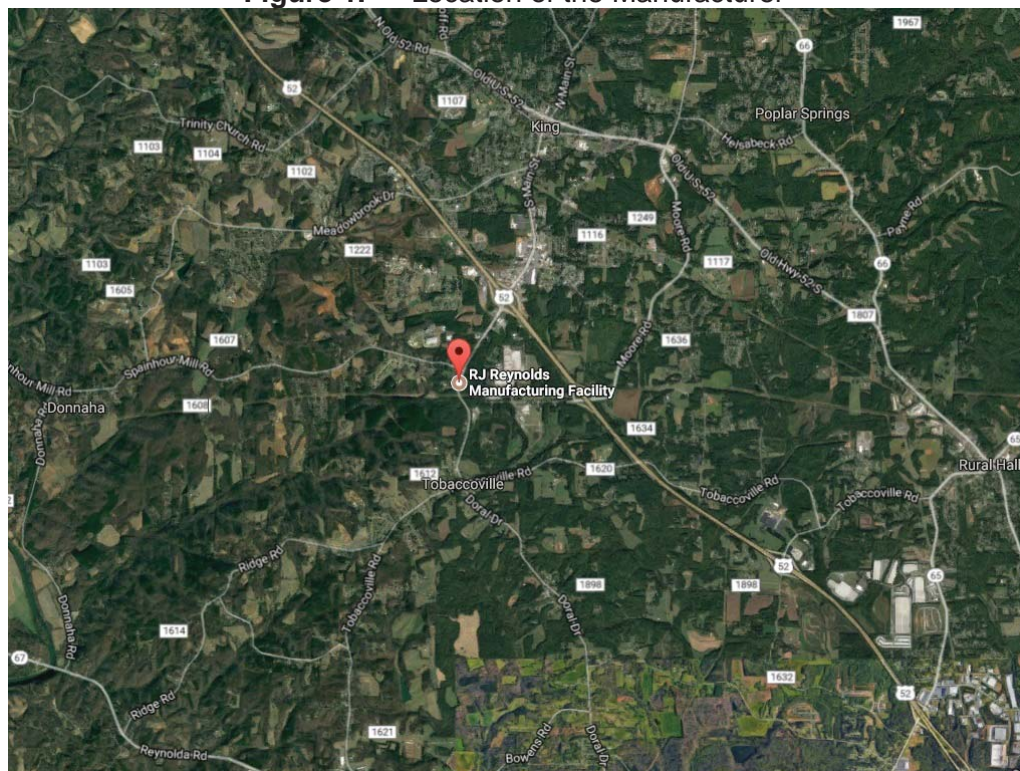
The packaging materials of the finished new products are identical in materials and composition to those of the corresponding original products. The new product packaging consists of a foil inner liner, soft paper pack, polypropylene, tear tape, and cartons. Details of the package components and weights of each packaging component for the new products are described in Confidential Appendix 2.

#### 4.3.4 Location of Manufacturing

R.J. Reynolds Tobacco Company  
7855 King-Tobacoville Road  
Tobacoville, NC 27050

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 U.S.

#### **4.3.6 Location of Disposal**

Once used, the new tobacco 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 cigarette. 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 anticipates the distribution of waste from disposal after use will correspond to the pattern of the product use.

#### **4.4 Modification(s) Identified as Compared to the Original Product**

The applicant states that the differences between the new and original products are the deletion of a complex tobacco additive and increase of an existing tobacco additive.

### **5. Environmental Introduction Due to the Proposed Actions**

#### **5.1. Introduction as a Result of Manufacturing the New Tobacco Products**

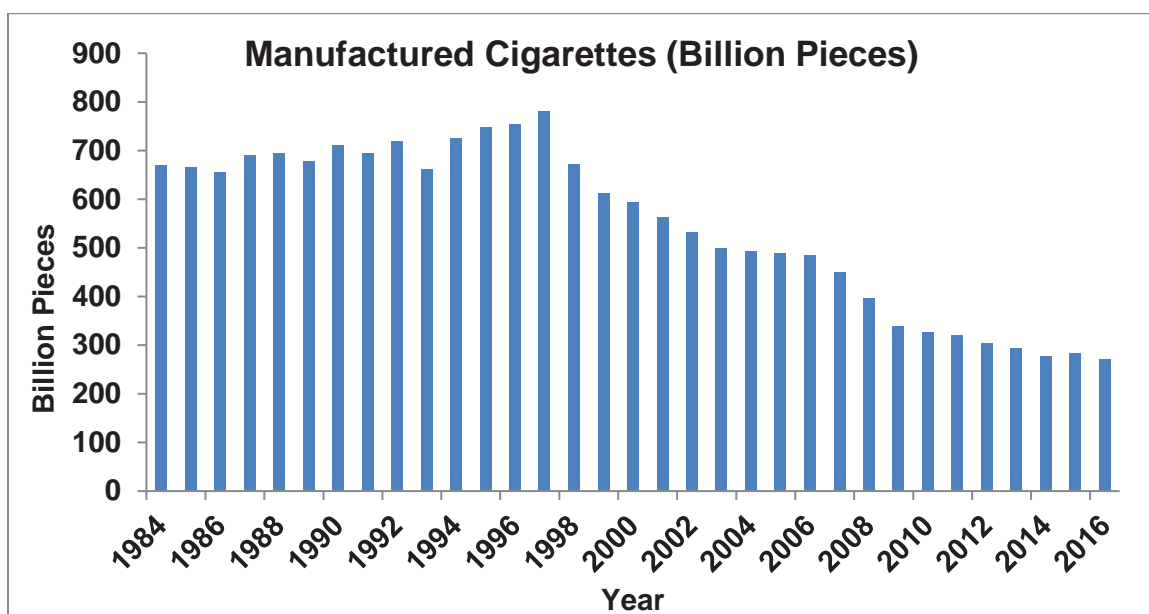
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<sup>1</sup> Manufacturer address via Google Map. Accessed June 2, 2017.

### 5.1.1. Tobacco Manufacture in the U.S. and Pollution Emission by R.J. Reynolds' Tobaccoville Facility

Tobacco Manufacturing in the U.S. As of June 2017, a total of 1242 tobacco production establishments are registered under 915(c) of the FD&C Act. These manufacturers produced 270 billion cigarettes (13.5 billion packs of 20 cigarettes each) in 2016 with a decline starting in 1997 (Figure 2) [1]. 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 [2].

Figure 2. Total Cigarettes Manufactured in the U.S. 1984-2016



Ammonia and Nicotine, Including Nicotine Salts from Tobacco Manufacturing Facilities. The emission information associated with all tobacco products as reported in the EPA's Toxic Release Inventory (TRI) database is publicly available.<sup>2</sup> In 2015, U.S. tobacco manufacturers released 475,000 pounds of ammonia and 280,000 pounds of nicotine and nicotine salts to the air<sup>3</sup>; no ammonia and 72,900 pounds of nicotine and

<sup>2</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 U.S., 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.

<sup>3</sup> [http://oaspub.epa.gov/enviro/ef\\_metadata.html.tri\\_page?p\\_column\\_name=air\\_total\\_release](http://oaspub.epa.gov/enviro/ef_metadata.html.tri_page?p_column_name=air_total_release)

nicotine salts to the land<sup>4</sup>; 220 pounds of ammonia and 279 pounds of nicotine and nicotine salts to the water<sup>5</sup>; and 19,550 pounds of ammonia and 83,384 pounds of nicotine and nicotine salts transferred to publicly owned treatment works (POTWs) or an off-site location.<sup>6</sup> A search in the TRI database indicates that the R.J. Reynolds Tobaccoville facility ranks 363 out of 1041 TRI facilities for waste release in the Food/Beverages/Tobacco industry category in 2015. The Tobaccoville facility released 13,865 pounds of nicotine and nicotine salts and 9,899 pounds of ammonia to the air, 938 pounds of nicotine and nicotine salts and 4,088 pounds of ammonia to POTW, and 1,6227 pounds of nicotine and nicotine salts and 499 pounds of ammonia to landfills<sup>7</sup>.

### **5.1.2. Environmental Introduction from Manufacturing the New Tobacco Products**

Introduction from Manufacturing the New Products in the Proposed Actions. The Agency anticipates the waste generated as a result of manufacturing the new combusted, filtered cigarettes will be released to the environment, transferred to POTWs, and disposed of in landfills in the same manner as the waste generated from any other products manufactured in the same facility and in a similar manner as other combusted, filtered cigarettes manufactured in the U.S. The applicant stated that the new products will also compete with other currently marketed combusted, filtered cigarettes. No expansion of the manufacturing facility is anticipated for manufacturing the new products. 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 information in the Exemption Requests, the only differences between the new products and the corresponding original products are the deletion of a complex tobacco additive and increase of an existing tobacco additive. Therefore, 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 3). Comparing the projected market volume of the new products with the forecasted use of all cigarettes produced in the U.S. in 2017 and 2021, the cumulative projected market volumes of the new products are a fraction of the total projected cigarette use in 2017 and 2021 (Appendix 2 and Confidential Appendix 4). Additionally, the applicant stated that the new products will compete with other currently marketed similar products. Therefore, no new control practices of air emission, water discharge, or solid waste disposal are needed.

The applicant stated that they are in compliance with all federal, state, and local environmental regulations and provided information on the manufacturer's air, storm water and wastewater permits. The applicant's air permit expired in November 2012 but the applicant reapplied in 2012 and is waiting for the renewed permit. The

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<sup>4</sup> [http://oaspub.epa.gov/enviro/ef\\_metadata\\_html.tri\\_page?p\\_column\\_name=land\\_total\\_release](http://oaspub.epa.gov/enviro/ef_metadata_html.tri_page?p_column_name=land_total_release)

<sup>5</sup> [http://oaspub.epa.gov/enviro/ef\\_metadata\\_html.tri\\_page?p\\_column\\_name=water\\_total\\_release](http://oaspub.epa.gov/enviro/ef_metadata_html.tri_page?p_column_name=water_total_release)

<sup>6</sup> [http://oaspub.epa.gov/enviro/ef\\_metadata\\_html.tri\\_page?p\\_column\\_name=off\\_site\\_total\\_transfers](http://oaspub.epa.gov/enviro/ef_metadata_html.tri_page?p_column_name=off_site_total_transfers)

<sup>7</sup> Information accessed from the "Find TRI Facilities" function (located at <https://www.epa.gov/toxics-release-inventory-tri-program>) using the reported manufacturer address (above) and choosing the R.J. Reynold Tobaccoville facility from the resulting map. Search performed June 27, 2017.



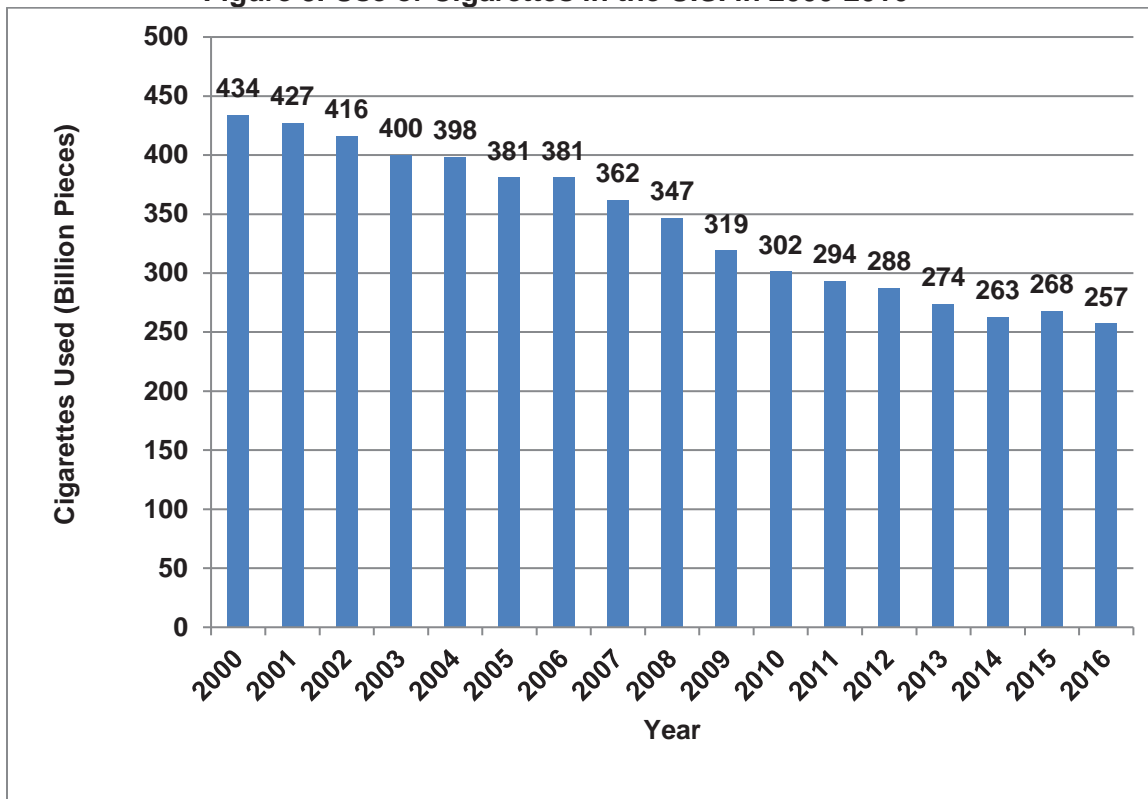
applicant also stated that their facility complies with other environmental regulations including maintaining EPA Spill Prevention Control and Countermeasure plans, reporting greenhouse gas (GHG) emissions to the EPA under the GHG reporting rule 40 CFR 98, submitting EPA Tier 2, EPA TRI, and North Carolina Right-to-Know reports, complying with the DHS Chemical Antiterrorism Standards, and complying with applicable solid and hazardous waste regulations.

## 5.2. Environmental Introduction as a Result of Use of the New Tobacco Products

### 5.2.1. Use of Cigarettes in the U.S.

According to the U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) Statistical Release reports, the use of cigarettes in the U.S. decreased from 434 billion in 2000 to 257 billion in 2016 (Figure 3) [1, 3].

Figure 3. Use of Cigarettes in the U.S. in 2000-2016<sup>4</sup>



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 [4, 5]. 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 [6].

- 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 [4, 5].
- Secondhand smoke causes more than 40,000 deaths a year [6].

### **5.2.2. Environmental Introduction from Use of the New Products**

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 applicant stated that the differences between the new and original products are the deletion of a complex tobacco additive and increase of an existing tobacco additive. 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 [4, 5]. 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 [6].
- 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 [4, 5].
- Secondhand smoke causes more than 40,000 deaths a year [6].

### **5.3. Environmental Introduction as a Result of Disposal Following Use of the New Tobacco Products**

The environmental consequences resulting from disposal following use of cigarettes are due to a) disposal of packaging materials, b) discarding of the used cigarettes, and c) GHG emissions.

#### **5.3.1. Disposal Following Use of Cigarettes**

##### **a) 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 U.S., including details about disposal of materials comparable to those used in cigarette products, can be informative about the disposal of cigarette packaging materials. Specifically, in 2014, approximately 258.46 million tons (234.47 million metric tons) of trash was generated in the U.S., and roughly 89.4 million tons of this material was recycled and composted, equivalent to a 34.6% recycling rate (Figure 4 and 5). Paper and paperboard account 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%), out of which 39.13 million tons was made of paper and paperboard. Of the total paper and paperboard MSW generated, 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 [7].

**Figure 4. Municipal Solid Waste (MSW) Generation Rates in the U.S., 1960-2014**

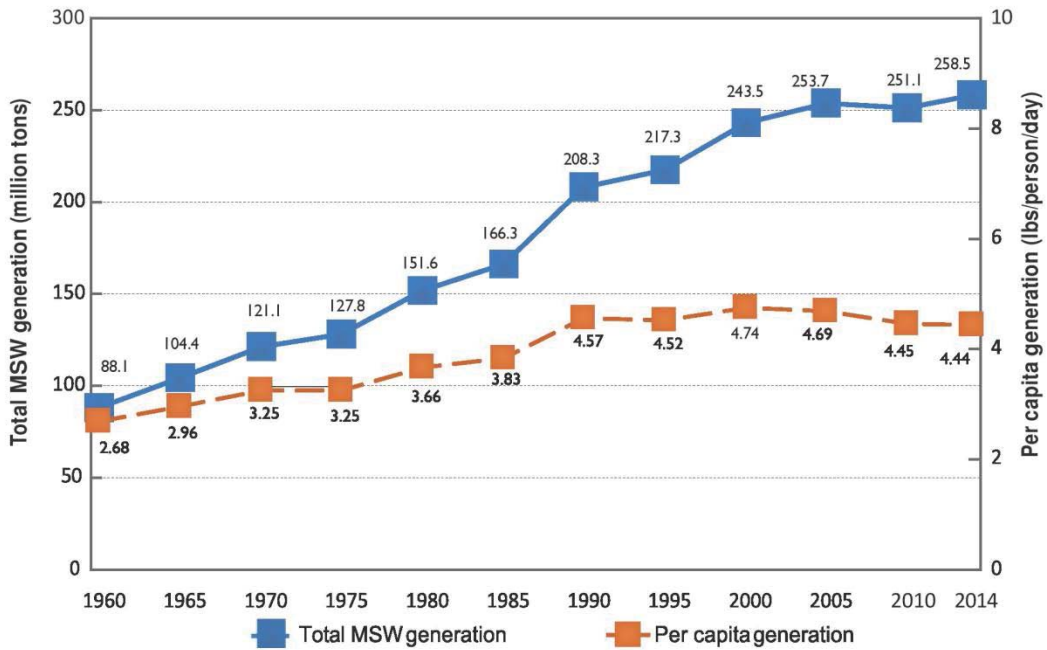


Figure excerpted from the U.S. EPA's "Advancing Sustainable Materials Management: 2014 Fact Sheet"

**Figure 5. MSW Recycling Rates in the U.S., 1960-2014**

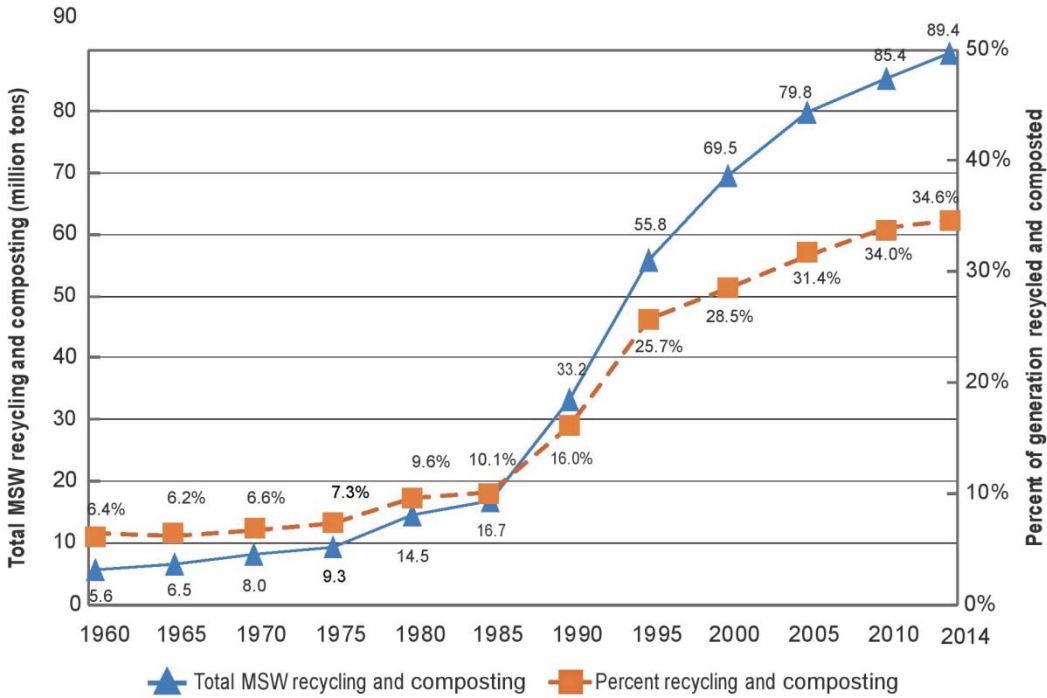


Figure excerpted from the U.S. EPA's "Advancing Sustainable Materials Management: 2014 Fact Sheet"

**b) Disposal of Used 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 U.S. to forecast the future use of cigarettes (Appendix 3) and calculate the projected tobacco waste accordingly. Assuming that all used cigarettes will be disposed of as MSW, the estimated waste of used cigarettes is a fraction of a percent of the total 258.46 million tons (234.47 million metric tons) of projected MSW to be generated in the U.S. Comparing the projected market volume of the new products as a surrogate for the projected waste from the new products, with the forecasted total U.S. MSW, the projected waste generated from use of the new products is negligible.

Forecast of Waste of Used Cigarettes as Compared to Total MSW Forecast in the U.S.		
Year	Projected Use (Equivalent to Projected Waste) of Cigarettes in the U.S. (Billion Pieces) <sup>a</sup>	Percent of Projected Waste of Cigarettes to Total MSW Forecasted in the U.S. (%) <sup>8</sup>
1 <sup>st</sup> Year	239.85	0.0918
5 <sup>th</sup> Year	205.21	0.0785

<sup>a</sup> See Appendix 3

### c) Air Emissions

The used tobacco products and packaging materials that are disposed of in MSW landfills or incinerated will produce GHGs.

Methane is a potent GHG that has a global warming potential 28-36 times greater than CO<sub>2</sub>, and has an atmospheric life of about 12 years. Global methane emissions from landfills are estimated between 30 and 70 million metric tons per year. MSW landfills are the third largest source of human-related methane emissions in the U.S., releasing an estimated 115.7 million metric tons of CO<sub>2</sub>-equivalents, accounting for approximately 15.4% of total methane emissions in 2015 [8]. Methane is a potent GHG that has a global warming potential of 28-36 times greater than CO<sub>2</sub>, and has an atmospheric life of about 12 years. The decomposition of landfill waste produces approximately 50% biogenic CO<sub>2</sub> and 50% methane, by volume, as well as trace amounts of non-methane organic compounds and volatile organic compounds. However, only methane generation and emissions are estimated and reported for landfills, a convention set forth by the 2006 Intergovernmental Panel on Climate Change (IPCC) Guidelines [9].

### 5.3.2. Environmental Introduction from Disposal Following Use of the New Products

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<sup>8</sup> Cigarettes in percentage:  $1^{\text{st}} \text{ Year} = \left( \frac{215,149 \text{ metric tons}}{234,470,000 \text{ metric tons}} \right) \times 100\% = 0.0918\%$   
 $5^{\text{th}} \text{ Year} = \left( \frac{184,073 \text{ metric tons}}{234,470,000 \text{ metric tons}} \right) \times 100\% = 0.0785\%$

The Agency believes that the disposal of the new products will be similar to the disposal conditions of other cigarettes and other tobacco products 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 determine the amount of waste due to disposal of packaging material and product material, the Agency used the projected market volumes in the first and fifth years after issuance of an authorization order for the new products. The calculated waste of the packaging materials and product materials of the new products were determined to be miniscule compared to the forecasted MSW to be generated in the U.S. (Confidential Appendix 4). In addition, paper components are more likely to be recycled; at least a portion of the waste is likely to be recycled.

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

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 5) in this PEA. The Clean Air Act requires that all landfills constructed or modified after July 17, 2014 that have a waste capacity of 2.5 million metric tons or more to have landfill gas collection-and-control systems installed. Additionally, all landfills must report GHG emissions to the EPA under 40 CFR 98. No additional control of GHG emissions is anticipated in the landfills.

## **6. Fate of Materials Released into the Environment Due to the Proposed Actions**

The Agency does not anticipate that the proposed actions will lead to the release of new chemicals into the environment because the new products are anticipated to be manufactured, used, and disposed of in the same way as other cigarettes. Therefore, the fate of any materials emitted is anticipated to be the same as any materials from other cigarettes manufactured in the facility. No new types of material are anticipated to be emitted to the environment at use.

## **7. Environmental Effects of New Materials Released into the Environment due to the Proposed Actions**

The applicant stated that the manufacturing operation is in compliance with all local, state, and federal environmental laws. Therefore, cumulative introduction of materials released into the environment is not expected to exceed what is allowed to be introduced to the environment under relevant environmental laws.

As discussed above, the amount of materials anticipated to enter the environment due to the manufacturing and use of the new products are small fractions when compared to that of the projected manufacture and use of cigarettes in the U.S. The Agency does not expect the introduction of the new products to notably affect the current manufacturing waste generated from the production of all cigarettes. In addition, the amount of materials anticipated to enter the environment due to disposal following use of the new products occupies a small fraction

of the total forecasted MSWs in the U.S. Consequently, no new substances or new type of emissions are expected to be released, and therefore no new environmental controls are needed. No new environmental effects are anticipated due to the new products.

## **8. 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 U.S., the Agency found that the projected market volumes of the new products are a small fraction of the total forecasted market volume in 2017 and 2021. Because the applicant stated that the new products will compete with similar cigarettes, 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.

## **9. 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 are discussed.

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

*Alternative A (No-action alternative):* The no-action alternative is to not authorize the marketing of the new tobacco products in the U.S. 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.

Therefore, the difference between the environmental impacts of these two alternatives is negligible, or non-existent.

## **11. List of Preparers**

In accordance with 40 CFR 1502.17, this section includes a list of names and qualifications (including education, experience, and expertise) of individuals who were primarily responsible for preparing and reviewing this environmental assessment.

Preparers:

Shannon K. Hanna, Ph.D., Center for Tobacco Products  
Education: PhD in Environmental Science and Management  
Experience: Four years in environmental science, three years in toxicology  
Expertise: Ecotoxicology of new substances and materials, bioaccumulation of chemicals including heavy metals, soil/sediment and water quality

Hoshing Chang, Ph.D., Center for Tobacco Products  
Education: M.S. in environmental science and PhD in Biochemistry  
Experience: Nine years in NEPA practice  
Expertise: NEPA analysis, wastewater treatment

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

Not applicable.

## **13. Appendix List**

- Appendix 1: Submission Tracking Numbers for the SE Reports and Package Sizes of the New and Original Products and Related Amendments Covered Under this Programmatic Environmental Assessment (PEA)
- Appendix 2: Forecast of Cigarettes Manufactured in the U.S.
- Appendix 3: Projected Use of Cigarettes in the U.S. in the First and Fifth Year of Marketing the New Products

## **14. Confidential Appendix List**

- Confidential Appendix 1: Changes Between New and Original Products
- Confidential Appendix 2: Projected Waste of Packaging Material and Cigarette Butts in the First and Fifth Year of Marketing the New Products
- Confidential Appendix 3: The First-, and Fifth-Year Market Volume Projections of the New Products
- Confidential Appendix 4: Comparison of the First- and Fifth-Year Market Volume Projections for the New Products with Total Cigarettes Used in the U.S.
- Confidential Appendix 5: The Agency's Estimated GHG in the First and Fifth Year of Marketing the New Products

## **15. References**

1. U.S. Department of Treasury Alcohol and Tobacco Tax and Trade Bureau (TTB). Tobacco Statistics. Available at <http://www.ttb.gov/tobacco/tobacco-stats.shtml>. Accessed March 15, 2017.
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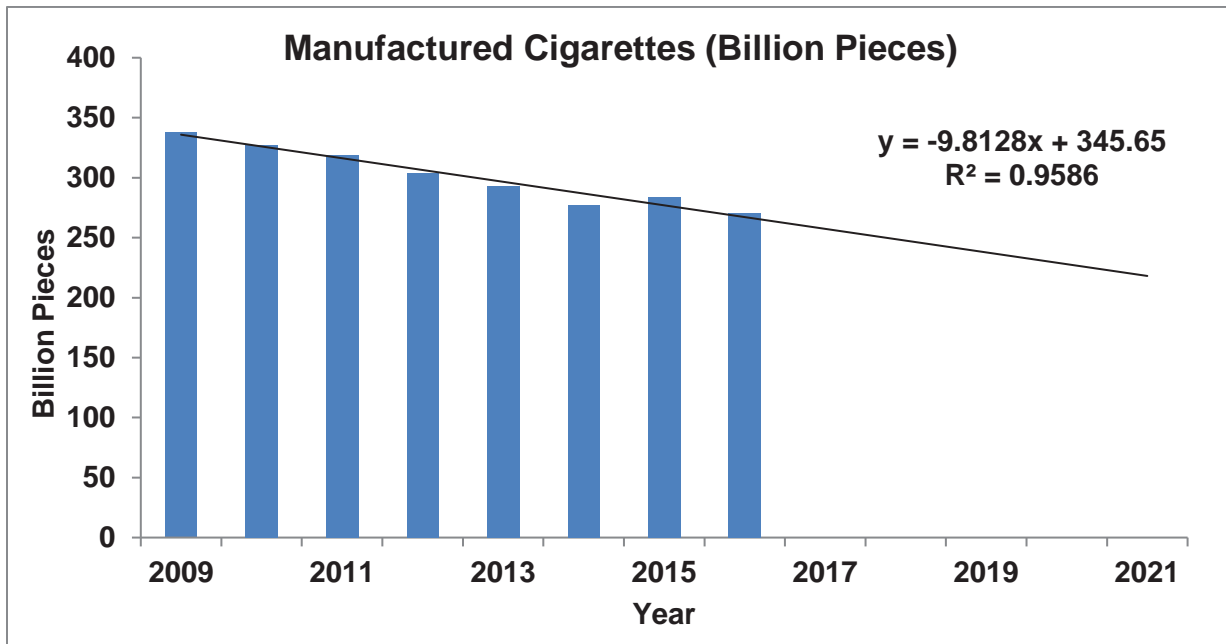
**APPENDIX 1**

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

<b>STN</b>	<b>Product Name</b>	<b>Amendments</b>
EX0000167	Monarch Red 100's Soft Pack	EX0000187
EX0000168	Monarch Gold 100's Soft Pack	
EX0000170	Monarch Blue 100's Soft Pack	
EX0000171	Monarch Red Box	
EX0000172	Monarch Gold Box	
EX0000173	GPC Non-Filter Soft Pack	

**APPENDIX 2**  
**Forecast of Cigarettes Manufactured in the U.S.**

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 U.S. from 2009 to 2016 was used to forecast the manufacture of cigarettes<sup>9</sup>. This was achieved by using one best-fit linear trend line with the R<sup>2</sup> value of 0.9586. Accordingly, the forecasted amount of all cigarettes projected to be manufactured in the U.S. is estimated to be 257 billion pieces in 2017 and 218 billion pieces in 2021. The amount of all cigarettes manufactured in the U.S. was 270 billion pieces in 2016.



<sup>9</sup> Department of the Treasury Alcohol and Tobacco Tax and Trade Bureau: Statistical Report – Tobacco for December 2016. Reported on February 16, 2017. Available at: <https://www.ttb.gov/statistics/2016/201612tobacco.pdf>. Accessed on June 27, 2017.

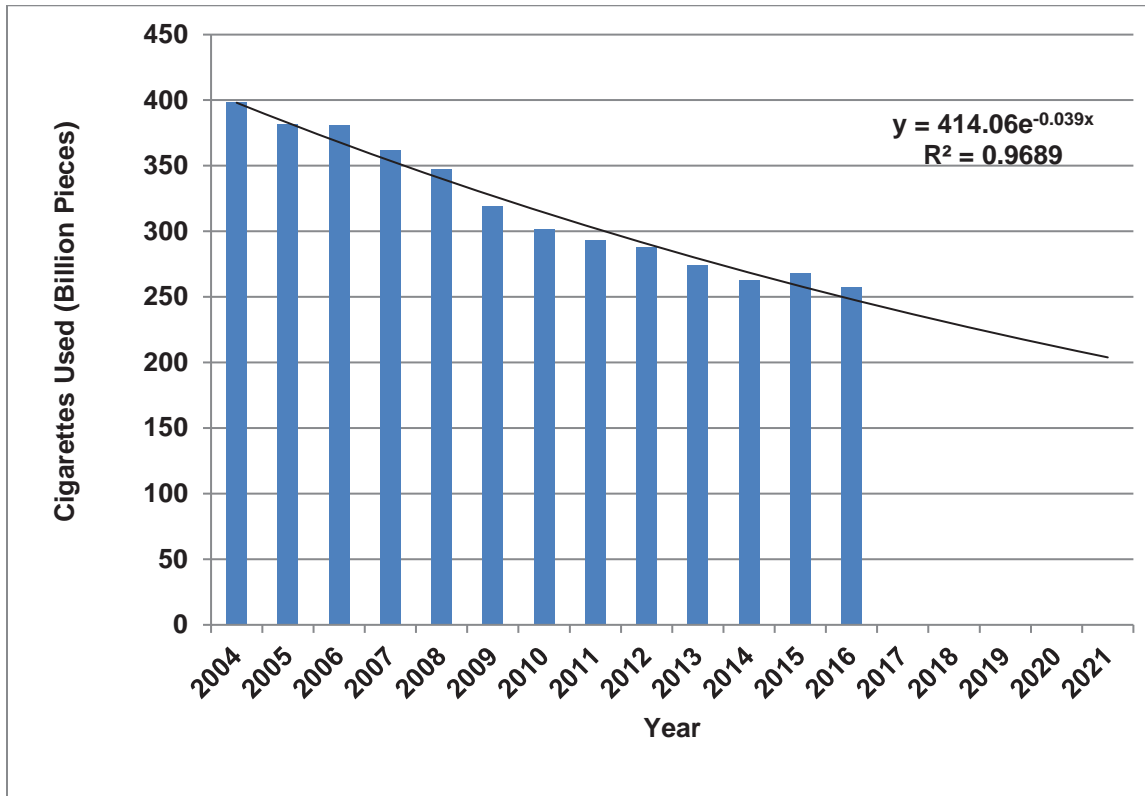
### APPENDIX 3

#### Projected Use of Cigarettes in the U.S. in the First and Fifth Year of Marketing the New Products

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 cigarettes used in the U.S.<sup>10</sup> This was achieved by using the one best-fit trend line with R<sup>2</sup> value above 0.9.

#### Projected Use of Cigarettes in the U.S.:

Using the best-fit power trend line with the R<sup>2</sup> value of 0.9689, the forecasted number of cigarettes projected to be used in the U.S. is estimated to be 239.85 billion in 2017 and 205.21 billion in 2021.



<sup>10</sup> Forecast trend lines extrapolated from TTB data. Available from <http://www.ttb.gov/tobacco/tobacco-stats.shtml>. Accessed March 15, 2017.

**CONFIDENTIAL APPENDIX 1**  
**Changes Between New and Original Products**

The applicant states that the only difference between the new and original products are the deletion of [REDACTED] mg/cigarette of a complex tobacco additive and increase of [REDACTED] mg/cigarette of [REDACTED].

**CONFIDENTIAL APPENDIX 2**

**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 2017 and 2021. Projected waste generation is the summation of the projected cardboard retail boxes, cardboard of the cartons, foil inner liner, plastic wrap of retail boxes, and cigarettes butts of the new products:

$\sum_{i=1}^6 A_i = \sum_{i=1}^6 (B_i + C_i + D_i + E_i + F_i)$ $B_i = \frac{G_i}{H_i} \times I_i \times S$ $C_i = \frac{G_i}{H_i \times J_i} \times K_i \times S$ $D_i = \frac{G_i}{H_i} \times L_i \times S$ $E_i = \frac{G_i}{H_i} \times M_i \times S$ $F_i = \frac{G_i \times O_i \times P_i}{100} \times S$ $P_i = \frac{Q_i}{R_i} \times 100$	<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)</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 soft pack + closure or empty box + innerframe (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>11</sup></p> <p><i>R<sub>i</sub></i>: Length of cigarette (millimeter)</p> <p><i>S</i>: 1.0 x 10<sup>-6</sup> metric tons/gram</p>
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<sup>11</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 as solid waste following use.

**a) Projected Waste of Packaging Material**

Projected packaging waste is calculated as below:

Projected Year	STN	Market volume $G_i$	# cigarettes per box $H_i$	Weight of retail box $I_i$	Retail box waste $B_i$	# 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	EX0000167	(b) (4)										
	EX0000168											
	EX0000170											
	EX0000171											
	EX0000172											
	EX0000173											
	<b>Total</b>											
Fifth-Year Projected Volume	EX0000167	(b) (4)										
	EX0000168											
	EX0000170											
	EX0000171											
	EX0000172											
	EX0000173											
	<b>Total</b>											

If all the projected packaging waste generated from use of the 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 2017 and (b) (4) metric tons in 2021. This is a negligible fraction of the 234.47 million metric tons of total waste reported in the U.S. in 2014. Likewise, the projected plastic waste of (b) (4) metric tons in 2017 and (b) (4) metric tons in 2021 is a negligible fraction of the 234.47 million metric tons of total waste reported in the U.S. 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 U.S. [7] If 64.7% of the cardboard boxes is recycled and the rest (35.3%) is disposed of as waste, the estimated cardboard waste disposed 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.

**b) Projected Waste of the Cigarette Butts in the First and Fifth Year of Marketing the New Product**

Projected cigarette butt waste generated is calculated as below:

Projected Year	STN	Market volume $G_i$	Cigarette length $R_i$	Cigarette weight $O_i$	Cigarette butt waste $F_i$
First-Year Projected Volume	EX0000167	(b) (4)			
	EX0000168				
	EX0000170				
	EX0000171				
	EX0000172				
	EX0000173				
	<b>Total</b>				
Fifth-Year Projected Volume	EX0000167				
	EX0000168				
	EX0000170				
	EX0000171				
	EX0000172				
	EX0000173				
	<b>Total</b>				

If all the projected filter waste generated from use of the products is disposed in landfills, the projected waste of (b) (4) metric tons in 2017 and (b) (4) metric tons in 2021 will be a negligible fraction of the 234.47 million metric tons of total waste reported in the U.S. in 2014.

**CONFIDENTIAL APPENDIX 3**  
**The First- and Fifth-Year Market Volume Projections of the New Products**

STN	Unit	First-Year Market Volume	Fifth-Year Market Volume
EX0000167	# of cigarettes	(b) (4)	
EX0000168	# of cigarettes		
EX0000170	# of cigarettes		
EX0000171	# of cigarettes		
EX0000172	# of cigarettes		
EX0000173	# of cigarettes		



**CONFIDENTIAL APPENDIX 4**

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

The first- and fifth-year market volumes of the new products projected to occupy the U.S. market were determined by comparing the projected market volume of the new products to the forecasted use of cigarettes in the U.S. (Appendices 2 and 3, and Confidential Appendix 2). The percent of the total cigarette market occupied in the projected first and fifth year of marketing of the new products was calculated using the equations below:

$$\text{First Year Market Occupation of New Products (\%)} = \frac{\text{First-Year Market Volume Projection (metric tons)}}{\text{Forecasted Use of cigarettes in the U.S. for 2017 (metric tons)}} \times 100\%$$

$$\text{Fifth Year Market Occupation of New Products (\%)} = \frac{\text{Fifth-Year Market Volume Projection (metric tons)}}{\text{Forecasted Use of cigarettes in the U.S. for 2021 (metric tons)}} \times 100\%$$

STN	Year	Forecasted Use of Total Cigarettes in the U.S. (billion cigarettes) <sup>12</sup>	Projected Market Volume of New Product (billion cigarettes) <sup>13</sup>	Projected Market Occupation of New Product in the U.S. (%)
EX0000167	2017	239.85	(b) (4)	
	2021	205.21		
EX0000168	2017	239.85		
	2021	205.21		
EX0000170	2017	239.85		
	2021	205.21		
EX0000171	2017	239.85		
	2021	205.21		
EX0000172	2017	239.85		
	2021	205.21		
EX0000173	2017	239.85		
	2021	205.21		

Comparing the projected market volume of the new products with the projected use of all cigarettes produced in the U.S. in 2017 and 2021, the cumulative projected market volumes of the new products are approximately (b) (4) of the total projected use in 2017 and (b) (4) of the projected use for 2021.

<sup>12</sup> See Appendix 3.

<sup>13</sup> See Confidential Appendix 3.

**CONFIDENTIAL APPENDIX 5**

**The Agency’s Estimated GHG 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 gases (CO<sub>2</sub>-eq) emitted from the use of one cigarette is estimated at 45-65 mg [10]. 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.) =

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

Metric Tons of CO <sub>2</sub> -eq		
STN	First-Year	Fifth-Year
EX0000167	(b) (4)	
EX0000168		
EX0000170		
EX0000171		
EX0000172		
EX0000173		
<b>Total</b>		

Estimated total GHG emissions associated with marketing the 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. This is a negligible fraction of the 6.87 billion metric tons of CO<sub>2</sub>-eq. reported in the U.S. in 2014 [8].

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

GHG emissions from the disposal of packaging and spent products following use of the new products were calculated using the Waste Reduction Model (WARM), version 14 [11]. 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
EX0000167	(b) (4)	
EX0000168		
EX0000170		
EX0000171		
EX0000172		
EX0000173		
<b>Total<sup>a</sup></b>		

<sup>a</sup> Note that the total is based on inputting the sum of waste for all products into the WARM model. Simply adding the individual outputs from individual products provides a different result that is impacted by rounding.

Taking into account the rates for recycling and landfill disposal of various material types, the total amount of GHG emissions from the disposal of packaging and products following use is estimated at █ metric tons of CO<sub>2</sub>-eq. for the first year of marketing and █ metric tons of CO<sub>2</sub>-eq. for the fifth year. This estimate is a negligible fraction █ of the 115.7 million metric tons of CO<sub>2</sub> equivalents reported in the U.S. in 2015 [8]. Recycling rate of paper was considered for entries into the WARM model to reduce the landfill input, however, the metric tons recycled was not entered into the model because the intent is to determine the GHG emissions associated with MSW generation.