Environmental Assessment for Marketing Order for Philip Morris USA Inc. “Marlboro Southern Cut 100’s Box”

Prepared by Center for Tobacco Products

U.S. Food and Drug Administration

December 22, 2017

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This environmental assessment (EA) is for the marketing order for a combusted, filtered cigarette manufactured by Philip Morris USA Inc. Information presented in the EA is based on the submissions referenced in Appendix 1, unless noted or referenced otherwise. This EA has been prepared in accordance to 21 CFR 25.40 as part of submissions under section 910(a)(2) of the Federal Food, Drug and Cosmetic Act (FD&C Act).

1. Name of Applicant

Philip Morris USA Inc.

2. Address

Philip Morris USA Inc.
6601 West Broad Street
Richmond, VA 23230

3. Manufacturer

Philip Morris USA Manufacturing Center
3601 Commerce Road
Richmond, VA 23234

4. Description of Proposed Action

The proposed action is for FDA to issue a marketing order under the provisions of sections 910 and 905(j) of the FD&C Act for the introduction of a combusted, filtered cigarette into interstate commercial distribution in the United States. This authorization is based on the finding that the new product is substantially equivalent to the predicate product. The predicate product is a grandfathered product, GF1200088, which received confirmation of grandfathered status June 25, 2012.

4.1 Requested Action

The applicant requests that FDA issue an order finding the listed tobacco product is substantially equivalent to the predicate product.

4.2 Need for Action

Philip Morris USA Inc. wishes to introduce the new tobacco product as described into interstate commerce for commercial distribution in the United States. The applicant states that the new and predicate products have different characteristics (sec 910(a)(3)(A)(ii) of the FD&C Act). The differences are in the amount and type of tobacco filler, the tipping paper, the cigarette length and circumference, and the filter. To assure adequate supply security, the applicant proposes to use several different interchangeable parts, that they claim does not alter the finished product, including the cigarette paper, filter, and tipping paper, to construct the new product. After considering the substantial equivalence (SE) report, the Agency shall issue an order under the provisions of sections 910 and 905(j) of the FD&C Act when finding the new product to be substantially equivalent to the predicate product.

4.3 Identification of the New Tobacco Product that is the Subject of the Proposed Action

4.3.1 Type of Tobacco Product

Combusted filtered cigarettes

4.3.2 Product Names and STNs

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

STN	New Product	STN	Predicate Product
SE0007204	Marlboro Southern Cut 100's Box	GF1200088	Marlboro 100's Box

4.3.3 Description of the Product Package

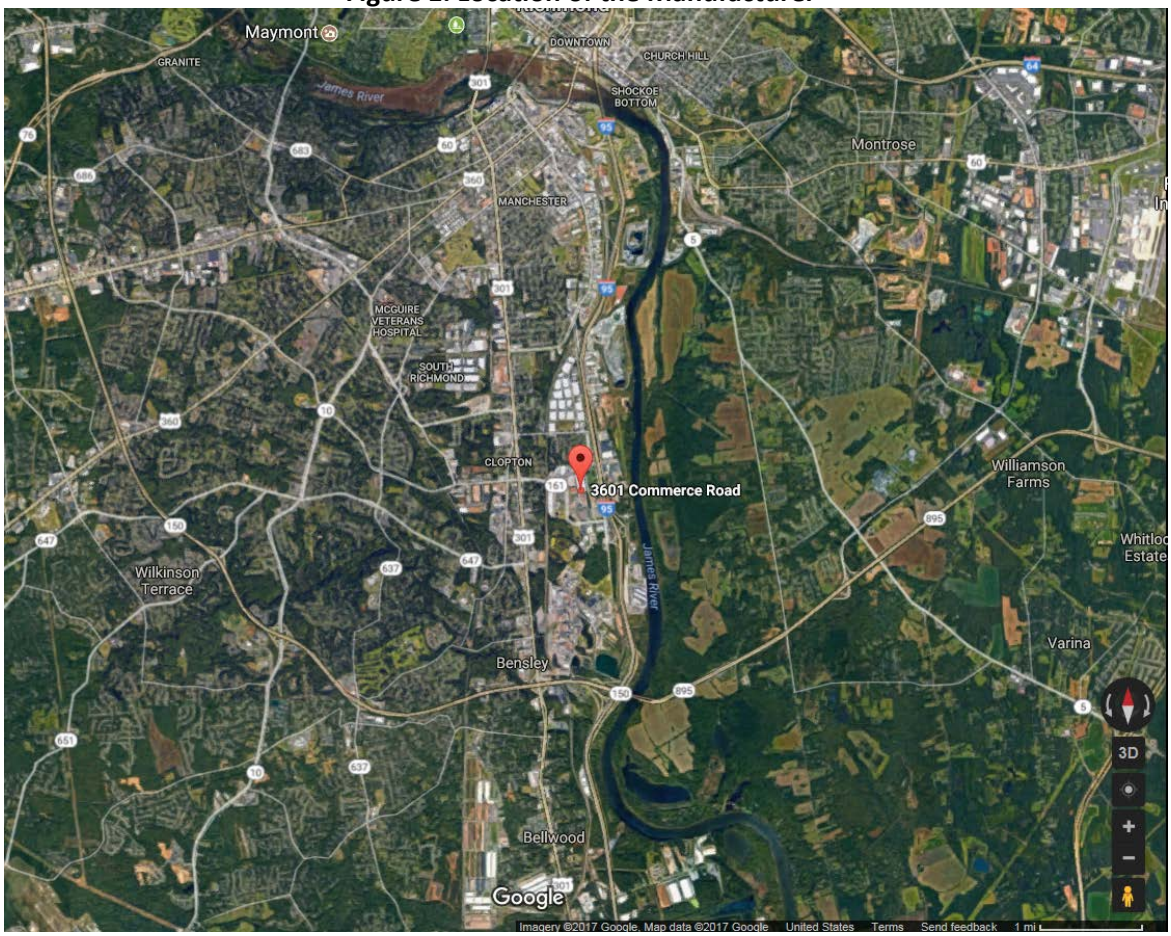
The packaging materials of the finished new product are different compared to the predicate product, however, the package construction is the same. The new product packaging consists of a foil inner liner, inner frame, box, film overlap, and carton.

4.3.4 Location of Manufacturing

Philip Morris USA Manufacturing Center
3601 Commerce Road
Richmond, VA 23234

The facility is in Richmond, VA, bounded by the James River to the east and north, US 64 to the north, state road 150 to the south, and surrounded by industrial land (Figure 1).

Figure 1. Location of the Manufacturer[1]



4.3.5 Location of Use

Philip Morris USA Inc. intends to distribute and sell the new tobacco product to consumers in the Unite States.

4.3.6 Location of Disposal

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

The applicant states that the differences between the new and predicate products are in the amount and type of tobacco filler, the tipping paper, the cigarette length and circumference, and the filter.

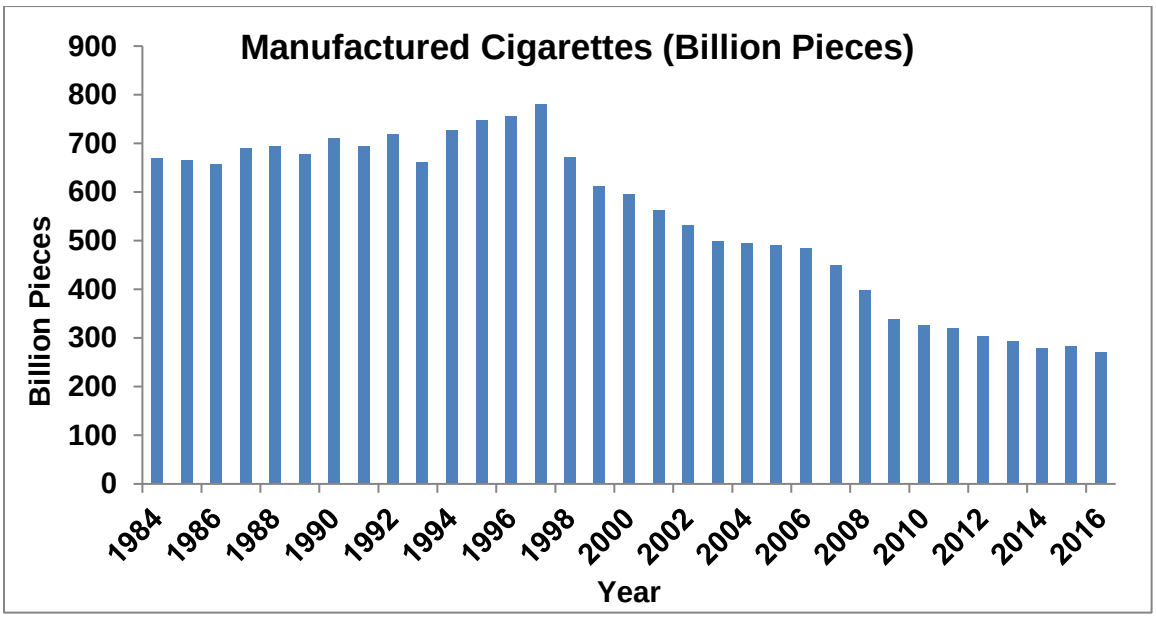
[1] Manufacturer address via Google Map. Accessed October 2, 2017.

5. Potential Environmental Impacts Due to the Proposed Action

5.1. Potential Environmental Impacts Due to Manufacturing the New Product

As of August 2017, a total of 1031 tobacco production establishments are registered under 915(c) of the FD&C Act[2]. 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].

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.[3] In 2015, U.S. tobacco manufacturers released 475,000 pounds of ammonia and 280,000 pounds of nicotine and nicotine salts to the air; 9,564 pounds of ammonia and 313,765 pounds of nicotine and nicotine salts to landfill; 220 pounds of ammonia and 279 pounds of nicotine and nicotine salts to the surface water; 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. In 2016, the Philip Morris USA Richmond facility released 20,347 pounds of ammonia and 11,671 pounds of nicotine and nicotine salts to the air; no ammonia, nicotine, or nicotine salts to the land or water; and

[2] Based on FDA's Establishment Registration & Tobacco Product Listing Database. Available at https://www.accessdata.fda.gov/scripts/ctpocerl/index.cfm?action=main.home Accessed August 30, 2017.

[3] 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.

transferred 2,483 pounds of ammonia and 84,422 pounds of nicotine and nicotine salts to POTWs [4].

The Agency anticipates the waste generated as a result of manufacturing the new combusted, filtered cigarette 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 to other combusted, filtered cigarettes manufactured in the United States. The applicant stated that the new product will also compete with other currently marketed combusted, filtered cigarettes. 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 information in the SE Report, the only differences between the new and predicate products are in the amount and type of tobacco filler, the tipping paper, the cigarette length and circumference, and the filter. However, these components are similar to that of the predicate product and other cigarettes currently on the market. 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 product.

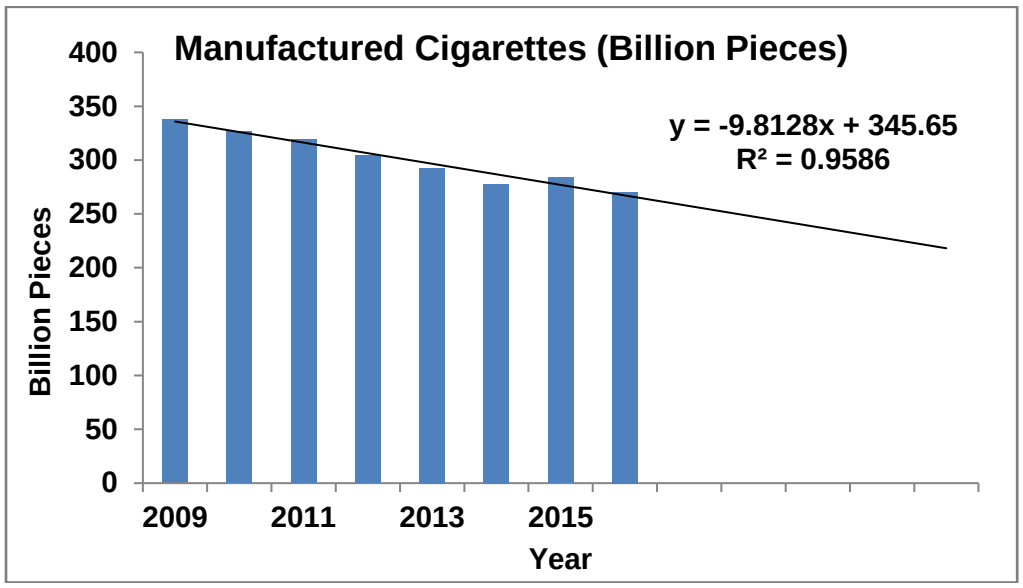
The applicant provided the first- and fifth-year market volumes for the new product (Confidential Appendix 1). To evaluate the environmental impact of the proposed action due to manufacturing of the new product, historical data regarding the manufacture of cigarettes in the United States from 2009 to 2016 was used to forecast the manufacture of cigarettes[5]. This was achieved by using one best-fit linear trend line with the R^2 value of 0.9586. Accordingly, the forecasted number of all cigarettes to be manufactured in the United States is estimated to be 257 billion pieces in 2017 and 218 billion pieces in 2021. The number of all cigarettes manufactured in the United States was 270 billion pieces in 2016.

Comparing the projected market volume of the new product with the forecasted manufacture of cigarettes in the United States in 2017 and 2021, the projected market volume of the new product is a fraction of the total projected number of cigarettes to be manufactured in 2017 and 2021 (Figure 3 and Confidential Appendix 2). Additionally, the applicant stated that manufacturing the new product will not require any new equipment or expansion of the current manufacturing facility. Therefore, no new control practices of air emission, water discharge, or solid waste disposal are needed.

Figure 3. Forecast of Cigarettes Manufactured in the United States

[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 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. Search performed October 3, 2017.

[5] 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.

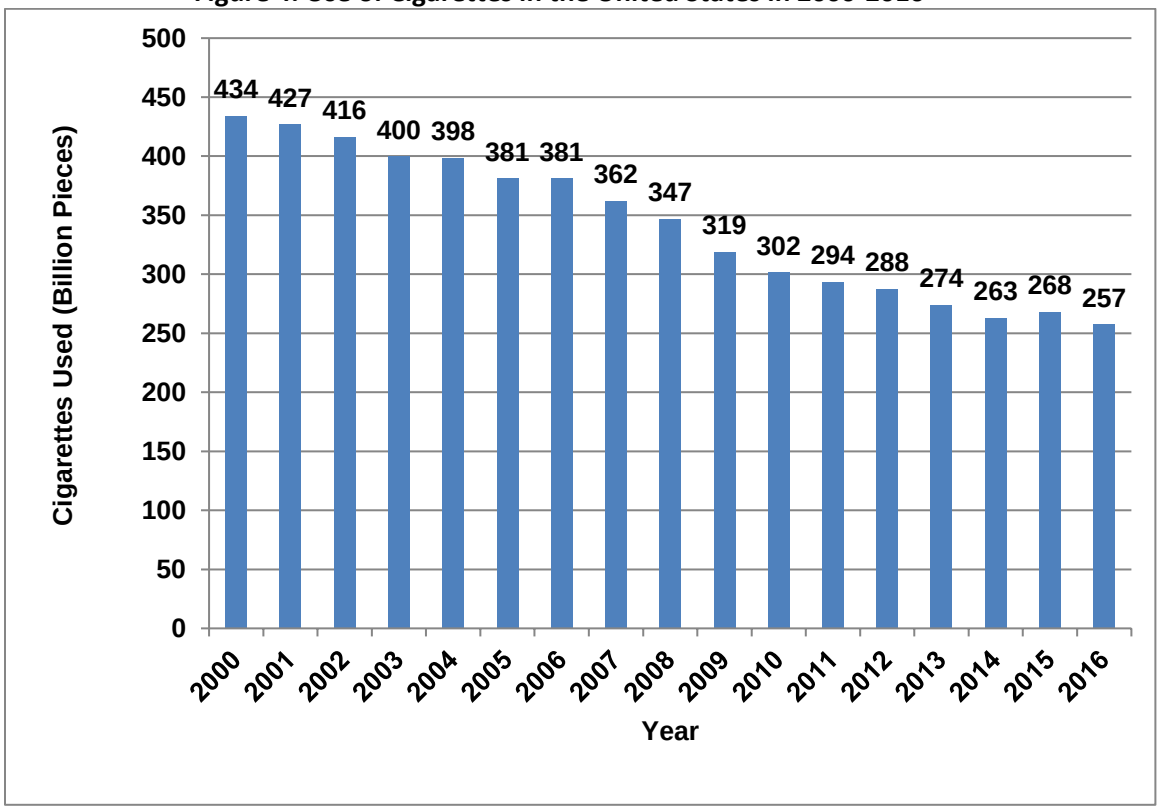


The applicant stated that they are in compliance with all federal, state, and local environmental regulations and provided information on the manufacturering facility's air and wastewater permits. The applicant holds a Federal Operating Permit for air emissions and an Industrial User Permit for wastewater pretreatment from the local POTWs.

5.2. Potential Environmental Introduction Due to Use of the New Product

According to the U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) Statistical Release reports, the use of cigarettes in the United States decreased from 434 billion in 2000 to 257 billion in 2016 (Figure 4) [1, 2].

Figure 4. Use of Cigarettes in the United States in 2000-2016



The Agency does not anticipate new substances to be released into the environment as a result of use of the new product, relative to the substances released by the predicate product, and other cigarettes already on the market. As noted, the only differences between the new product and predicate product are in the amount and type of tobacco filler, the tipping paper, the cigarette length and circumference, and the filter. When burned, cigarettes release tobacco smoke to the environment, referred to as secondhand smoke. There is no safe level of exposure to secondhand smoke [3, 4]. 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% [5].

- 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 [3, 4].

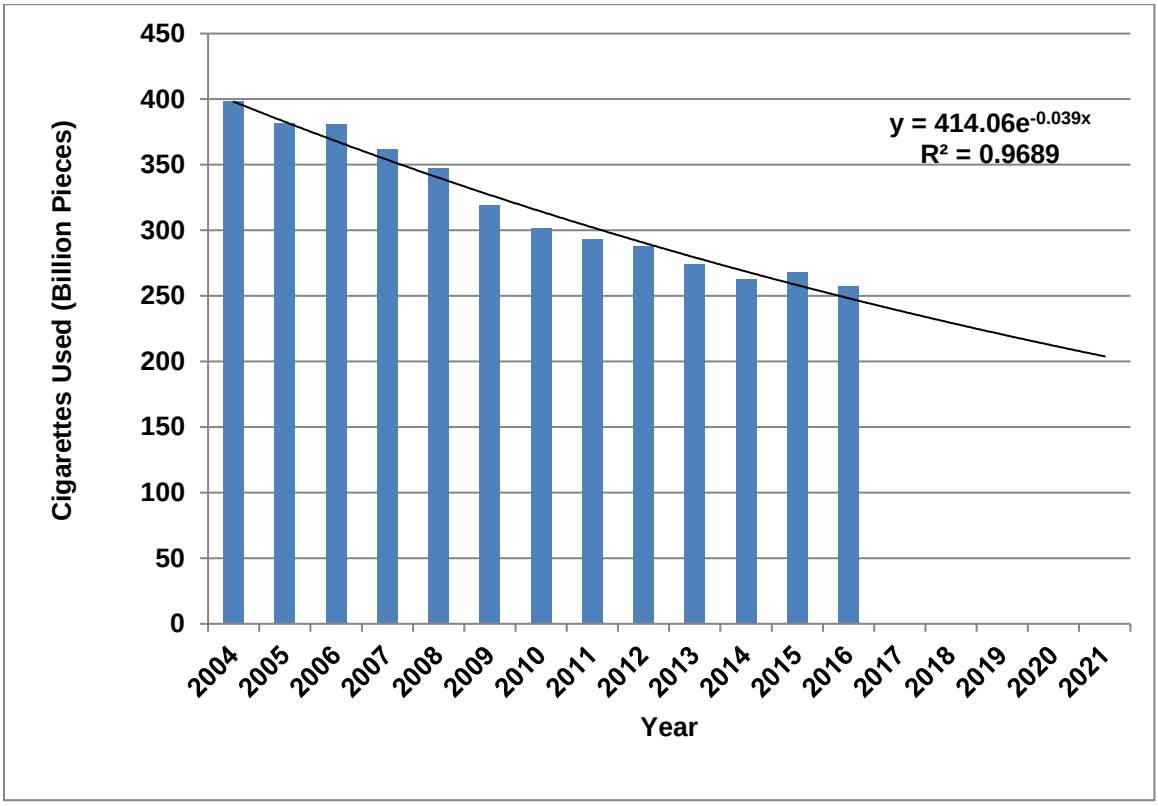
- Secondhand smoke causes more than 40,000 deaths a year [5].

To evaluate the environmental impact of the proposed action due to use of the new product, historical data regarding total use of cigarettes from 2004 to 2016 was employed to mathematically estimate the

forecast of the total number of cigarettes used in the United States.[6] This was achieved by using the one best-fit trend line with R^2 value above 0.9.

Using the best-fit power trend line with the R^2 value of 0.9689, the forecasted number of cigarettes that will be used in the United States is estimated to be 239.85 billion in 2017 and 205.21 billion in 2021.

Figure 5. Projected Use of Cigarettes in the United States in the First and Fifth Year of Marketing the New Product



The Agency does not anticipate that the proposed action will lead to the release of new chemicals into the environment due to use because the changes in the new product compared to the predicate product are changes in components that are similar to that of the predicate product and other cigarettes currently on the market . Therefore, the fate of any materials emitted is anticipated to be the same as any materials emitted due to other cigarettes. No new types of material are anticipated to be emitted to the environment at use.

[6] Forecast trend lines extrapolated from TTB data. Available from http://www.ttb.gov/tobacco/tobacco-stats.shtml. Accessed March 15, 2017.

5.3. Potential Environmental Impacts Due to Disposal Following Use of the New Tobacco Product

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, in 2014, approximately 258.46 million tons (U.S. short tons in section 5.3 of the EA, unless specified) of trash was generated in the United States, and roughly 89.4 million tons of this material was recycled and composted, equivalent to a 34.6% recycling rate (Figure 4 and 5) [6]. 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 [6].

Figure 6. Municipal Solid Waste (MSW) Generation Rates in the United States, 1960-2014

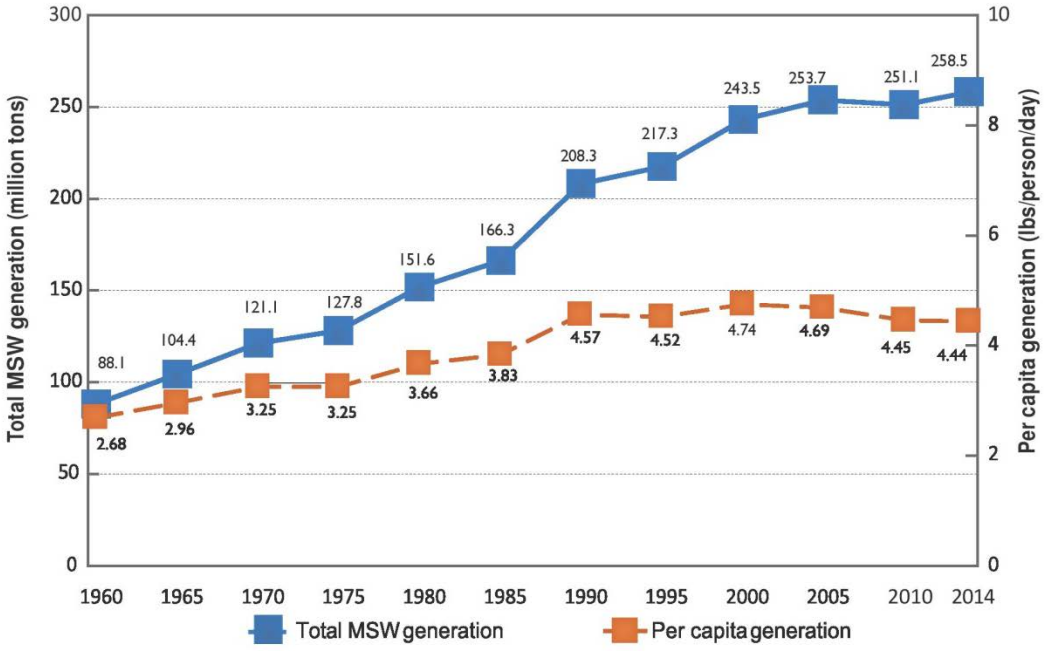


Figure excerpted from the U.S. EPA's "Advancing Sustainable Materials Management: 2014 Fact Sheet"

Figure 7. MSW Recycling Rates in the United States, 1960-2014

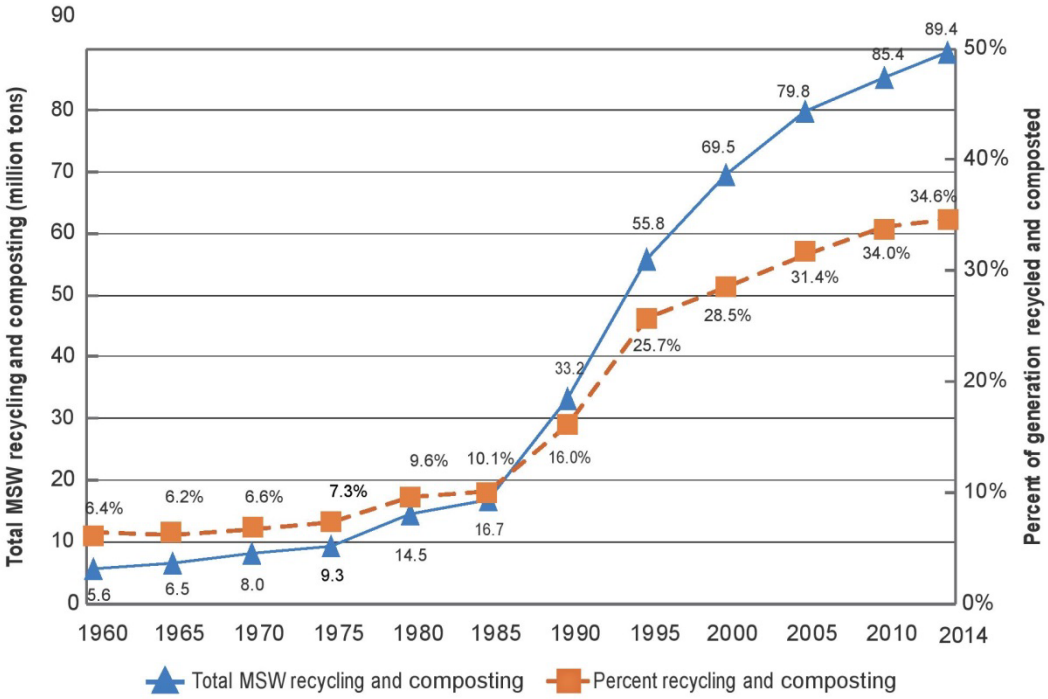


Figure excerpted from the U.S. EPA's "Advancing Sustainable Materials Management: 2014 Fact Sheet"

The Agency believes that the disposal of the new 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 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 a marketing order for the new product. The calculated waste of the packaging materials and product materials of the new product were determined to be miniscule compared to the forecasted MSW to be generated in the United States (Confidential Appendix 2). 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 product will compete with other 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 action.

The Agency does not anticipate that the proposed action will lead to the release of new chemicals into the environment due to manufacturing. 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. Discarding Used Cigarettes Following Use

Cigarette butt[7] waste may have an end-of-life-cycle scenario as either managed or unmanaged waste.

Managed waste is handled by an organized solid waste collection and management system. For the managed waste, 80.4% by weight enters landfills, and the remaining 19.6% by weight is incinerated for energy recovery [7]. The Agency used the projected market volumes for the first and fifth years of marketing the new product to estimate the waste from discarding the used new product, i.e., the cigarette butts. The estimated waste from cigarette butt disposal as MSW (Confidential Appendix 3) would be miniscule compared to the total MSW forecasted to be discarded in the United States. Because the new combusted, filtered cigarette product will compete with other similar combusted, filtered cigarette products on the market and the estimates described above and detailed in Confidential Appendix 3 indicate a negligible contribution to United States MSW, construction of new solid waste landfills or incinerators is not anticipated due to disposal of the used new product under the proposed action.

Litter, including littered cigarette butts, is considered unmanaged waste. The environmental effects of cigarette butt litter were summarized as follows [8]:

> Cigarette butts are the most commonly discarded piece of waste globally and are the most frequent item of litter picked up on beaches and water edges worldwide… The non-biodegradable cellulose acetate filter attached to most manufactured cigarettes is the main component of cigarette butt waste... Hazardous substances have been identified in cigarette butts – including arsenic, lead, nicotine and ethyl phenol. These substances are leached from discarded butts into aquatic environments and soil.

Introducing the new product into the U.S. market is not expected to increase the nationwide use of combusted, filtered cigarettes; instead, they would compete for market share with existing products. Thus, authorizing the new product is not expected to affect the overall level of cigarette butt litter in the United States, but may displace the level of litter from other cigarette products.

5.3.3. Air Emissions

The used tobacco product and packaging materials that are disposed of in MSW landfills or incinerated will produce greenhouse gasses (GHGs). 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.

[7] "Cigarette butt" is defined in this PEA as the filter and cigarette rolling paper containing remainder tobacco that is disposed of following use.

Methane (CH_4) is a potent GHG that has a global warming potential of 28-36 times greater than carbon dioxide (CO_2), and has an atmospheric life of about 12 years. Global CH_4 emissions from landfills are estimated between 30 and 70 million metric tons per year. MSW landfills are the third largest source of human-related CH_4 emissions in the United States, releasing an estimated 115.7 million metric tons of CO_2 equivalents, accounting for approximately 15.4% of total CH_4 emissions in 2015 [9]. The decomposition of landfill waste produces approximately 50% biogenic CO_2 and 50% CH_4, by volume, as well as trace amounts of non-methane organic compounds and volatile organic compounds. However, only CH_4 generation and emissions are estimated and reported for landfills, a convention set forth by the 2006 Intergovernmental Panel on Climate Change (IPCC) Guidelines [9].

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 4) in this EA. 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 emitted as a result of 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 is manufactured compared to the predicate product. The same raw materials and energy will be used to manufacture the new product compared to the predicate 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 volume of the new product is a small fraction of the total forecasted cigarette market volume in 2017 and 2021. Because the applicant stated that the new product will compete with other similar cigarettes, 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.

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 are discussed.

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 (Confidential Appendices 2-5).

9. 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: Ph.D. 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

Reveiwer:

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 SE Reports and Package Sizes of the New and Predicate Products and Related Amendments Covered Under this Programmatic Environmental Assessment (PEA)

12. Confidential Appendix List

Confidential Appendix 1:	The First-, and Fifth-Year Market Volume Projections of the New Product
Confidential Appendix 2:	Comparison of the First- and Fifth-Year Market Volume Projections for the New Product 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 Product
Confidential Appendix 4:	The Agency's Estimated GHG in the First and Fifth Year of Marketing the New Product

13. 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.
2. Centers for Disease Control and Prevention (CDC). Economic Facts about Tobacco Production and Use. Available at http://www.cdc.gov/tobacco/data_statistics/fact_sheets/economics/econ_facts/. Accessed January 16, 2015.
3. 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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5. U.S. Department of Health and Human Services (HHS). 2014. The Health Consequences of Smoking—50 Years of Progress. A Report of the Surgeon General. Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health. Atlanta, GA.
6. U.S. Environmental Protection Agency (EPA). Materials and Waste Management in the United States Key Facts and Figures. Available at https://www.epa.gov/smm/advancing-sustainable-materials-management-facts-and-figures. Accessed May 17, 2016.
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9. Intergovernmental Panel on Climate Change (IPCC) *2006 IPCC Guidelines for National Greenhouse Gas Inventories*. 2006; Available from: http://www.ipcc-nggip.iges.or.jp/public/2006gl/. Accessed July 20, 2017.
10. U.S. Environmental Protection Agency (EPA). *Inventory of U.S. Greenhouse Gas Emissions and Sinks: 1990-2015.* 2017(EPA 430-P-17-001).
11. (IPCC), I.P.o.C.C. *2006 IPCC Guidelines for National Greenhouse Gas Inventories*. 2006; Available from: http://www.ipcc-nggip.iges.or.jp/public/2006gl/.
12. Geiss, O. and K. Dimitrios, *Tobacco, Cigarettes and Cigarette Smoke: An Overview.* European Commission, Directorate-General Joint Research Centre, Institute for Health and Consumer Protection, 2007(EUR 22783 EN).

APPENDIX 1

Submission Tracking Numbers for the SE Report of the New Product and Related Amendments Covered Under this Environmental Assessment (EA)

STN	Product Name	Amendments
SE0007204	Marlboro Southern Cut 100's Box	SE0008798 SE0010111 SE0012368 SE0014349

CONFIDENTIAL APPENDIX 1

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

STN	Unit	First-Year Market Volume	Fifth-Year Market Volume
SE0007204	# of cigarettes	(b) (4)	

CONFIDENTIAL APPENDIX 2

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

The first- and fifth-year market volumes of the new product projected to occupy the United States market were determined by comparing the projected market volume of the new product to the forecasted manufacture and use of cigarettes in the United States (Figures 3 and 5). The percent of the total cigarette market occupied in the projected first and fifth year of marketing of the new product was calculated using the equations below:

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

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

STN	Year	Forecasted Manufacture of Total Cigarettes in the U.S. (billion cigarettes)[8]	Forecasted Use of Total Cigarettes in the U.S. (billion cigarettes)[9]	Projected Market Volume of New Product (billion cigarettes)[10]	Projected Market Occupation of Manufacture of New Product in the U.S. (%)[10]	Projected Market Occupation of Use of New Product in the U.S. (%)
SE0007204	2017	257.33	239.85	(b) (4)		
	2021	218.08	205.21			

Comparing the projected market volume of the new product with the projected manufacture and use of all cigarettes produced in the United States in 2017 and 2021, the projected market volume of the new product is approximately (b) (4) of the total projected cigarette manufacture and (b) (4) of the total projected cigarette use in 2017 and (b) (4) of the projected manufacture and (b) (4) of the projected use for 2021.

[8] See Figure 3.

[9] See Figure 5.

[10] See Confidential Appendix 3.

CONFIDENTIAL APPENDIX 3

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

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 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 product.

$\sum_{i=1}^{10} A_i = \sum_{i=1}^{10} (B_i + C_i + D_i + E_i + F_i + G_i)$	A_i: Projected total waste generation of the product (metric tons)
$B_i = \frac{H_i}{I_i} \times J_i \times U$	B_i: Projected waste generation of retail cardboard boxes of the new product (metric tons)
$C_i = \frac{H_i}{I_i \times K_i} \times L_i \times U$	C_i: Projected waste generation of the retail cardboard cartons of the new product (metric tons)
$D_i = \frac{H_i}{I_i \times K_i \times M_i} \times N_i \times U$	D_i: Projected waste generation of the shipping carboard boxes of the new product (metric tons)
$E_i = \frac{H_i}{I_i} \times O_i \times U$	E_i: Projected waste generation of the foil inner liner (metric tons)
$F_i = \frac{H_i}{I_i} \times P_i \times U$	F_i: Projected waste generation of retail box plastic of the new product (metric tons)
$G_i = H_i \times Q_i \times R_i \times U$	G_i: Projected waste generation of cigarette butts of the new product (metric tons)
$R_i = \frac{S_i}{T_i} \times 100$	H_i: Total Projected market volume of the new product (total number of individual cigarettes) I_i: Number of cigarettes per retail box J_i: Weight of empty retail cardboard box (grams) K_i: Number of retail boxes per carton L_i: Weight of empty retail carton (grams) M_i: Number of cartons per shipping box N_i: Weight of empty shipping box (grams) O_i: Weight of foil inner liner (grams) P_i: Weight of plastic wrap per retail box (grams) Q_i: Weight of cigarette (gram) R_i: Cigarette butt ratio (%) S_i: Cigarette butt length [11] T_i: Length of cigarette (millimeter) U: 1.0×10^{-6} metric tons/gram

[11] 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.

a) Projected Waste of Packaging Material

Projected packaging waste is calculated as below:

Projected Year	*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	(b) (4)	20	6.31	(b) (4)	10	21.54	(b) (4)	1.01	(b) (4)	0.44	(b) (4)
Fifth-Year Projected Volume	(b) (4)	20	6.31	(b) (4)	10	21.54	(b) (4)	1.01	(b) (4)	0.44	(b) (4)

If all the projected packaging waste generated from use of the 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) 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 United States 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 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.[12] 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.

[12] 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 April 4, 2017).

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	*Market volume* G_i	*Cigarette length* R_i	*Cigarette weight* O_i	*Cigarette butt waste* F_i
First-Year Projected Volume	(b) (4)	98.5	1.0852	(b) (4)
Fifth-Year Projected Volume	(b) (4)	98.5	1.0852	

If all the projected filter waste generated from use of the product is disposed of 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 United States in 2014.

CONFIDENTIAL APPENDIX 4

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 CO_2-equivalent (CO_2-eq) gasses 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_2 emitted per cigarette to calculate the GHG emissions from use of the new product.

GHG Emissions from Use of Product (metric tons of CO_2-eq.) =

$$Projected\ Market\ Volume\ of\ Product\ (cigarette) \times 0.065 gCO2 - eq/cigarette \times 0.000001\ metric\ tons/g$$

Metric Tons of CO_2-eq	
First-Year	Fifth-Year
(b) (4)	(b) (4)

Estimated total GHG emissions associated with marketing the new product are (b) (4) metric tons CO_2-eq in the first year and (b) (4) metric tons CO_2-eq. in the fifth year. This is a negligible fraction of the 6.87 billion metric tons of CO_2-eq. reported in the United States in 2014 [11].

b) GHG Emissions from Disposal of Product Following Use:

GHG emissions from the disposal of packaging and spent product following use of the new product were calculated using the Waste Reduction Model (WARM), version 14 [12]. 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	
First-Year	Fifth-Year
(b) (4)	

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 product for the new product following use is estimated at (b) (4) metric tons of CO_2-eq. for the first year and (b) (4) metric tons of CO_2-eq. for the fifth year. This estimate is a negligible fraction (b) (4)) of the 115.7 million metric tons of CO_2 equivalents reported in the United States in 2015 [10]. 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.