

**Environmental Assessment for Marketing Order for
Philip Morris USA Inc. “Marlboro Menthol Gold Pack Box”**

Prepared by Center for Tobacco Products

U.S. Food and Drug Administration

March 1, 2018

Contents

1. Name of Applicant 3

2. Address 3

3. Manufacturer 3

4. Description of Proposed Action 3

4.1 Requested Action..... 3

4.2 Need for Action..... 3

4.3 Identification of the New Tobacco Product that is the Subject of the Proposed Action..... 3

4.3.1 *Type of Tobacco Product*..... 3

4.3.2 *Product Name and Submission Tracking Number* 4

4.3.3 *Description of the Product Package* 4

4.3.4 *Location of Manufacturing* 4

4.3.5 *Location of Use*..... 5

4.3.6 *Location of Disposal* 5

4.4 Modification(s) Identified as Compared to the Predicate Product..... 5

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

5.1 Potential Environmental Impacts Due to Manufacturing the New Product..... 5

5.2 Potential Environmental Impacts Due to Use of the New Product 7

5.3 Potential Environmental Impacts Due to Disposal of the New Tobacco Product 9

5.3.1 *Disposal of Packaging Materials*..... 9

5.3.2 *Disposal of Cigarette Waste*..... 11

6 Use of Resources and Energy..... 12

7 Mitigation..... 12

8 Alternatives to the Proposed Action..... 12

9 List of Preparers 12

10 List of Agencies and Persons Consulted..... 13

11 Appendix List..... 13

12 Confidential Appendix List 13

13 References 13

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 submission 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

3601 Commerce Road,
Richmond, VA 23234

3. Manufacturer

Philip Morris USA Inc.

4. Description of Proposed Action

This 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 commerce for commercial distribution in the United States. The authorization is based on the finding that the new product is substantially equivalent to the predicate product that was on the market as of February 15, 2007.

4.1 Requested Action

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 claims that the new product differs from the predicate product only in product quantity (sec 910(a)(3)(A)(ii) of the FD&C Act), however there is also an ingredient in the predicate product that is not present in 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 cigarette

4.3.2 Product Name and Submission Tracking Number

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

STN	New Product	Predicate Product
SE0014203	Marlboro Menthol Gold Pack Box	Marlboro Lights Menthol Box

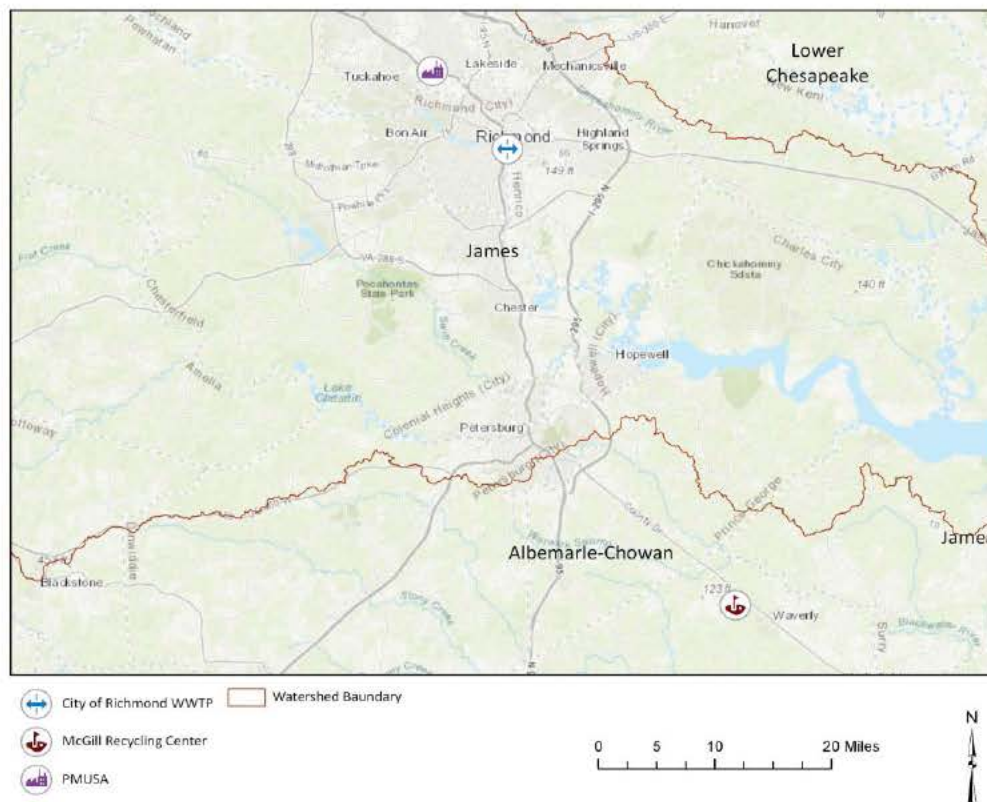
4.3.3 Description of the Product Package

The new product has 20 cigarettes in each pack and the cigarettes are wrapped in a foil inner liner. Ten cigarette packs are put into each carton and ten cartons are packaged into shipping cartons.

4.3.4 Location of Manufacturing

The manufacturer of the new product is located at 3601 Commerce Rd, Richmond, VA 23234 (Figure 1).

Figure 1. Location of the Manufacturer, Wastewater Treatment Plant and Recycling Center



The facility is located in the James River Watershed with the 6-digit hydrologic unit code (HUC): 020802 (US EPA , 2017). This watershed covers approximately 10,000 square miles. The James River begins in the Allegheny Mountains and flows approximately 340 miles to the Chesapeake Bay. Land use within the watershed is predominantly forest, with agriculture and farming accounting for approximately 20% of land use (James River Association, 2018). Major cities in the watershed include Richmond with a population of 204,000 (US Census Bureau , 2010). Administratively, the facility is located in Henrico county.

4.3.5 Location of Use

Philip Morris USA Inc. 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 tobacco product will be disposed of in municipal solid waste (MSW) landfills or as litter, in the same manner as the predicate product and any other combusted, filtered cigarette. Disposal of the packaging materials will either enter the recycling stream or be disposed of in MSW landfills or as litter. The Agency anticipates that the distribution of waste from disposal will correspond to the pattern of the product use.

4.4 Modification(s) Identified as Compared to the Predicate Product

The applicant stated that the difference between the new and predicate products is removal of an ingredient, (b)(4), from the tobacco filler of the new product. Aside from this removal, all other characteristics of the new and predicate products are identical.

5 Potential Environmental Impacts Due to the Proposed Action

5.1 Potential Environmental Impacts Due to Manufacturing the New Product

The EPA's Toxic Release Inventory (TRI) program, gathers information from facilities in the United States on the quantities of certain toxic chemicals that they manage (recycle, combust for energy recovery, treat for destruction) and release¹ on- and off-site. In 2016, 32 tobacco facilities reported 1,873,852 pounds of waste managed and released.² Of this total, 34.10% (638,980 pounds) was managed and 65.90% (1,234,872 pounds) was released to the environment (US EPA, 2016). In this context, managed means TRI-reportable chemicals that are recycled, combusted for energy recovery and treated for

¹ In the TRI context, a "release" of toxic chemical generally refers to a toxic chemical that is emitted to the air, discharged to water, or placed in some type of land disposal unit.

² 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. 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.

destruction and released means TRI-reportable chemicals that is emitted to the air, discharged to water, or placed in some type of land disposal unit.

The tobacco facilities release the toxic chemicals into the environment either on-site or off-site. In 2016, of the total of TRI-reported, on-site released chemicals, 89.61% of the chemicals were emitted to air, 0.29% of the chemicals were discharged to the water and 10.09% of the chemicals were disposed of on land (Table 1) (US EPA, 2016). The TRI database shows that from 2005 to 2016 the top four chemicals contributing to the production-related waste managed and released from the TRI-reportable tobacco facilities are nicotine and nicotine salts (38%), nitrate compounds (27%), ammonia (15%), and zinc compounds (12%).

A search in the TRI program indicates that Philip Morris USA Inc. at Commerce Rd. ranks 2 out of 32 tobacco facilities in the total waste managed and released in 2016, however the facility ranks 11 out of 32 in total waste released in 2016. The facility reported 345,113 pounds of waste managed and released in 2016 (Table 1). Of this total, 65.97% (227,680 pounds) was managed and 34.03% (117,433 pounds) was released to the environment. From the total released, 32,018 pounds were emitted to the air and 85,415 pounds were discharged to the city of Richmond wastewater treatment plant (WWTP), located in the James watershed, and disposed of in McGill Environmental System, and Veolia Es Technical Solutions LLC (Figure 1). Nicotine and nicotine salts and ammonia are the only two chemical categories reported to the TRI program by this facility (US EPA, 2016).

Table 1. Total Waste Managed or Released by the Facility 2016

Waste Managed or Released		Chemicals Mass (lb)	Percent of Total
Recycled		113,477	32.88
Energy Recovery		0	0.00
Treated		114,203	33.09
Subtotal: Waste Managed		227,680	65.97
On-site Released	Air	32,018	9.28
	Water	0	0.00
	Land	0	0.00
Off-site Released		85,415	24.75
Subtotal: Waste Released		117,433	34.03
Total		345,113	100

According to the TRI program, since 2005 the total waste managed and released from the facility has fluctuated some but overall has shown a trend towards decreasing (Figure 4). Furthermore, the facility had no energy recovery from waste since 2005.

According to Virginia's Fish and Wildlife Service, as of February 2015, 72 federally-threatened and endangered species exist³ in Virginia (US FWS, 2017). Of these species, an endangered species

³ The Endangered Species Act of 1973 (ESA) protects species of plants and animals that are in danger of extinction. The purpose of the ESA is to protect and recover jeopardized species and their habitats. The ESA is administered by the U.S. Fish and Wildlife Service (USFWS) and the Commerce Department's National Marine Fisheries Service (NMFS). The ESA allows the USFWS and the NMFS to list species of plants and animals as threatened or endangered. "endangered" means a species is in danger of extinction throughout all or a significant portion of its range. "threatened" means a species is likely to become endangered within the foreseeable future [FWS].

Pleurobema collina) and three threatened species (*Aeschynomene virginica*, *Helonias bullata*, and *Myotis septentrionalis*) are observed in Henrico county (US FWS, 2015). The applicant claimed 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. Therefore, the agency does not anticipate any adverse effects on the species or the critical habitat of a species identified under the ESA due to the manufacture and commercial introduction of the new product.

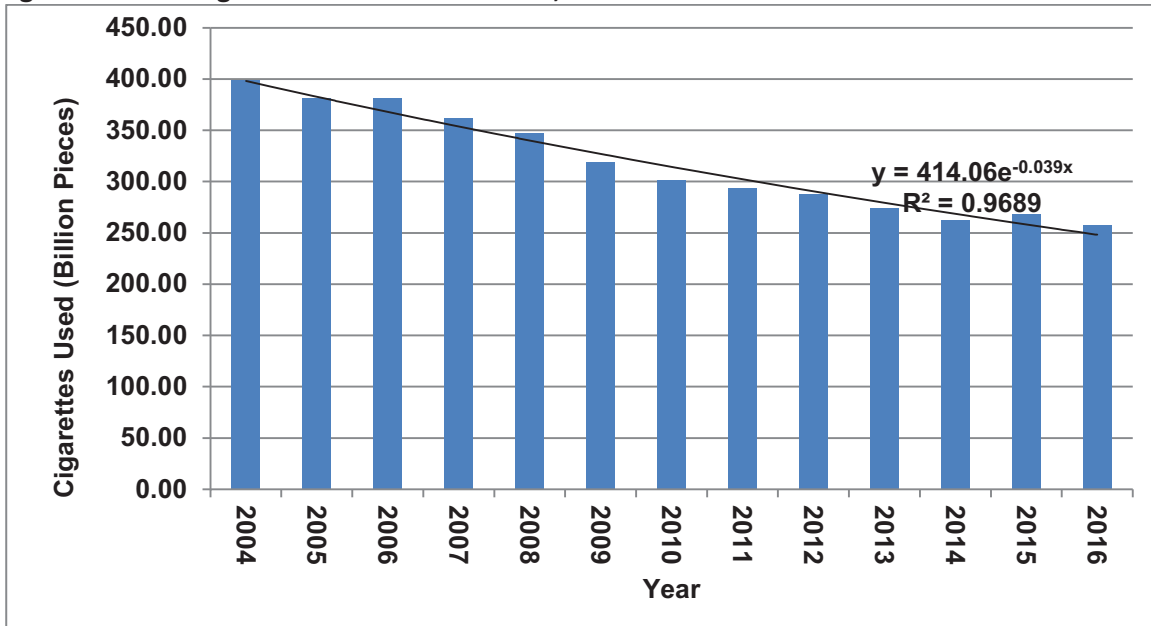
The applicant claimed that they maintain two district permits issued by the Virginia Department of Environmental Quality for air and wastewater. The applicant also claimed that the methods they used to control air emissions at the manufacturing facility are contained in the most recent PM USA Manufacturing Center Complex - Federal Operating Permit (i.e., Title V Air Permit) and the most recent stationary source permit to construct and operate. Both air permits were issued in accordance with applicable agencies including US Environmental Protection Agency (USEPA).

The applicant predicted that the manufacturing of the new product will not result in any need to expand the current manufacturing facility. Therefore, no expansion of the manufacturing facility is anticipated for manufacturing of the new product.

5.2 Potential Environmental Impacts Due to Use of the New Product

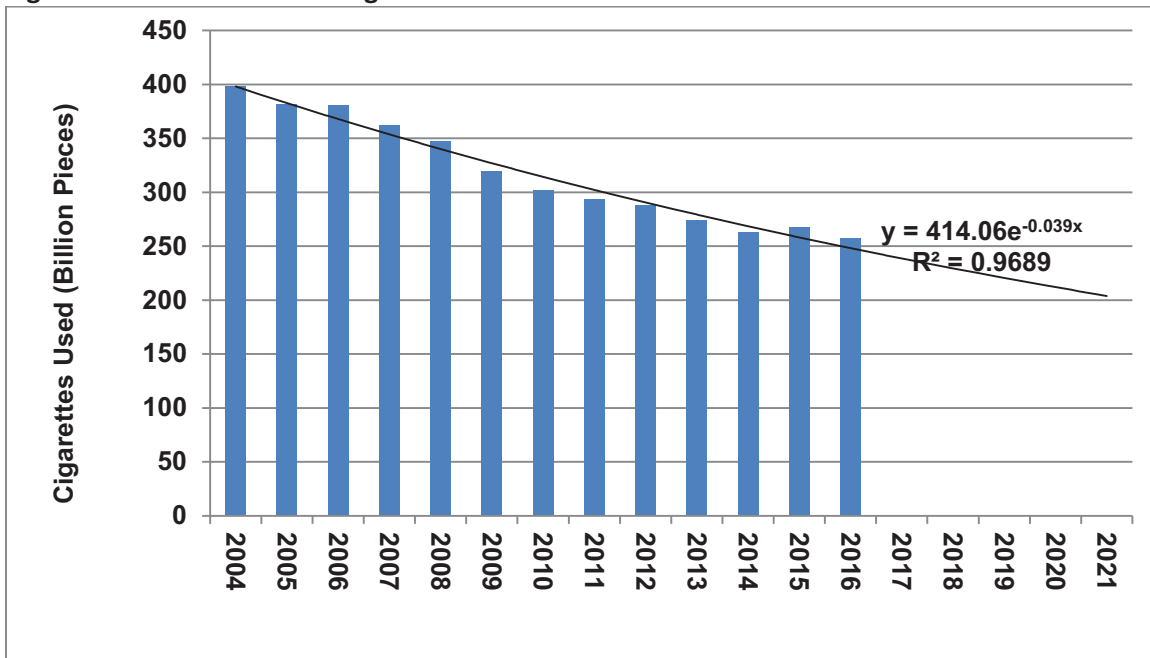
According to the U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) Statistical Release reports, the use of cigarettes in the United States decreased from 398 billion cigarettes in 2004 to 257 billion cigarettes in 2016 (Figure 5) (US TTB, 2017).

Figure 5. Use of Cigarette in the United States, 2000-2016



To evaluate the environmental impact of the proposed action due to the use of the new product, the Agency analyzed historical use data for 2004-2016 to forecast the future use of cigarette products in the United States. This was achieved by using one best-fit power trend line with the R^2 value of 0.97. Using this approach, the number of cigarettes forecasted to be used is estimated to be 239.85 billion in 2017 and 205.21 billion in 2021 (Figure 6).

Figure 6. Forecasted Use of Cigarettes in the United States



The projected market volumes for the new product in the first and fifth year of marketing occupy a small fraction of the total projected estimate of use of cigarettes in the United States (Confidential Appendix 1

and 2). Therefore, the Agency does not anticipate more chemicals to be released into the environment from the use of the new cigarette product, compared to the chemicals released by the predicate product.

When burned, a cigarette produces environmental tobacco smoke (ETS) or secondhand smoke. The ETS is composed of sidestream smoke (SS), emitted from the smoldering tobacco between puffs, and exhaled mainstream smoke (MS) from the smoker. ETS contains many of the toxic agents and carcinogens that are present in MS, but in diluted form. (DHHS, 1991).

There is no safe level of exposure to secondhand smoke. Even low levels of secondhand smoke can harm children and adults in many ways, as detailed below.

- The U.S. Surgeon General estimates that living with a smoker increases a nonsmoker's chances of developing lung cancer by 20 to 30% (DHHS, Surgeon General Report, 2010).
- 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 (Surgeon General Report, 2010).
- Secondhand smoke causes more than 40,000 deaths a year (Surgeon General Report, 2010).

As noted, the applicant claimed that the new product differs from the predicate product in the removal of an ingredient. Therefore, the Agency does not anticipate new chemicals to be emitted into the environment from the use of the new product, compared to the chemicals released by the predicate product.

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

To better understand the potential environmental impacts due to disposal of the new tobacco product, it is important to look at the pathways of disposed packaging materials and of discarded cigarette waste.

5.3.1 Disposal of Packaging Materials

Disposal of the packaging materials 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 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 7 and 8) (US EPA, 2014). 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 (US EPA, 2014).

To estimate the waste from the disposal of packaging material, the Agency utilized the projected market volumes for the first and fifth years of marketing the new and predicate products, assuming all used product material is disposed of in MSW. The estimated waste from packaging disposal and product

material following product use would be a very small portion of the total MSW forecasted to be disposed of in the United States. (Confidential Appendix 3).

Figure 7. Municipal Solid Waste Generation Rates in the United States, 1960-2014

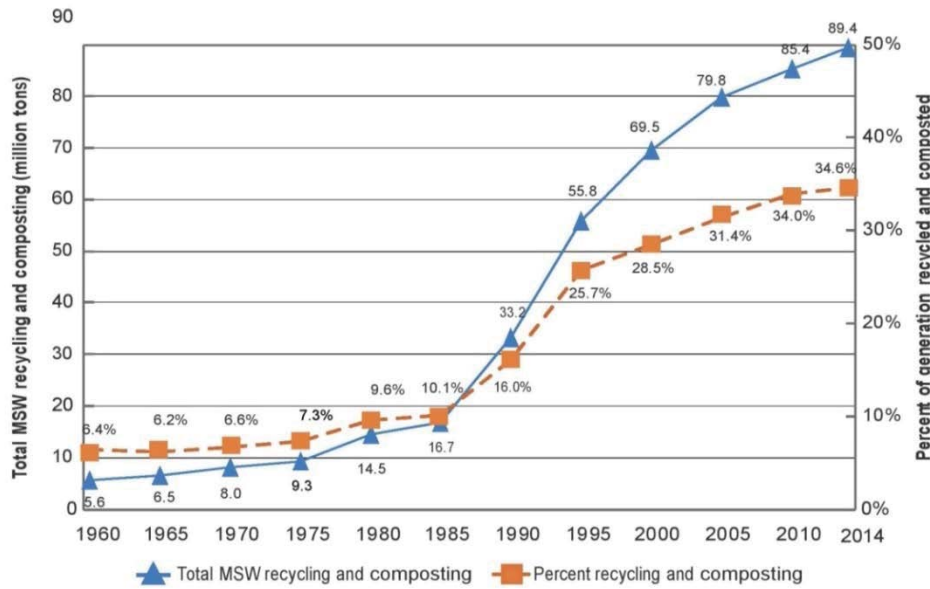


Figure excerpted from the U.S. EPA's "Advancing Sustainable Materials Management: 2014 Fact Sheet"

Figure 8. Municipal Solid Waste Recycling Rates in the United States, 1960-2014

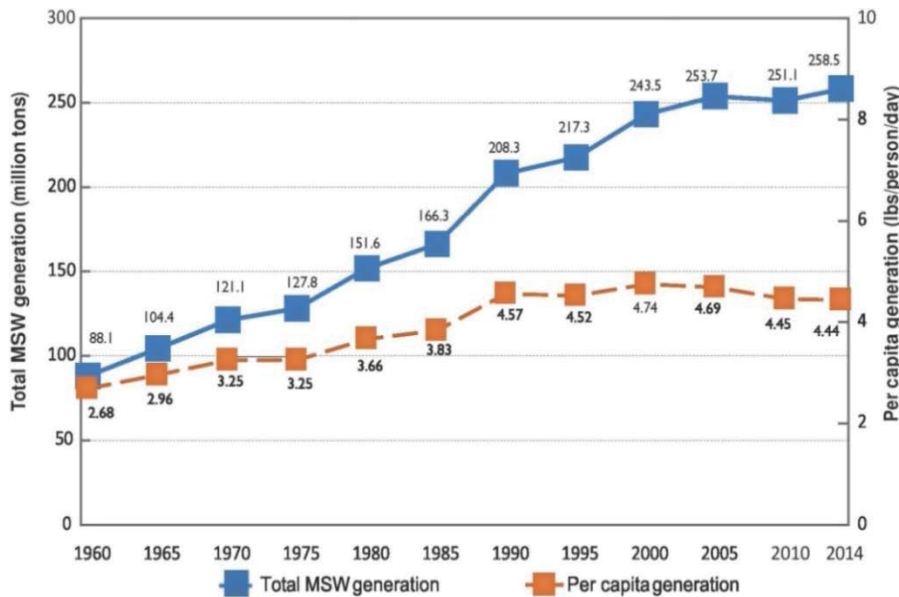


Figure excerpted from the U.S. EPA's "Advancing Sustainable Materials Management: 2014 Fact Sheet"

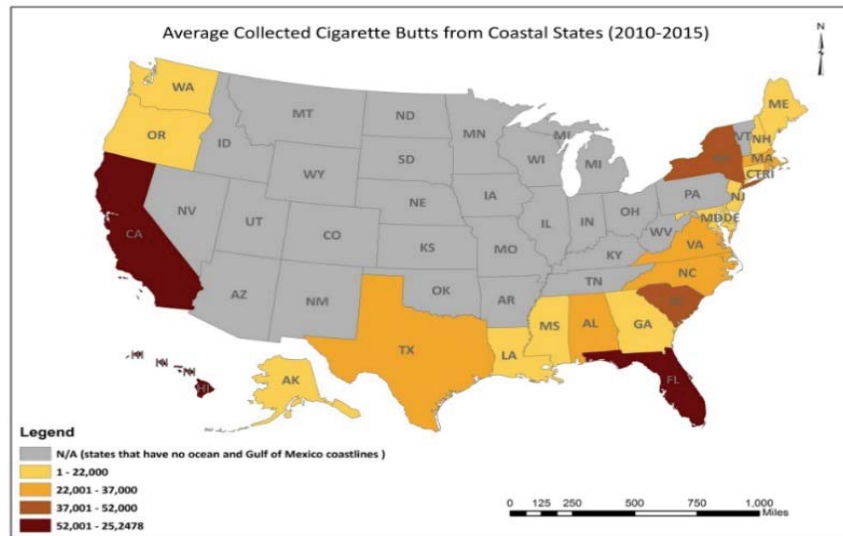
As previously discussed, because the applicant stated that the new product will compete with other similar products on the market and based on the above-mentioned information regarding waste, construction of new publicly owned treatment works (POTWs) or landfills is not anticipated due to the proposed action.

5.3.2 Disposal of Cigarette Waste

Once discarded, cigarette butt waste usually undergoes two main scenarios of managed and unmanaged waste. The Agency uses information from the U.S. EPA and the non-profit organization Keep America Beautiful to estimate the rates of managed and unmanaged cigarette butt waste entering the environment from disposal of cigarettes. The managed waste is treated as MSW and either incinerated with energy recovery or landfilled. As discussed previously, based on the 2014 information by the U.S. EPA (U.S. EPA, 2014) of all of the trash generated in the United States, 34.6% is recycled and composted. This leaves 65.4% of the trash that was moved to landfills and possibly combusted with energy recovery. This is how the managed waste of the used cigarettes would be handled. For managed waste, 80.4% by weight enters landfills, and the remaining 19.6% by weight is incinerated for energy recovery (US EPA, 2014).

The majority of unmanaged cigarette waste ends up in oceans and beaches across the United States and worldwide. The annual Ocean Conservancy's International Coastal Cleanup (ICC) reports that cigarette waste has been the single most collected item since coastal clean-ups began (Novotny, Lum, & Smith, 2009). Using the data from ICC, the Agency produced a map displaying the average collected cigarette waste (2010-2015) from coastal states (excluding the Great Lakes coast) on the international coastal cleanup day (Niazi & Forche, 2016) (Figure 8). Cigarette waste is a mixture of chemicals, especially ethyl phenol, nicotine, heavy metals and polycyclic aromatic compounds, with adverse effects to organisms (Micevska et al., 2006; Moerman and Potts, 2011; Moriwaki et al., 2009).

Figure 9. Collected Cigarette Waste from Coastal States (2010-2015)



A threat assessment study focusing on the most common types of litter that are found along the world's coastlines, based on data gathered during three decades of international coastal clean-up efforts, was conducted by Wilcox et al., 2016. The study was conducted based on elicited information from experts on the ecological threat of entanglement, ingestion and chemical contamination for three major marine taxa: seabirds, sea turtles and marine mammals (Wilcox & Mallos, 2016). The result of this study shows

that cigarette butts are ranked seventh out of 20 marine debris items of interest for which information was elicited.

As previously discussed, the new tobacco product will compete with other similar tobacco products on the market. As such, introducing the new product into the U.S. market is not expected to increase the nationwide use of cigarettes. Thus, authorizing the new product is not expected to affect the overall level of cigarette butt litter in the United States. Based on this, and the above-mentioned information regarding waste, construction of new POTWs or landfills is not anticipated due to the proposed action.

6 Use of Resources and Energy

The applicant claimed that there will be no change in how the new product is manufactured compared to the predicate product. The applicant noted that the facility tracks its energy usage through an environmental metric information system where for the past few years it shows a declining trend. The applicant also claimed that the decreasing trend would be projected to continue given historical decline in cigarette production and sale volumes. 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 states that the proposed action will not require an expansion of the manufacturing facility. Because the applicant states that the new product will compete with other similar tobacco products, no increase of overall tobacco products market volume and no net increase of energy use will be expected from the proposed action. The applicant states 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 manufacturing, use, and disposal of 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 of tobacco products as many other similar tobacco products will continue to be marketed.

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

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.

Preparer:

Mehran Niazi, Ph.D., Center for Tobacco Products

Education: Ph.D. in Environmental Sciences

Experience: 12 years in environmental fate and transport and environmental modeling

Expertise: water quality modeling, environmental fate and transport

Reviewer:

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

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

Experience: 9 years in FDA-related NEPA review

Expertise: NEPA analysis, environmental risk assessment, wastewater treatment

10 List of Agencies and Persons Consulted

Not applicable.

11 Appendix List

Appendix 1: Submission Tracking Number and Related Amendments for the SE Report Covered Under this Environmental Assessment (EA) and Package Sizes of the New and Predicate Products

12 Confidential Appendix List

Confidential Appendix 1: The First-, and Fifth-Year Market Volume Projections for 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: The Projected Waste of Packaging Material in the First and Fifth Year of Marketing the New Product

13 References

DHHS. (1991). Environmental Tobacco Smoke in the Workplace: Lung Cancer and Other Health Effects. *Current Intelligence Bulletin*, pp. 91-108.

James River Association. (2018). <https://jrava.org/about-the-james-river/>.

- Niazi, M., & Chang, H. (2018). An Overview on Toxic Chemical Releases by Tobacco Facilities and Their Surrounding Environment. *SRNT*. Baltimore.
- Niazi, M., & Forche, R. (2016). Using GIS to Enrich Our Understanding of Tobacco Life Cycle. *SETAC North America 37th Annual Meeting*. Orlando.
- Novotny, T., Lum, K., & Smith, E. (2009). Cigarettes Butts and the Case for an Environmental Policy on Hazardous Cigarette Waste. *Int J Environ Res Public Health*, 1695-1705.
- (2010). *Surgeon General Report*. Atlanta: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health,.
- US Census Bureau* . (2010, October). Retrieved from <https://www.census.gov/2010census/popmap/>
- US EPA*. (2014). Retrieved 10 20, 2017, from Materials and Waste Management in the United States Key Facts and Figures: <https://www.epa.gov/smm/advancing-sustainable-materials-management-facts-and-figures>
- US EPA*. (2016). *Toxics Release Inventory (TRI) Program*. Retrieved from TRI Data and Tools: <https://www.epa.gov/toxics-release-inventory-tri-program>
- US FWS*. (2015). *Fish & Wildlife Service*. Retrieved from Environmental Conservation Online System: <https://ecos.fws.gov/ecp0/reports/species-by-current-range-county?fips=13089>
- US TTB*. (2017). Retrieved 10 20, 2017, from <https://ttb.gov/tobacco/index.shtml>
- Wilcox, C., & Mallos, N. (2016). Using Expert Elicitation to Estimate the Impacts of Plastic Pollution on Marine Wildlife. *Marine Policy*, 107-114.

APPENDIX 1

Submission Tracking Number and Related Amendments for the SE Report Covered Under this Environmental Assessment (EA) and Package Sizes of the New and Predicate Products

STN	New Product			Predicate Product			Amendments
	Package Quantity	Retail Box Weight (g)	Foil Weight (g)	Package Quantity	Retail Box Weight (g)	Foil Weight (g)	
SE0014203	20	4.86	0.9	20	4.86	0.9	SE0014243 SE0014424 SE0014508

CONFIDENTIAL APPENDIX 1

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

STN	Name	1 st -Year Projected Volume (Cigarettes)	5 th -Year Projected Volume (Cigarettes)
SE0014203	Marlboro Menthol Gold Pack Box	(b) (4)	(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

STN	Year	Forecasted Use of Total Cigarettes in the United States (million cigarettes) ⁴	Projected Market Volume (million cigarettes) ⁵	Projected Market Occupation of New Product in the United States (%)
SE0014203	First	239,850	(b) (4)	
	Fifth	205,210		

First Year Market Occupation of New Product (%)

$$= \frac{\text{First Year Market Volume Projection}}{\text{Forecasted Use of Cigarettes in the U.S. for 2017}} \times 100\%$$

Fifth Year Market Occupation of New Product (%)

$$= \frac{\text{Fifth Year Market Volume Projection}}{\text{Forecasted Use of Cigarettes in the U.S. for 2021}} \times 100\%$$

The projected market volume for the new product is (b) (4) and (b) (4) million cigarettes in 2017 and 2021, respectively. Compared to the number of cigarettes projected to be used in the United States, the new product would occupy (b) (4) and (b) (4) of the total market of cigarettes used in 2017 and 2021, respectively (see section 5.2).

⁴ See Figure 6.

⁵ See Confidential Appendix 1.

CONFIDENTIAL APPENDIX 3

Projected Waste of Packaging Material 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 of the new product in 2017 and 2021. Projected waste generation is the summation of the projected foil inner liner, cardboard retail boxes, and cardboard of the cartons of retail boxes of the new product.

$$\sum_{i=1}^1 A_i = \sum_{i=1}^1 (B_i + C_i + D_i)$$

$$B_i = \frac{F_i}{G_i} \times I_i \times L$$

$$C_i = \frac{F_i}{H_i \times G_i} \times J_i \times L$$

$$D_i = \frac{F_i}{G_i} \times K_i \times L$$

- A_i : Projected total waste generation of the product (metric tons)
- B_i : Projected waste generation of retail cardboard box of the new product (metric tons)
- C_i : Projected waste generation of retail cardboard cartons of the new product (metric tons)
- D_i : Projected waste generation of foil inner liner of the new product (metric tons)
- F_i : Projected market volume of the new product (# cigarettes)
- G_i : Number of cigarettes per retail box
- H_i : Number of retail boxes per carton
- I_i : Weight of empty retail cardboard box (grams)
- J_i : Weight of empty retail carton (grams)
- K_i : Weight of foil inner liner (grams)
- L : 1.0×10^{-6} metric tons/gram

	STN	G_i	I_i	H_i	J_i	K_i	F_i	B_i	C_i	D_i	A_i
First Year	SE0014203	20	4.86	10	17.71	0.9	(b) (4)				
Fifth Year	SE0014203	20	4.86	10	17.71	0.9					

If all of the projected packaging waste generated from use of the new product is disposed of in landfills, the projected cumulative paper 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.

A portion of the generated paper 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 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.