

**Programmatic Environmental Assessment for Marketing
Orders for Philip Morris USA Inc. “Basic Soft Pack, Marlboro
72’s Box, Marlboro 25’s, and Basic Box” Tobacco Products**

Prepared by Center for Tobacco Products

U.S. Food and Drug Administration

January 31, 2018

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This programmatic environmental assessment (PEA) is for marketing orders for combusted, filtered cigarettes manufactured by Philip Morris USA Inc. 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 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

4. Description of Proposed Actions

The proposed actions are for FDA to issue marketing orders under the provisions of section 910 and 905(j) of the FD&C Act for the introduction of combusted, filtered cigarettes into interstate commercial distribution in the United States. This authorization is based on the finding that the new products are substantially equivalent to the predicate products. In this case the predicates are grandfathered products: GF1200071, GF1200099, and GF1200091.

4.1 Requested Action

Orders finding the listed tobacco products are substantially equivalent to the corresponding predicate products.

4.2 Need for Action

Philip Morris USA Inc. wishes to introduce the new tobacco products 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 monogram inks and the use of fire standards compliant (FSC) paper in the new products. After considering the substantial equivalence (SE) reports, the Agency shall issue orders under the provisions of section 910(a)(2) of the FD&C Act when finding the new products to be substantially equivalent to the predicate products.

4.3 Identification of the New Tobacco Products that are the Subject of the Proposed Actions

4.3.1 Type of Tobacco Products

Combusted, filtered cigarettes

4.3.2 Product Names and The Submission Tracking Numbers (STN)

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

STN	Name	Predicate Product (GF Number)
SE0013978	Basic Soft Pack	Basic Full Flavored Box (GF1200071)
SE0013979	Marlboro Seventy-Twos Box	Marlboro 72's Box (GF1200099)
SE0013980	Marlboro 25's Box	Marlboro 25's Box (GF 1200091)
SE0013981	Basic Full Flavor Box	Basic Full Flavored Box (GF1200071)

4.3.3 Description of the Product Package

The packaging materials of the finished new products are different compared to the corresponding predicate products, however, the package construction is the same. The new products' packaging consists of a foil inner liner, inner frame, box, film overlap, and carton. Details of the package components and weights of each packaging component for the new products are described in Confidential Appendix 1.

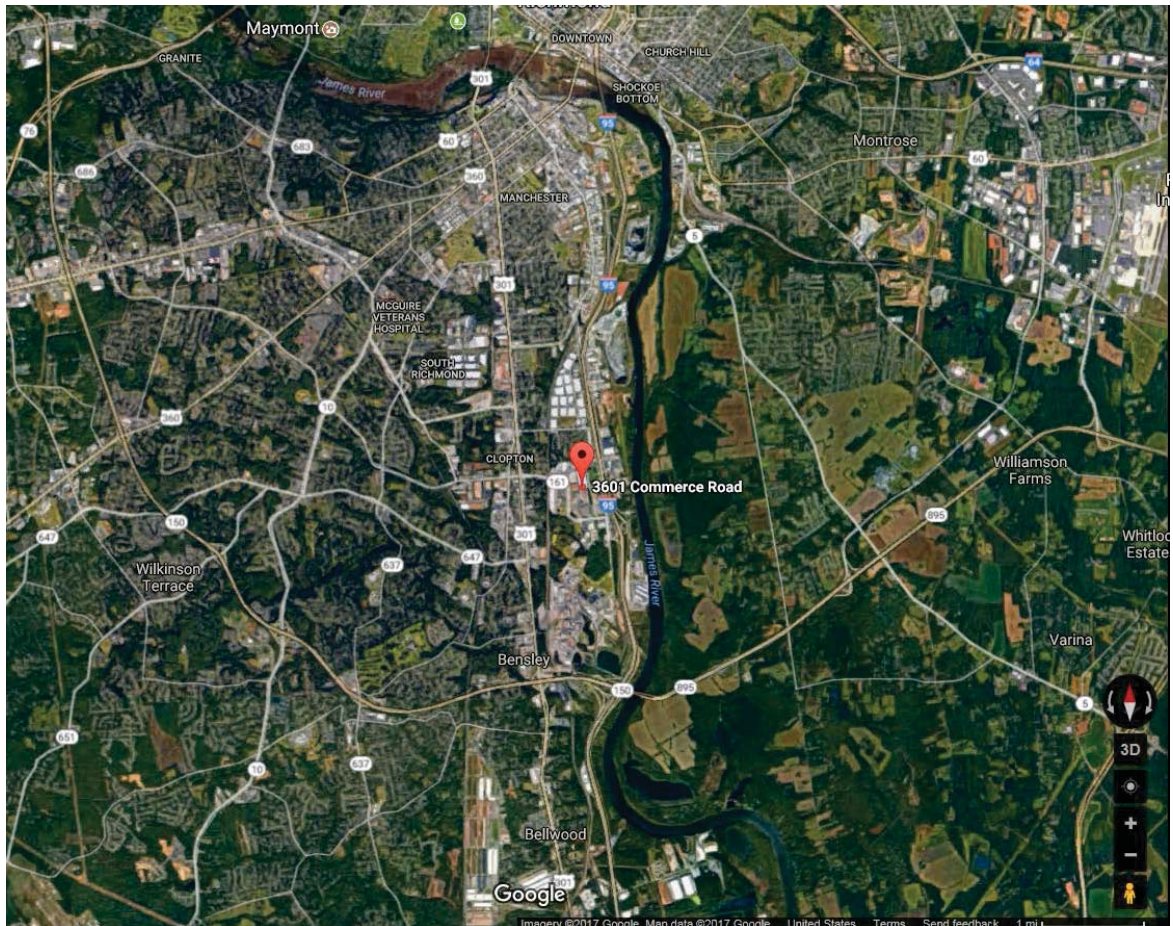
4.3.4 Location of Manufacturing

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 Manufacturer¹

¹ Manufacturer address via Google Map. Accessed June 2, 2017.



4.3.5 Location of Use

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

4.3.6 Location of Disposal

Once used, the new tobacco products will be disposed of in landfills as municipal solid waste (MSW) or as litter in the same manner as the predicate products and any other combusted, filtered cigarettes. Disposal of the packaging materials following use will either enter the recycling stream or be disposed of in MSW landfills or as litter. The Agency 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

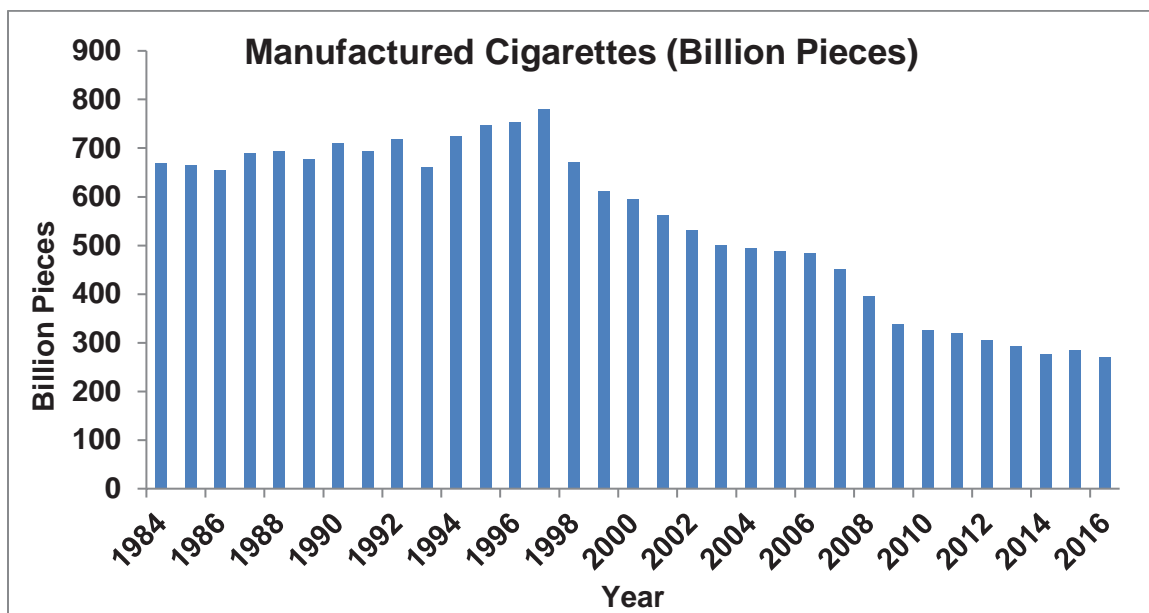
The applicant states that the differences between the new and predicate products are the use of FSC paper and differences in the monogram inks.

5. Potential Environmental Impact Due to the Proposed Actions

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

As of August 2017, a total of 2,524 tobacco production establishments are registered under 915(c) of the FD&C Act². 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 the manufacturing of 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 landfills; 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 were released to the land or water; and 2,483 pounds of ammonia and 84,422 pounds of nicotine and nicotine salts were transferred to POTWs⁴.

² Based on FDA's Establishment Registration & Tobacco Product Listing Database. Available at <https://www.accessdata.fda.gov/scripts/ctpcerl/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.

⁴ The estimation is done by using the Toxics Release Inventory (TRI), a dataset (<http://www.epa.gov/tri/>) compiled by the U.S. Environmental Protection Agency (EPA). This database allows users to retrieve information on toxic chemicals handled by many facilities across the United States, including details on quantities of chemicals managed through disposal or other release,

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 to other combusted, filtered cigarettes manufactured in the United States. 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. Therefore, the Agency does not foresee the introduction of the new products to notably affect the current manufacturing waste generated from the production of all combusted, filtered cigarettes.

Based on information in the SE Reports, the only differences between the new and predicate products are the use of FSC banded paper and different dye pigments used in the monogram inks. Packaging materials would be the same for both new and predicate products. Disposal of the packaging materials following use will either enter the recycling stream or be disposed of in MSW landfills or as litter.

The applicant provided the first- and fifth-year market volumes for the new products (Confidential Appendix 1). Comparing the projected market volume of the new products with the forecasted manufacture of all cigarettes produced in the United States in 2017 and 2021, the projected market volumes of the new products are a fraction of the total projected manufacture in 2017 and 2021 (Appendix 2 and Confidential Appendix 2). Additionally, the applicant stated that manufacturing the new products 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.

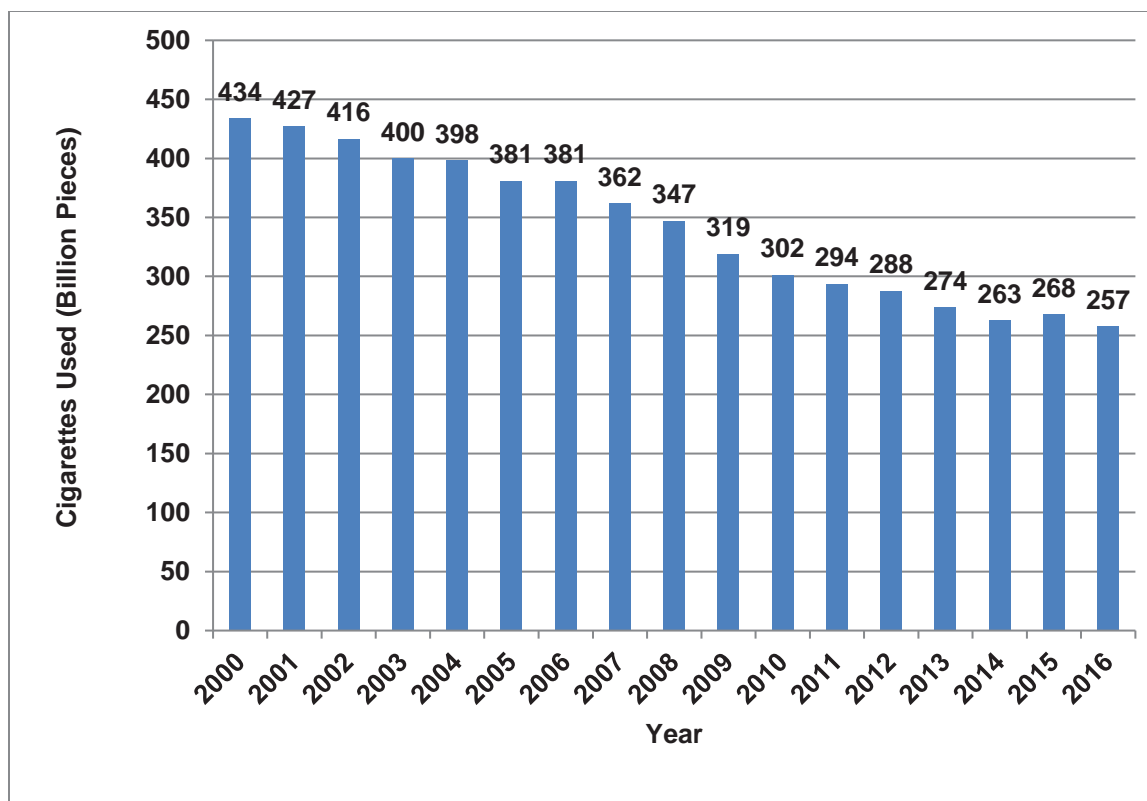
The applicant provided their permit numbers for air and wastewater discharge.

5.2. Environmental Impacts Due to Use of the New Tobacco Products

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 3) [1, 2].

Figure 3. Use of Cigarettes in the United States in 2000-2016⁴

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.



The Agency does not anticipate new substances to be released into the environment because of use of the new products, relative to the substances released by the predicate products, and other cigarettes already on the market. As noted, the only differences between the new products and predicate products are the use of FSC paper and differences in the composition of monogram inks. 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].

As noted, according to the SE Reports, the new and corresponding predicate products differ only in the composition of monogram inks and the addition of FSC paper. Furthermore, the applicant claimed that the new products will compete with and replace other currently marketed RYO products. During use, the new products are usually burned to ash, carbon dioxide, water vapor, and products from incomplete combustion such as carbon monoxide. These combustion products are released in a similar manner from the new and predicate products, as well as other cigarettes. The released substances during use of the new products are negligible from the environmental viewpoint. Therefore, the Agency does not

anticipate new substances to be released into the environment as a result of use of the new products, in comparison to the substances released by the predicate products or by other combusted cigarettes currently on the market. Additionally, comparing the projected market volume of the new products with the forecasted use of all cigarettes produced in the United States in 2017 and 2021, the projected market volumes of the new products are a fraction of the total projected volume of cigarette use in 2017 and 2021 (Appendix 3 and Confidential Appendix 3)

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

5.3.1 Disposal of Packaging Material

Disposal of the packaging materials following use would either enter the recycling stream or be disposed of in MSW landfills or as litter. Information about trash generation in the United States, including details about disposal of materials comparable to those used in cigarette products, can be informative about the disposal of cigarette packing materials. Specifically, in 2014, approximately 258.46 million tons (234.47 million metric 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 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 4. Municipal Solid Waste (MSW) Generation Rates in the United States, 1960-2014

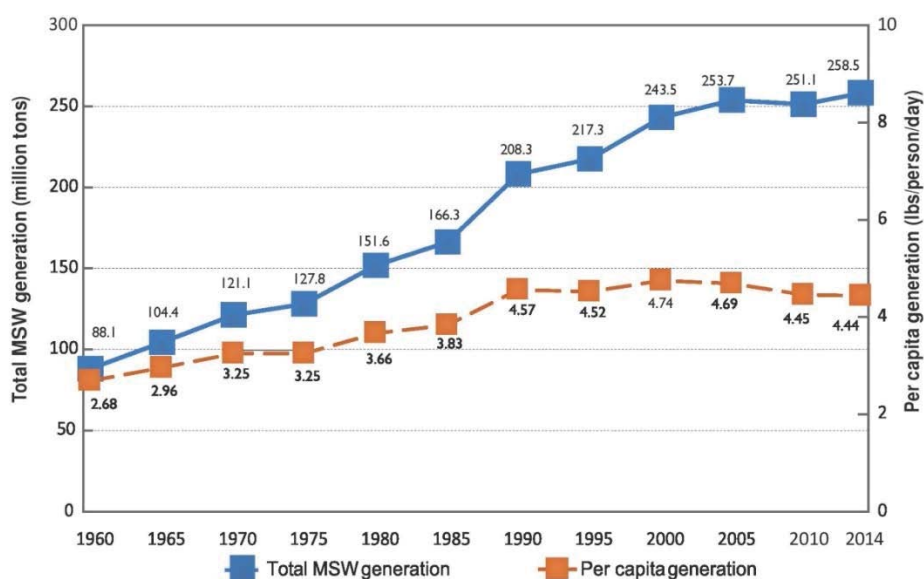


Figure excerpted from the U.S. EPA's "Advancing Sustainable Materials Management: 2014 Fact Sheet"

Figure 5. MSW Recycling Rates in the United States, 1960-2014

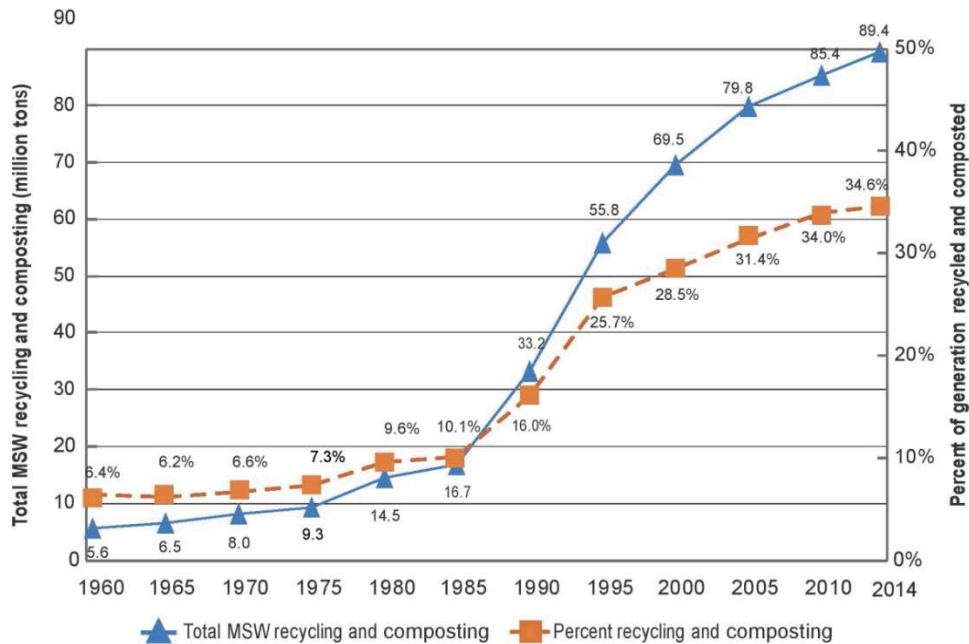


Figure excerpted from the U.S. EPA's "Advancing Sustainable Materials Management: 2014 Fact Sheet"

The Agency believes that the disposal of the new products' packaging material will be similar to the disposal conditions of the packaging material used for other RYO cigarette tubes, and any other RYO tobacco products that are currently being marketed. After using the new products, the users may dispose of or recycle the packaging material.

To calculate the amount of waste from disposal of paper packaging material and plastic wrap, the Agency used the first- and fifth-year projected volumes of marketing the new and predicate products after issuance of the marketing orders for the new products (Confidential Appendix 4). The calculated cumulative waste of the packaging material is a miniscule fraction of the forecasted MSW that would be generated in the United States. In addition, because paper components and plastic wrap are more likely to be recycled, at least a portion of the waste is likely to be recycled.

Because the new products will compete with other cigarettes on the market and based on the information regarding waste, construction of new landfills for disposal of packaging material is not anticipated due to the proposed actions.

5.3.2 Disposal of Used Cigarette Waste

Used cigarettes are usually disposed of in MSW landfills or as litter. When discarded as litter, the spent products are likely to move by run-off to the ocean. When discarded as MSW, the products would enter landfills. The Agency utilized the historical data for use of cigarettes in the United States to forecast the future use of cigarettes (Appendix 3) and calculate the projected tobacco waste accordingly. If 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 United States. 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. This is shown in Confidential Appendix 4.

Cigarette butt⁵ 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 (U.S. Environmental Protection Agency, 2016a). The Agency used the projected market volumes for the first and fifth years of marketing to estimate the waste from discarding used products (cigarette butts). The estimated waste from cigarette butt disposal as MSW would be miniscule compared to the total MSW forecasted to be discarded in the United States (Appendix 2). Because the new combusted, filtered cigarettes products will compete with other similar combusted, filtered cigarette products on the market and the estimates described above and detailed in Confidential Appendix 4 indicate a negligible contribution to U.S. MSW, construction of new solid waste landfills or incinerators is not anticipated due to disposal of used products under the proposed actions.

Unmanaged waste consists of littered cigarette butts. The environmental effects of cigarette butt litter have been summarized as follows (Novotny, et al., 2015):

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 products 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 similar products. Thus, authorizing the new products 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.

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 materials are anticipated to be emitted to the environment.

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.

⁵ "Cigarettes butt" is defined in this PEA as the filter and cigarettes rolling paper containing remainder tobacco that is disposed of following use.

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 total manufacture and use of cigarettes in the United States. 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 United States. 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 predicate products. The same raw materials and energy will be used to manufacture the new products compared to the predicate 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 for the new products with the forecasted volume for all cigarettes in the United States, the Agency found that the projected market volume of the new products is a small fraction of the total forecasted cigarette market volume in 2017 and 2021. Because the applicant stated that the new products 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 actions. The applicant stated that no adverse effects to endangered or threatened species or critical habitat are expected from manufacturing the new products.

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 United States. The environmental impact of the no-action alternative would not change the existing condition of the manufacturing, use, and disposal following use of tobacco products as many similar tobacco products would continue to be marketed.

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

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.

Preparer:

James F. Hobson, Ph.D. DABT Center for Tobacco Products

Education: M.S. in Toxicology and Ph.D. in Environmental Toxicology

Experience: 38 Years in Regulatory Toxicology and Environmental Toxicology

Expertise: Ecotoxicology, Toxicology, Environmental Assessments, Risk Assessment

Reviewer:

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

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

Experience: About 9 years in NEPA practice

Expertise: Waste water treatment, environmental impact analysis

12. List of Agencies and Persons Consulted

Not applicable.

13. Appendix List

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

14. Confidential Appendix List

- Confidential Appendix 1: Projected Market Volumes of the New Products in the United States in the First and Fifth Year of Marketing
- Confidential Appendix 2: Comparison of the First- and Fifth-Year Market Volume Projections for the New Products with Total Cigarettes Manufactured in the United States
- Confidential Appendix 3: Comparison of the First- and Fifth-Year Market Volume Projections for the New Products with Total Cigarettes Used in the United States
- Confidential Appendix 4: Projected Waste of Packaging Material and Cigarette Butts in the First and Fifth Year of Marketing the New 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.
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.
4. 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—Secondhand Smoke: What It Means to You (Consumer Booklet). 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.
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. 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.
7. 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).
8. EPA, U.S., *Waste Reduction Model (WARM)*. Available at: <https://www.epa.gov/warm>. Accessed July 20, 2017.

APPENDIX 1

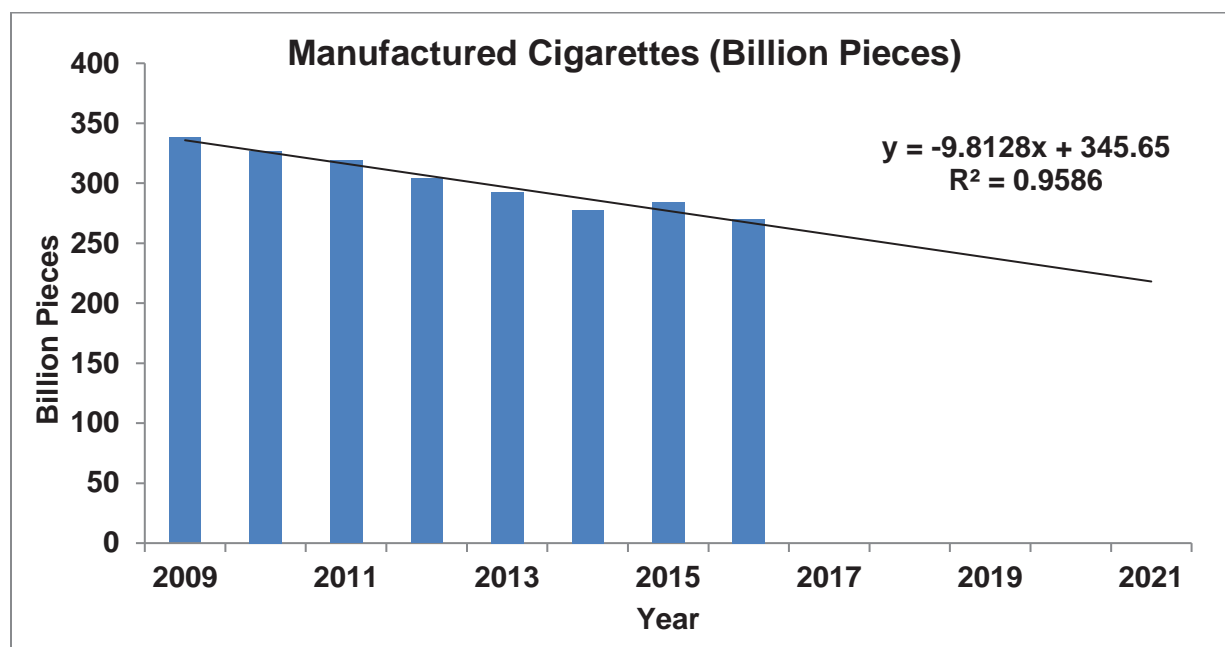
Submission Tracking Numbers for the SE Reports of the New Products and Related Amendments Covered Under this Programmatic Environmental Assessment (PEA)

STN	Product Name	Amendments
SE0013978	Basic Soft Pack	SE0014231 SE0014396
SE0013979	Marlboro 72's Box	SE0014231 SE0014396
SE0013980	Marlboro 25's Box	SE0014231 SE0014396
SE0013981	Basic Box	SE0014231 SE0014396

APPENDIX 2

Forecast of Cigarettes Manufactured in the United States

To evaluate the environmental impact of the proposed actions due to manufacturing of the new products, historical data regarding the manufacture of cigarettes in the United States from 2009 to 2016 was used to forecast the manufacture of cigarettes⁶. 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.



⁶ 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.

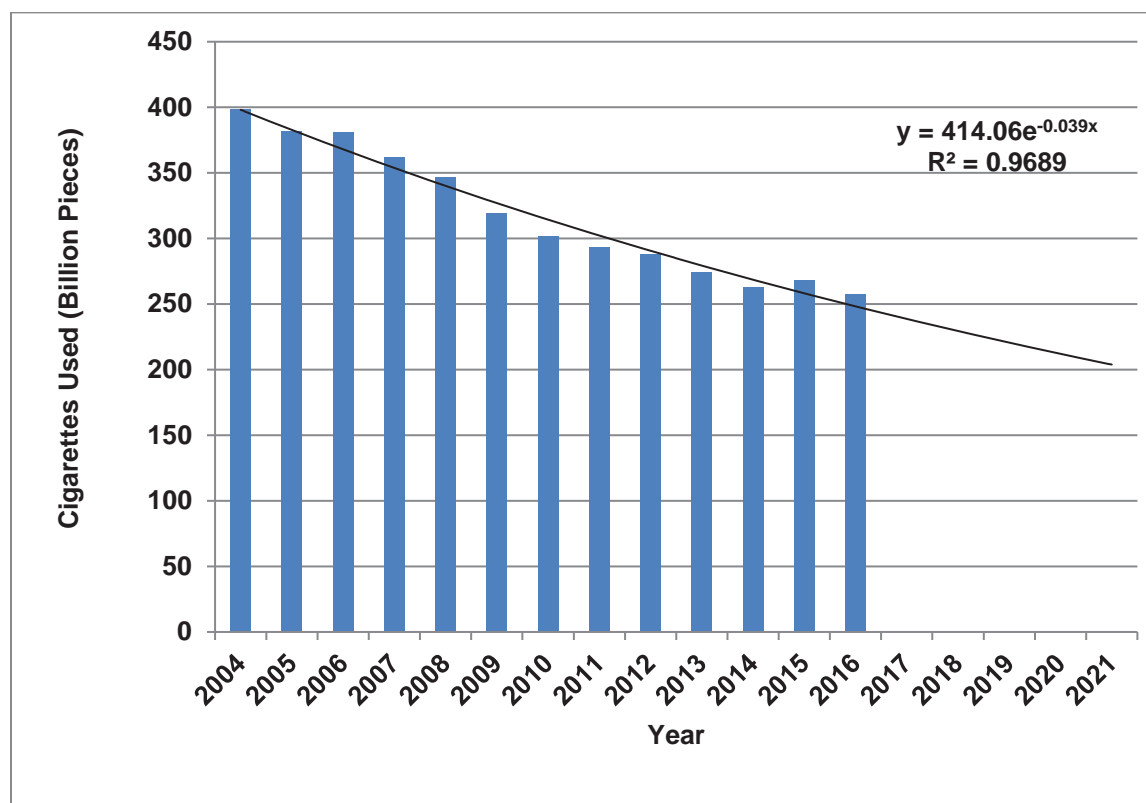
APPENDIX 3

Projected Use of Cigarettes in the United States 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 number of cigarettes used in the United States.⁷ This was achieved by using the one best-fit trend line with R² value above 0.9.

Projected Use of Cigarettes in the United States:

Using the best-fit power trend line with the R² 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.



⁷ Forecast trend lines extrapolated from TTB data. Available from <http://www.ttb.gov/tobacco/tobacco-stats.shtml>. Accessed March 15, 2017.

CONFIDENTIAL APPENDIX 1
Projected Market Volumes of the New Products in the United States
in the First and Fifth Year of Marketing

STN	Projected Volume for 2017	Projected Volume for 2021
SE0013978	(b) (4)	
SE0013979		
SE0013980		
SE0013981		

CONFIDENTIAL APPENDIX 2

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

The first- and fifth-year market volumes of the new products projected to occupy the United States market were determined by comparing the projected market volume of the new products to the forecasted manufacture of cigarettes in the United States (Figure 2 and Appendix 1). The percent of the total cigarette market occupied in the projected first and fifth year of marketing of the new products, based on the comparison to total cigarettes manufactured, was calculated using the equations below:

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

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

STN	Year	Forecasted Manufacture of Total Cigarettes in the U.S. (billion cigarettes) ⁸	Projected Market Volume of New Product (billion cigarettes)	Projected Market Occupation of Manufacture of New Product in the U.S. (%)
SE0013978	2017	257.33	(b) (4)	
	2021	218.08		
SE0013979	2017	257.33		
	2021	218.08		
SE0013980	2017	257.33		
	2021	218.08		
SE0013981	2017	257.33		
	2021	218.08		
Total for all New Products	2017	-		
	2021	-		

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

⁸ See Figure 3.

CONFIDENTIAL APPENDIX 3

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

The first- and fifth-year market volumes of the new products projected to occupy the United States market were similarly determined by comparing the projected market volume of the new products to the forecasted use of cigarettes in the United States (Figure 3 and Appendix 1). The percent of the total cigarette market occupied in the projected first and fifth year of marketing of the new products, based on the comparison to total cigarettes used, 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 Use of Total Cigarettes in the U.S. (billion cigarettes) ⁹	Projected Market Volume of New Product (billion cigarettes)	Projected Market Occupation of Use of New Product in the U.S. (%)
SE0013978	2017	238.85	(b) (4)	
	2021	205.21		
SE0013979	2017	238.85		
	2021	205.21		
SE0013980	2017	238.85		
	2021	205.21		
SE0013981	2017	238.85		
	2021	205.21		
Total for all New Products	2017	-		
	2021	-		

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

⁹ See Figure 3.

CONFIDENTIAL APPENDIX 4

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

To analyze the environmental effects from total waste due to the proposed 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 for each new product is the summation of the projected cardboard retail boxes, cardboard of the cartons, foil inner liner, plastic wrap of retail boxes, and cigarette butts of that new product:

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

¹⁰ 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.

STN	Market Volume H _i	# of Cig. Per Box I _i	# of Boxes	Weight of Empty Box (g) J _i	Weight of Inner box paper (g)	Waste of Paper Box (Tons) B _i	Weight of Foil Inner liner (g) O _i	Waste of Foil Inner liner (Tons) E _i	Number of Boxes Per Carton K _i	Number of Cartons	Weight of Carton (g) L _i	Waste of paper box Cartons (tons) C _i
SE0013978	(b) (4)	20	(b) (4)	1.48	0.34	(b) (4)	1.19	(b) (4)	10	(b) (4)	18.58	(b) (4)
SE0013979	(b) (4)	20	(b) (4)	4.36	0.79	(b) (4)	0.82	(b) (4)	10	(b) (4)	17.53	(b) (4)
SE0013980	(b) (4)	20	(b) (4)	5.61	0.79	(b) (4)	1.06	(b) (4)	10	(b) (4)	19.32	(b) (4)
SE0013981	(b) (4)	20	(b) (4)	4.86	0.79	(b) (4)	0.9	(b) (4)	10	(b) (4)	19.39	(b) (4)
Total	(b) (4)		(b) (4)			(b) (4)		(b) (4)		(b) (4)		(b) (4)

STN	Market Volume H _i	# of Cig. Per Box L _i	# of Boxes	Weight of Empty Box (g) J _i	Weight of Inner box paper	Waste of Paper Box (Tons) B _i	Weight of Foil Inner liner O _i	Waste of Foil Inner liner (tons) E _i	Number of Boxes Per Carton K _i	Number of Cartons	Weight of Carton (g) L _i	Waste of paperbox Cartons (tons) C _i
SE0013978	(b) (4)	20	(b) (4)	1.82	0.00	(b) (4)	1.19	(b) (4)	10	(b) (4)	18.58	(b) (4)
SE0013979	(b) (4)	20	(b) (4)	4.71	0.79	(b) (4)	0.82	(b) (4)	10	(b) (4)	17.53	(b) (4)
SE0013980	(b) (4)	20	(b) (4)	6.07	0.79	(b) (4)	1.06	(b) (4)	10	(b) (4)	19.32	(b) (4)
SE0013981	(b) (4)	20	(b) (4)	5.24	0.79	(b) (4)	0.9	(b) (4)	10	(b) (4)	19.39	(b) (4)
Total	(b) (4)		(b) (4)			(b) (4)		(b) (4)		(b) (4)		(b) (4)

If all the projected packaging waste generated from use of the new products is disposed of in landfills, the projected cumulative cardboard waste generated in the first and fifth years of marketing the new products would be (b) (4) metric tons in 2017 and (b) (4) (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.

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

Projected cigarette butt waste generated is calculated as below:

STN	Projected Market Volumes for 2017	Projected Market Volumes for 2021	Projected Cigarette Butt Waste in 2017 Gi	Projected Cigarette Butt Waste in 2021 Gi
SE0013978	(b) (4)			
SE0013979				
SE0013980				
SE0013981				

* Based on a cigarette length of 98.5 (T_i) and a cigarette weight of 1.0852 (Q_i)

If all the projected cigarette butt waste generated from use of the products is disposed of in landfills, the projected waste of a maximum of (b) (4) metric tons in 2017 and a maximum of (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.