Environmental Assessment for Exemption Requests by RAI Services Company on behalf of R.J. Reynolds Tobacco Company for "Vantage Silver"

Prepared by Center for Tobacco Products

U.S. Food and Drug Administration

August 17, 2017

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This environmental assessment (EA) is for the market authorization for the Exemption Request for a combusted, filtered cigarette product manufactured by "R.J. Reynolds Tobacco Company". Information presented in the Environmental Assessment (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 905(j)(3) of the Federal Food, Drug and Cosmetic Act (FD&C Act).

1. Name of Applicant

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

2. Address

401 N. Main Street
Winston-Salem, NC 27101

3. Manufacturer

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

4. Description of Proposed Actions

This proposed action is for FDA to issue an exemption from SE Report for the market authorization under section 905(j)(3) of the FD&C Act for the introduction of a combusted, filtered cigarette into interstate commercial distribution in the U.S. This authorization is based on the finding that the modification would be a minor modification of a tobacco product that can be sold under the FD&C Act. An SE Report is not necessary to ensure that permitting marketing of the modified tobacco product would be appropriate for the protection of the public health, and an exemption is otherwise applicable. The original product for EX0000174 was commercially marketed as of February 15, 2007 and is a grandfathered product, GF1501380, which received confirmation of grandfathered status March 29, 2016.

4.1 Requested Action

The applicant, RAI Services on behalf of R.J. Reynolds Tobacco Company, submitted a request to FDA to exempt from SE requirements the new "Vantage Silver", which is a combusted, filtered cigarette.

4.2 Need for Action

RAI Services Company on behalf of R.J. Reynolds Tobacco Company wishes to introduce the new tobacco product as described into interstate commerce for commercial distribution in the U.S. The applicant states that the only difference is that for the new product has State mandated fire standard compliant (FSC) paper. In addition, the applicant claimed that there are no other differences in the characteristics between the new and original products. The applicant must obtain a written notification that FDA has granted the product an exemption from demonstrating

substantial equivalence under section 905(j)(3) before submitting an abbreviated report. Ninety days after FDA receipt of the abbreviated report, the applicant may introduce or deliver for introduction into interstate commerce for commercial distribution the new product for which the applicant has obtained the exemption from substantial equivalence.

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

4.3.1 Type of Tobacco Product

Combusted, filtered cigarette

4.3.2 Product Names and Their Original STN

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

New Product		Original (Grandfathered) Product	
STN	**Name**	**STN**	**Name**
EX0000174	Vantage Silver	GF1501380	Vantage Ultra Light Box

4.3.3 Description of the Product Package

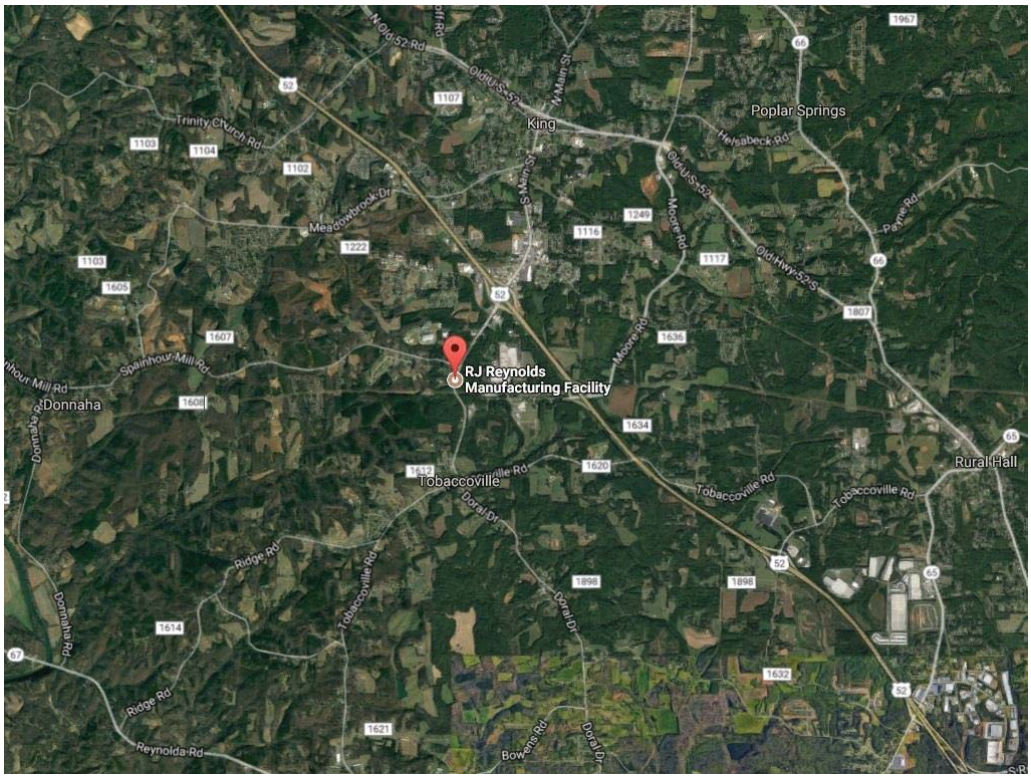
The packaging materials of the finished new product are identical in materials and composition to those of the original product. The new product packaging consists of a foil inner liner, inner frame, box, film overlap, and carton. The packs are comprised of cardboard, aluminum foil and a polypropylene outer wrap with tear tape. Details of the package components and weights of each packaging component for the new product is described in Confidential Appendix 1.

4.3.4 Location of Manufacturing

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

The facility is surrounded by woodlands, bounded by the city of King, NC to the north, US 52 (a four-lane divided highway) to the east, and mixed use residential, commercial, and agricultural land to the south and west (Figure 1).

Figure 1. Location of the Manufacturer[1]



4.3.5 Location of Use

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

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 original product and any other combusted, filtered cigarette 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 Agency anticipates the distribution of waste from disposal after use will correspond to the pattern of the product use. This will be the same as the original product being replaced.

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

The applicant states that the differences between the new and original products are the replacement of non- fire standard compliant (FSC) cigarette paper with FSC cigarette paper.

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

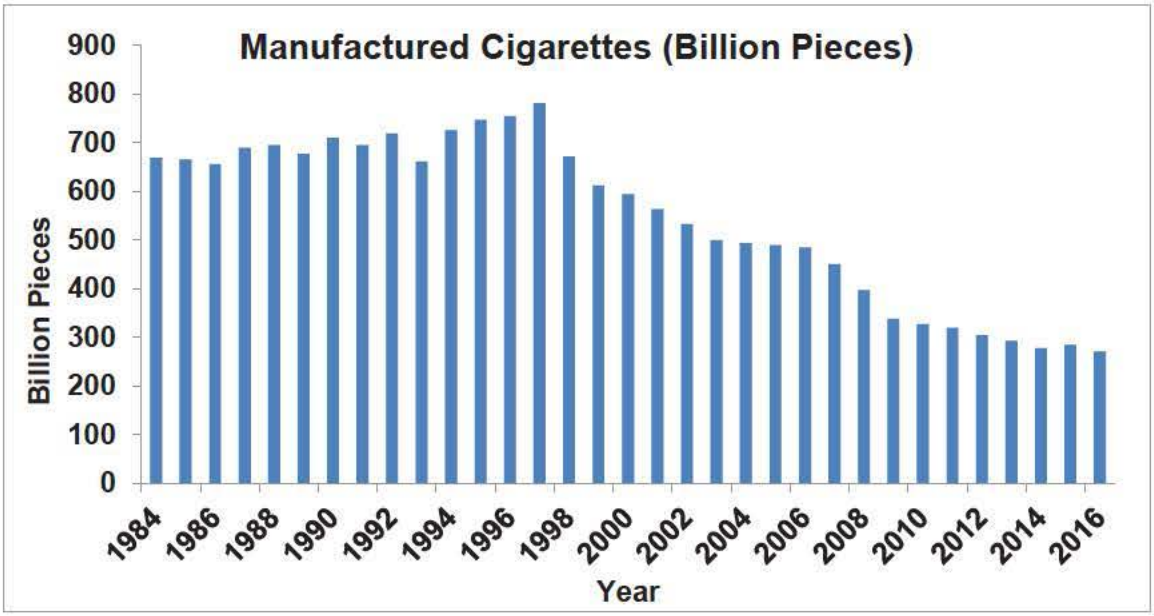
5. Environmental Introduction Due to the Proposed Actions

5.1 Introduction into the Environment as a Result of Manufacturing the New Tobacco Product

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

Tobacco Manufacturing in the U.S. As of June 2017, a total of 1242 tobacco production establishments are registered under 915(c) of the FD&C Act. These manufacturers produced 270 billion cigarettes (13.5 billion packs of 20 cigarettes each) in 2016 with a decline starting in 1997 (Figure 2) [1]. As of June 2017, 29 different tobacco manufacturers were registered as a "non-participating manufacturer" under the Master Settlement Agreement and 128 were registered as a "participating manufacturer" in the State of North Carolina, including R.J. Reynolds Tobacco Company [2].

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



Ammonia and Nicotine, Including Nicotine Salts from Tobacco Manufacturing Facilities. The emission information associated with all tobacco products as reported in the EPA's Toxic Release Inventory (TRI) database is publicly available.[2] In 2015, U.S. tobacco manufacturers

[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 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-

released 475,000 pounds of ammonia and 280,000 pounds of nicotine and nicotine salts to the air[3]; no ammonia and 72,900 pounds of nicotine and nicotine salts to the land[4]; 220 pounds of ammonia and 279 pounds of nicotine and nicotine salts to the water[5]; 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.[6] A search in the TRI database indicates that the R.J. Reynolds Tobaccoville facility ranks 363 out of 1041 TRI facilities for waste release in the Food/Beverages/Tobacco industry category in 2015. The Tobaccoville facility released 13,865 pounds of nicotine and nicotine salts and 9,899 pounds of ammonia to the air with no releases of either nicotine and nicotine salts or ammonia to water or land in 2015[7].

5.1.2 Environmental Introduction from Manufacturing the New Tobacco Product

Introduction from Manufacturing the New Product in the Proposed Action. The Agency anticipates that manufacturing the waste generated as a result of manufacturing the new combusted, filtered cigarette product will be released to the environment, transferred to POTWs, and disposed of in landfills. This is in the same manner as the waste generated from the original product or any other products manufactured in the same facility and in a similar manner to other combusted, filtered cigarette products manufactured in the U.S. The new product is expected to replace the original product in the market and to decline in volume of production over five years. The production of the original product will stop when the manufacturing of the new product begins. Therefore, neither expansion of the manufacturing facility nor increases of the waste disposal requirements are anticipated for manufacturing the new product.

Based on information in the Exemption Request, the new product differs from the original product only in the use of FSC paper; that is, the same general rod paper is used in the FSC paper plus low levels of three solvents, a binder, a filler, two plasticizers, and an optical brightener . These materials are added as bands in the paper that slows the burning of the cigarette. The added chemicals represent less than 10% of the formulation and less than 10% of the paper by weight. The formulation of the FCS paper is not new. The Agency does not anticipate any new substances or type of emissions to be released into the environment because of manufacturing the new product. Therefore, no new control practices of air emission, water discharge, and solid waste disposal are needed at the manufacturing facility.

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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.

[3] http://oaspub.epa.gov/enviro/ef_metadata_html.tri_page?p_column_name=air_total_release

[4] http://oaspub.epa.gov/enviro/ef_metadata_html.tri_page?p_column_name=land_total_release

[5] http://oaspub.epa.gov/enviro/ef_metadata_html.tri_page?p_column_name=water_total_release

[6] http://oaspub.epa.gov/enviro/ef_metadata_html.tri_page?p_column_name=off_site_total_transfers

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

The applicant provided the first- and fifth-year market volumes for the new product (Confidential Appendix 2). Comparing the projected market volume of the new product with the forecasted use of all cigarettes produced in the U.S. in 2017 and 2021, the cumulative projected market volumes of the new product is a fraction of the total projected cigarette use in 2017 and 2021 (Appendix 2 and Confidential Appendix 3). Additionally, the applicant stated that the new product will compete with similar currently marketed products. Any increase in one product would be balanced by a concomitant decrease in the other product, therefore, no new control practices of air emission, water discharge, or solid waste disposal are needed.

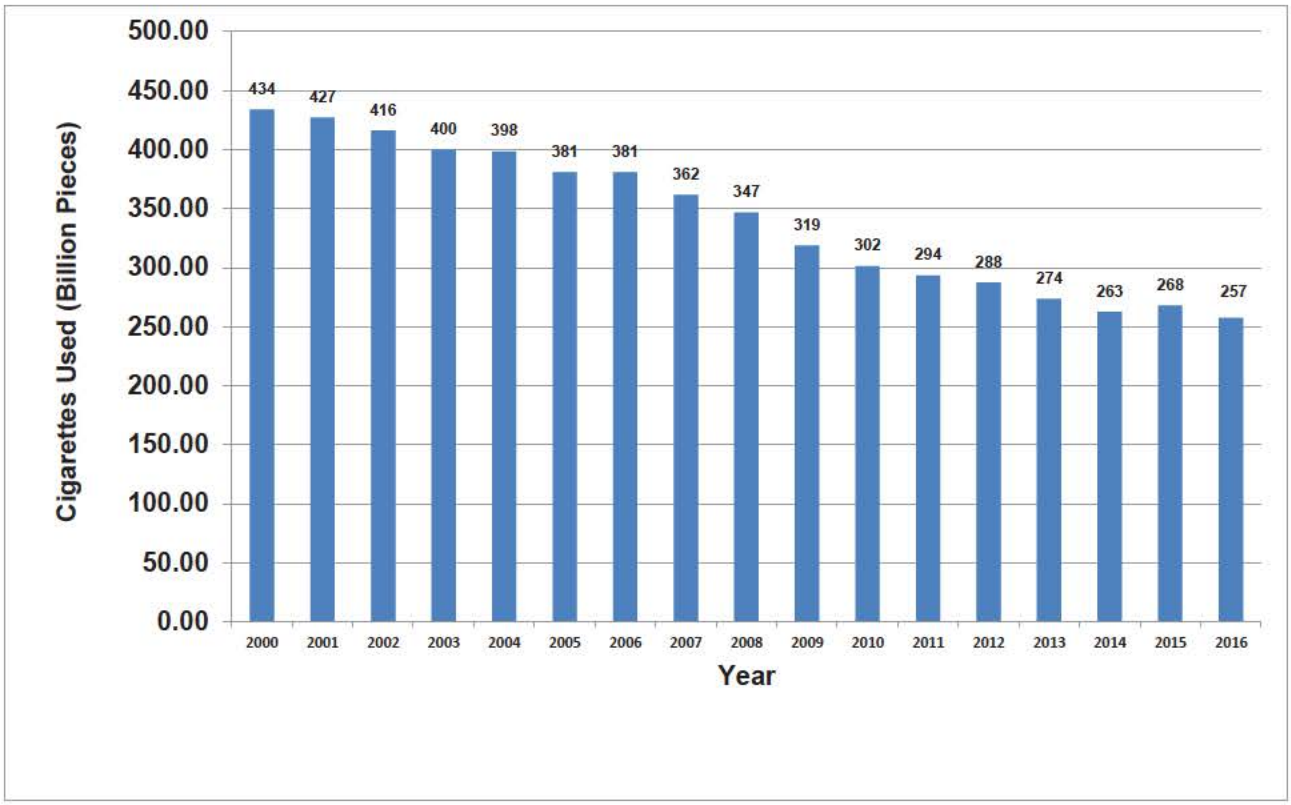
The applicant states that they are in compliance with all federal, state, and local environmental regulations. They provide information on the manufacturer's air, storm water and wastewater permits. The applicant's air permit expired in November 2012 but the applicant reapplied in 2012 and is waiting for the renewed permit. The applicant also stated that their facility complies with other environmental regulations including maintaining EPA Spill Prevention Control and Countermeasure plans, reporting GHG emissions to the EPA under the GHG reporting rule 40 CFR 98, submitting EPA Tier 2, EPA TRI, and North Carolina Right-to-Know reports, complying with the DHS Chemical Antiterrorism Standards, and complying with applicable solid and hazardous waste regulations.

5.2 Environmental Introduction as a Result of Use of the New Tobacco Product

5.2.1 Use of the Combusted Cigarette Tobacco Product in the U.S.

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

Figure 3. Use of Cigarettes in the U.S. in 2000-2016[4]



5.2.2 Environmental Introduction from Use of the New Product

The Agency does not anticipate new substances to be released into the environment due to use of the new cigarette, relative to the substances released by the original product, and other cigarettes already on the market. As noted, the only differences between the new product and original product are the replacement of non-FSC cigarette paper with FSC cigarette paper. When using cigarettes, the users inhale the mainstream smoke and release tobacco smoke to the environment, referred to as secondhand smoke. There is no safe level of exposure to secondhand smoke [4, 5]. Even low levels of secondhand smoke can harm children and adults in many ways, including the following:

- The U.S. Surgeon General estimates that living with a smoker increases a nonsmoker's chances of developing lung cancer by 20 to 30 percent [6].
- Exposure to secondhand smoke increases school children's risk for ear infections, lower respiratory illnesses, more frequent and more severe asthma attacks, and slowed lung growth, and it can cause coughing, wheezing, phlegm, and breathlessness [4, 5].
- Secondhand smoke causes more than 40,000 deaths a year [6].

5.3 Environmental Introduction as a Result of Disposal Following Use of the New Tobacco Product.

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

5.3.1 Disposal Following Use of Combusted Cigarette Products

a) Disposal of Packaging Material

Disposal of the packaging materials following use would either enter the recycling stream or be disposed of in MSW landfills or as litter. Information about trash generation in the U.S., including details about disposal of materials comparable to those used in cigarette products, can be informative about the disposal of cigarette packing materials. Specifically, in 2014, approximately 258.46 million tons (234.47 million metric tons) of trash was generated in the U.S., and roughly 89.4 million tons of this material was recycled and composted, equivalent to a 34.6% recycling rate (Figure 4 and 5) [7]. Paper and paperboard account for 68.61 million tons (26.5%) of the total MSW generated in 2014. Containers and packaging comprised the largest portion of total MSW generated at 76.67 million tons (29.7%), out of which 39.13 million tons was made of paper and paperboard. Of the total paper and paperboard MSW generated, 44.4 million tons (64.7%) was recycled, 19.47 million tons (28.4%) was disposed of in landfills, and 4.74 million tons (6.9%) was combusted with energy recovery [7].

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

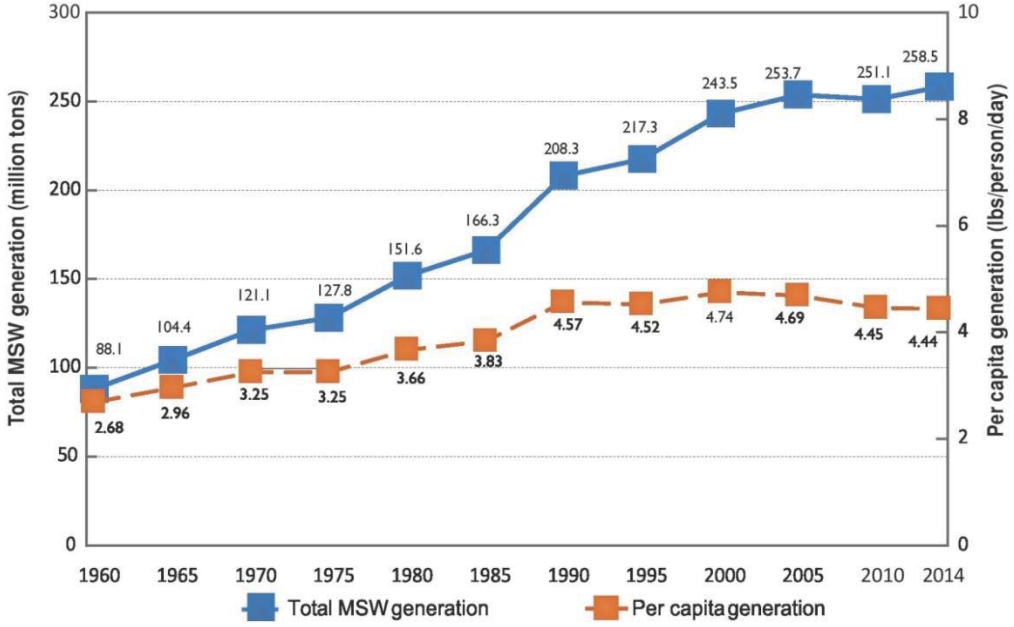


Figure excerpted from the U.S. EPA's "Advancing Sustainable Materials Management: 2014 Fact Sheet"

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

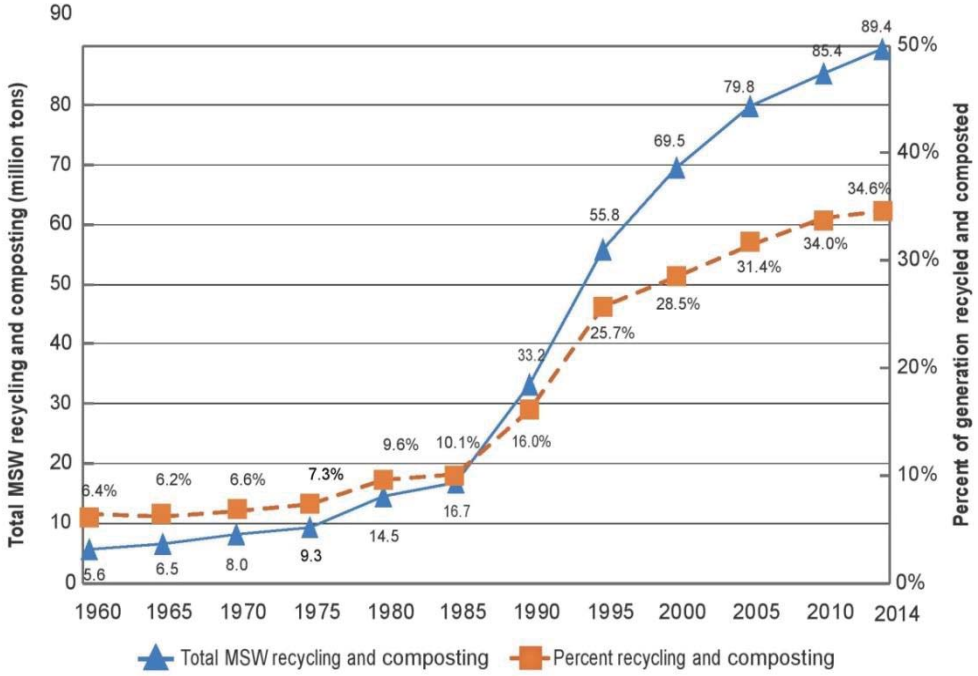


Figure excerpted from the U.S. EPA's "Advancing Sustainable Materials Management: 2014 Fact Sheet"

b) Disposal of Used Cigarette Products Following Use

Used combusted cigarette tobacco products are usually disposed of in MSW landfills or as litter. When discarded as litter, the spent product is likely to move by run-off to the ocean and eventually decompose. When discarded as MSW, the product would enter landfills. The Agency utilized the historical data for use of cigarettes in the U.S. to forecast the future use of cigarettes (Appendix 3) and calculate the projected tobacco waste accordingly. 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 U.S. Comparing the projected market volume of the new product as a surrogate for the projected waste from the new product, with the forecasted total U.S. MSW, the projected waste generated from use of the new products is negligible.

Forecast of Waste of Used Cigarettes as Compared to Total MSW Forecast in the U.S.		
Year	**Projected Use (Equivalent to Projected Waste) of Cigarettes in the U.S. (Billion Pieces)[a]**	**Percent of Projected Waste of Cigarettes to Total MSW Forecasted in the U.S. (%)[8]**
1st Year	239.85	1.10×10^{-6}
5th Year	205.21	5.54×10^{-7}

[a] See Appendix3

c) Air Emissions

The used tobacco products and packaging materials that are disposed of in MSW landfills or incinerated will produce GHGs. Methane is a potent GHG that has a global warming potential of 28-36 times greater than CO_2, and has an atmospheric life of about 12 years. Global methane emissions from landfills are estimated between 30 and 70 million metric tons per year. MSW landfills are the third largest source of human-related methane emissions in the U.S., releasing an estimated 115.7 million metric tons of CO_2 equivalents, accounting for approximately 15.4% of total CH_4 (methane) emissions in 2015 [8]. 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].

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

[8] Cigarettes in percentage:

$$\text{1st Year} = \left(\frac{2.58 \text{ metric tons}}{234{,}470{,}000 \text{ metric tons}}\right) \times 100\% = 0.00000110\%$$

$$\text{5th Year} = \left(\frac{1.13 \text{ metric tons}}{234{,}470{,}000 \text{ metric tons}}\right) \times 100\% = 0.000000554\%$$

under 40 CFR 98. However, the percentage of metric tons represented here is so minuscule that GHG emissions were not calculated and are considered negligible. No additional control of GHG emissions is anticipated in the landfills.

5.3.2 Environmental Introduction from Disposal Following Use of the New Product

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 an authorization order for the new product. The calculated waste of the packaging materials and product materials of the new product was determined to be miniscule compared to the forecasted MSW to be generated in the U.S. (Confidential Appendix 3). 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 product 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.

Because the waste generated from the new product comprises a miniscule fraction of the total MSW, the GHG emitted from waste associated with the new product is negligible and GHG emissions were not quantified in this EA .

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 product is anticipated to be manufactured, used, and disposed of in the same way as other cigarettes. Additionally, the inclusion of FSC paper in the new product is based on regulation that requires all cigarettes sold in the U.S. to be fire safety compliant. As of July 1, 2011, all 50 states and the District of Columbia require cigarettes sold to be FSC[9]. Therefore, the fate of any materials emitted is anticipated to be the same as any materials from other cigarettes manufactured in the facility. No new types of material are anticipated to be emitted to the environment at use.

7. Environmental Effects of New Materials Released into the Environment Due to the Proposed Actions

The Agency does not anticipate that the proposed action will lead to the release of new chemicals into the environment because the new product is anticipated to be manufactured, used, and disposed of in the same way as other cigarettes. Additionally, the inclusion of FSC paper in the new products is based

[9] National Fire Protection Association: http://www.nfpa.org/public-education/by-topic/top-causes-of-fire/smoking/coalition-for-fire-safe-cigarettes/states-that-have-passed-fire-safe-cigarette-laws

on regulation that requires all cigarettes sold in the U.S. to be fire safety compliant. As of July 1st, 2011 all 50 states and the District of Columbia require cigarettes sold to be FSC. Therefore, the fate of any materials emitted is anticipated to be the same as any materials from other cigarettes manufactured in the facility. No new types of material are anticipated to be emitted to the environment at use.

8. Use of Resources and Energy

The applicant stated that there will be no change in how the new product is manufactured compared to the original product. The same raw materials and energy will be used to manufacture the new product compared to the original product and the applicant does not anticipate any increased energy or resource needs to manufacture the new product. The applicant stated that the proposed actions will not require an expansion of the manufacturing facility. When comparing the market volume projections with the forecasted total cigarette volumes in the U.S., the Agency found that the projected market volumes of the new product is a miniscule fraction of the total forecasted 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. Additionally, the applicant stated that the manufacturing facility has a goal to minimize GHG emissions by 20%, reduce energy use by 25%, reduce water use by 30%, and increase recycling to at least 60% of the waste at the facility by 2020.

9. Mitigation

During the review of the available data and information, the Agency did not identify adverse environmental effects for the new product and the proposed used in cigarettes. 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 product in the U.S. The environmental impact of the no-action alternative would not change the existing condition of the manufacturing, use, and disposal following use of tobacco products as many similar tobacco products would continue to be marketed.

Alternative B (Proposed actions): There is no substantial environmental effect due to the proposed action of authorizing the new product and associated manufacture, use, and disposal following use of the new tobacco product (Confidential Appendices 2-3).

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

11. List of Preparers

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

Preparer:

James F. Hobson, Ph.D., DABT

Education: M.S. in Toxicology, Ph.D. in Biology and Environmental Toxicology
Experience: 36 years in Regulatory and Environmental Toxicology
Expertise: NEPA analysis, risk assessment, toxicology and ecotoxicology,

Reviewer

Gregory G. Gagliano, M.S., Center for Tobacco Products

Education: M.S. in Environmental Science
Experience: 34 years in Environmental Toxicology and Risk Assessment
Expertise: NEPA analysis, environmental risk assessment, environmental toxicology, environmental fate and effects

12. List of Agencies and Persons Consulted

Not applicable.

13. Appendix List

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

14. Confidential Appendix List

Confidential Appendix 1: Projected Waste of Packaging Material and Cigarette Butts in the First-and Fifth-Year of Marketing the New Product
Confidential Appendix 2: The First-, and Fifth-Year Market Volume Projections of the New Product
Confidential Appendix 3: Comparison of the First- and Fifth-Year Market Volume Projection for the New Product with Total Cigarettes Used in the U.S.

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. North Carolina Department of Justice. *Tobacco Lists*. 2017. Available at http://www.ncdoj.gov/getdoc/3b96da5a-6384-4bfc-bd2f-3636a5bb8711/2-6-4-3-6-Tobacco-Lists.aspx. Accessed June 27, 2017.
3. 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.

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. 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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8. Environmental Protection Agency (EPA). *Inventory of U.S. Greenhouse Gas Emissions and Sinks: 1990-2015.* 2017(EPA 430-P-17-001).
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. 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 EX Requests of the New Product and Related Amendments Covered Under this Environmental Assessment (EA)

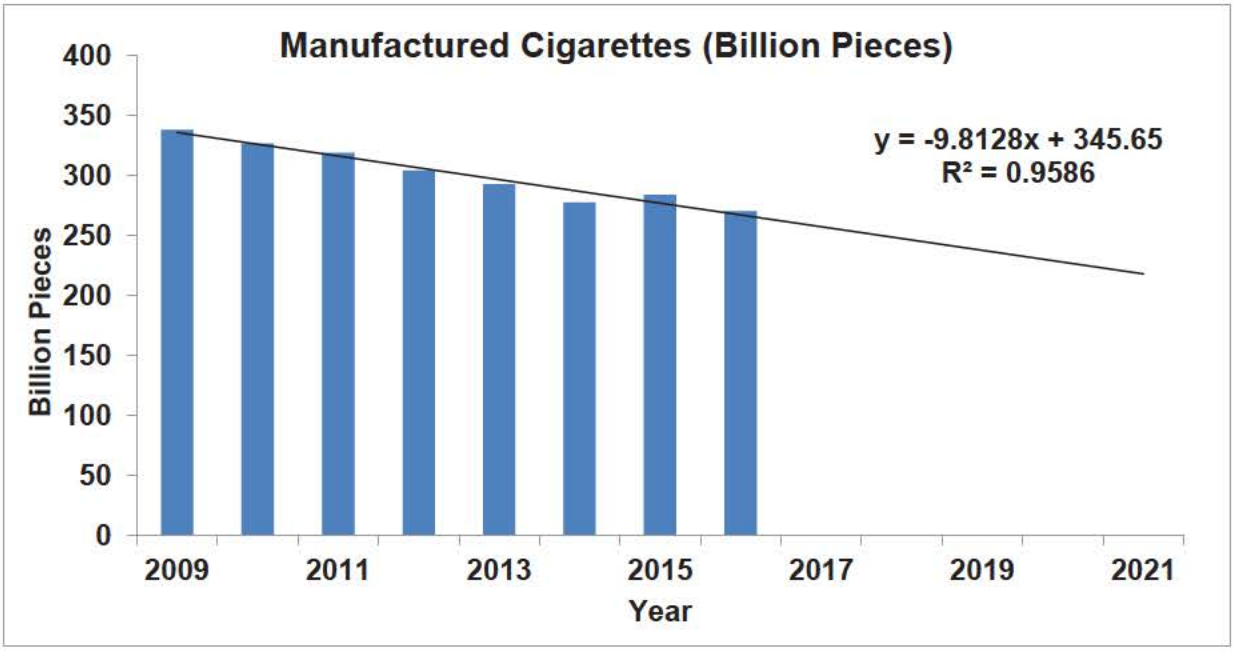
STN	Product Name	Amendments
EX0000174	Vantage Silver	EX0000179

New Product		Original (Grandfathered) Product	
STN	Name	STN	Name
EX0000174	Vantage Silver	GF1501380	Vantage Ultra Light Box

APPENDIX 2

Forecast of Cigarettes Manufactured in the U.S.

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 U.S. from 2009 to 2016 was used to forecast the manufacture of cigarettes10. This was achieved by using one best-fit linear trend line with the R2 value of 0.9586. Accordingly, the forecasted amount of all cigarettes to be manufactured in the U.S. is estimated to be 257 billion pieces in 2017 and 218 billion pieces in 2021. The amount of all cigarettes manufactured in the U.S. was 270 billion pieces in 2016.



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

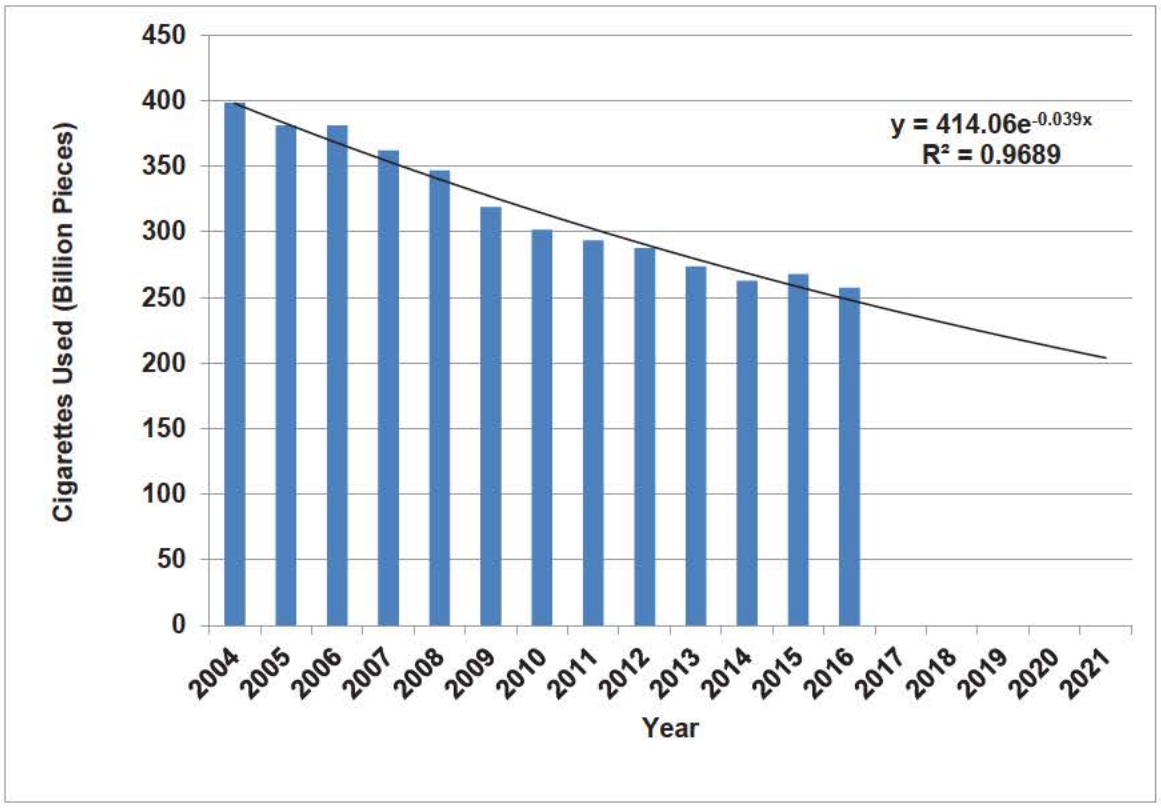
APPENDIX 3

Projected Use of Cigarettes in the U.S. in the First- and Fifth-Year of Marketing the New Product

To evaluate the environmental impact of the proposed action due to use of the new product, historical data regarding total use of cigarettes from 2008 to 2016. This information was employed to mathematically estimate the total yearly amount of cigarettes used in the U.S.[11] This was achieved by using the one best-fit trend line with R^2 value above 0.9.

Projected Use of Cigarettes in the U.S.:

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



[11] 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 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:

$$\sum_{i=1}^{10} A_i = \sum_{i=1}^{10}(B_i + C_i + D_i + E_i + F_i)$$	A_i: Projected total waste generation of the product (metric tons)
$$B_i = \frac{G_i}{H_i} \times I_i \times S$$	B_i: Projected waste generation of retail cardboard boxes of the new product (metric tons)
$$C_i = \frac{G_i}{H_i \times J_i} \times K_i \times S$$	C_i: Projected waste generation of the retail cardboard cartons of the new product (metric tons)
$$D_i = \frac{G_i}{H_i} \times L_i \times S$$	D_i: Projected waste generation of the foil inner liner (metric tons)
$$E_i = \frac{G_i}{H_i} \times M_i \times S$$	E_i: Projected waste generation of retail box plastic of the new product (metric tons)
$$F_i = \frac{G_i \, X \, O_i \, X \, P_i}{100} \times S$$	F_i: Projected waste generation of cigarette butts of the new product (metric tons)
$$P_i = \frac{Q_i}{R_i} \times 100$$	G_i: Total Projected market volume of the new product (total number of individual cigarettes) H_i: Number of cigarettes per retail box I_i: Weight of empty retail cardboard box (grams) J_i: Number of retail boxes per carton K_i: Weight of empty retail carton (grams) L_i: Weight of foil inner liner (grams) M_i: Weight of plastic wrap per retail box (grams) O_i: Weight of cigarette (gram) P_i: Cigarette butt ratio (%) Q_i: Cigarette butt length 12 R_i: Length of cigarette (millimeter) S: 1.0 x 10-6 metric tons/gram

[12] ISO 15592-3 (Section 9.3) prescribes a standard termination line for machine smoking (cigarette butt length) of 27 mm. This value is an estimate of the cigarette butt length that is disposed as solid waste following use.

a) Projected Waste of Packaging Material

Projected packaging waste is calculated as below:

Projected Year	STN	*Number of cigarettes G_i*	*# of Cigarettes per retail box H_i*	*Wt. retailcardboard box (g) I_i*	*Projected waste of cardboard boxes (metric tons)B_i*	*# of retail boxes per carton J_i*	*Wt. empty retail carton (g) K_i*	*Projected waste retail cardboard boxes (metric tons) C_i*	*Wt. of foil liner (g) L_i*	*Projected waste of foil liner (metric tons) D_i*	*Wt.plastic of retail boxes (g) M_i*	*Projected waste of plastic (metric tons)E_i*
First-Year Projected Volume	EX0000174	(b) (4)										
Fifth-Year Projected Volume	EX0000174											

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 U.S. in 2014. Likewise, the projected plastic waste of (b) (4) metric tons in 2017 and (b) (4) metric tons in 2021 is a negligible fraction of the 234.47million metric tons of total waste reported in the U.S. in 2014.

A portion of the generated cardboard waste is likely to be recycled, with an overall recycling rate for paper and paperboard products of 64.7% in the U.S.[13] If 64.7% of the cardboard boxes is recycled and the rest (35.3%) is disposed of as waste, the estimated cardboard waste disposed in landfills (Variable B and C above) would be decreased to (b) (4) metric tons) in the first year and (b) (4) metric tons) in the fifth-year of marketing the new product.

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

Projected cigarette butt waste generated is calculated as below:

[13] 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).

Projected Year	STN	# of cigarettes G_i	Length of cigarette (mm) R_i	Wt. of cigarette (g) O_i	Projected waste of cigarette butts (metric tons) F_i
First-Year Projected Volume	EX0000174	(b) (4)			
Fifth-Year Projected Volume	EX0000174				

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

CONFIDENTIAL APPENDIX 2

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

STN	Unit	First-Year Market Volume	Fifth-Year Market Volume
EX0000174	# of cigarettes	(b) (4)	

CONFIDENTIAL APPENDIX 3

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

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

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

STN	Year	Forecasted Use of Total Cigarettes in the U.S. (billion cigarettes)[14]	Projected Market Volume of New Product (billion cigarettes)[15]	Projected Market Occupation of New Product in the U.S. (%)
EX0000174	2017	239.85	(b) (4)	
	2021	205.21		

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

[14] See Appendix 3.
[15] See Confidential Appendix 3.