

**Programmatic Environmental Assessment for
Market Authorizations of “Vera Cruz Nocturne King
Size Slim, Vera Cruz Midnight King Size Slim, and
Vera Cruz Elegante King Size Slim”**

Prepared by Center for Tobacco Products U.S.
Food and Drug Administration

March 25, 2016

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This programmatic environmental assessment (PEA) is for the market authorizations of three roll-your-own (RYO) tobacco filtered cigarette tubes manufactured by “Silverfoiltubes International, 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 with 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

Silverfoiltubes International, Inc.

2. Address

79 Watchung Avenue
Upper Montclair, NJ 07043

3. Manufacturer

Silverfoiltubes International, Inc.

4. Description of the Proposed Action

The proposed action is for FDA to issue market authorizations under section 910(a)(2) of the FD&C Act for the introduction of three new roll-your-own (RYO) tobacco filtered cigarette tubes, Vera Cruz Nocturne King Size Slim, Vera Cruz Midnight King Size Slim, and Vera Cruz Elegante King Size Slim,” into interstate commerce for commercial distribution in the U.S. These authorizations are based on the finding that these new products are substantially equivalent to their corresponding predicate products that were on the market as of February 15, 2007.

4.1. Requested Action

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

4.2. Need for Action

Silverfoiltubes International Inc. wishes to introduce the new tobacco products (as described) into interstate commerce for commercial distribution in the U.S. The applicant claims that the new products and the corresponding predicate products have the same characteristics (sec. 910(a)(3)(A)(i)) as described in FDA guidance to industry issued on March 4, 2015.¹ After considering the SE Reports, the Agency shall issue orders pursuant to section 910(a)(2) of the FD&C Act when finding the new products to be substantially equivalent to their corresponding predicate products.

¹ FDA Guidance for Industry. Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions. Issued March 4, 2015. Available at: <http://www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM436468.pdf>. Accessed on December 28, 2015)

4.3. Identification of the New Tobacco Products that are Subjects of the Proposed Action

4.3.1. Type of Tobacco Products

Roll-your-own (RYO), filtered cigarette tubes

4.3.2. Product Names and Their Original STNs

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

STN	New Product	Predicate Product
SE0002200	Vera Cruz Nocturne King Size Slim	Zen Full Flavor Cigarette Tubes King Size
SE0002202	Vera Cruz Midnight King Size Slim	Zen Full Flavor Cigarette Tubes King Size
SE0002220	Vera Cruz Elegante King Size Slim	Zen Light Cigarette Tubes King Size

4.3.3. Description of the Product Package

The new products are RYO tobacco filtered cigarette tubes. Two hundred tubes are contained in a box and 50 boxes are contained in a case.

4.3.4. Location of Manufacturing

Blk1 Lot 10 Light Industry & Science Park III (LISP III)
San Rafael, Sto. Tomas, Batangas
Philippines 4234

4.3.5. Location of Use

Silverfoiltubes International Inc. intends to distribute and sell the new tobacco products to consumers in the U.S.

4.3.6. Location of Disposal

The used and unused portioned moist snuff would be disposed of in municipal solid waste (MSW) landfills or as litter, in the same manner as any other marketed RYO tobacco filtered cigarette tube. Disposal of the packaging materials following use either would enter the recycling stream or be disposed of in MSW landfills or as litter. The distribution of waste from disposal after use should correspond to the pattern of product use.

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

The applicant claims that changes in product name and package size are the only differences between the new products and their corresponding predicate products.

5. Environmental Introduction Due to the Proposed Action

5.1. Introduction as a Result of Manufacturing the New Products

5.1.1 *Filtered Cigarette Tubes and Cigarette Booklet Manufacture in the Philippines*

The worldwide U.S. import of cigarette papers increased to 6,191 tons cigarette papers in 2014 from 5,810 tons in 2013, similarly the import from the Philippines increased to 1,204 tons of cigarette papers in 2014 from 809 tons cigarette papers in 2013 (see Table 1).² However, the U.S. imports of all tobacco products from the Philippines decreased to 7,669 tons in 2014 from 7,870 tons in 2013 (Figure 1).³

Table 1 All Tobacco Products Imported from the Philippines and the Cigarette Papers Imported from the Philippines and Worldwide in 2013 and 2014

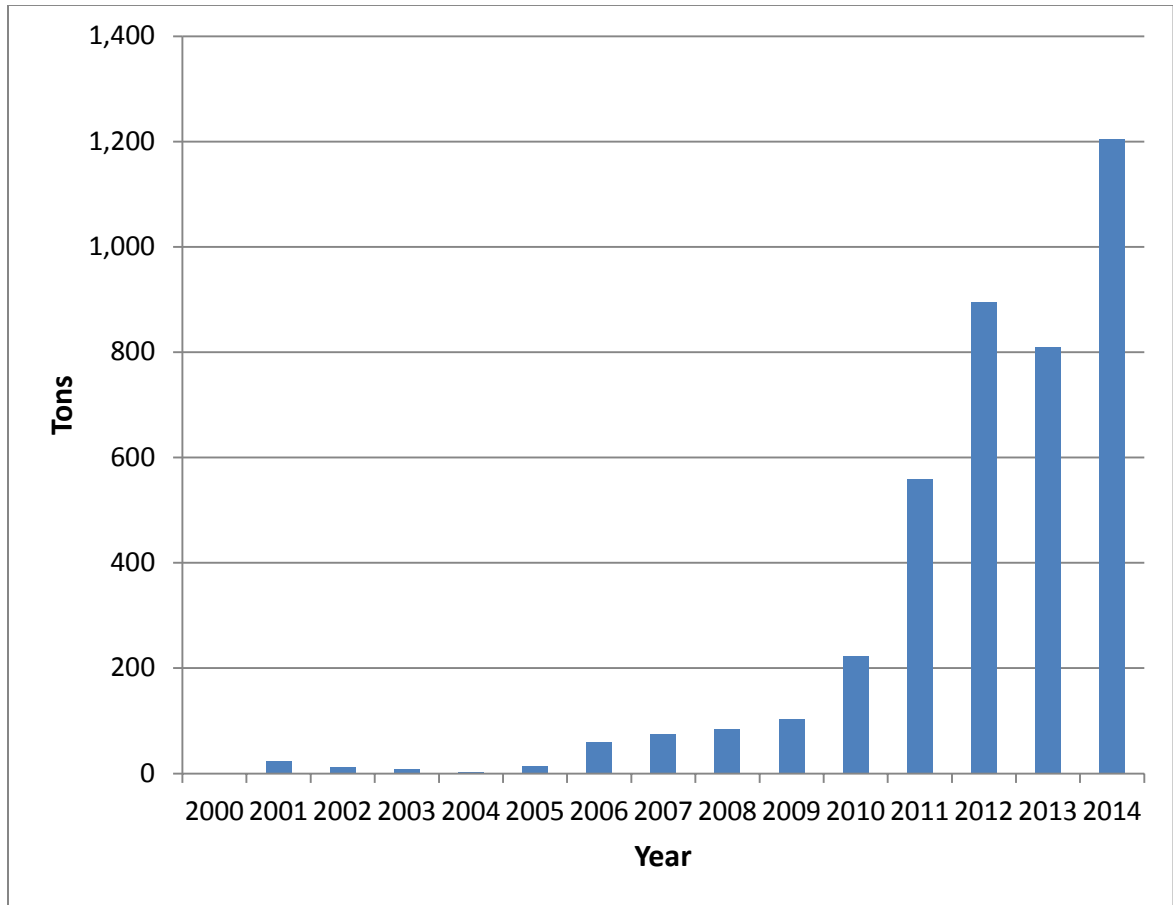
Year	Total Weight of Cigarette Papers Imported from All Countries	Total Weight of Cigarette Papers Imported from the Philippines	Total Weight of All Tobacco Products Imported from the Philippines
2013	5,810 tons	809 tons	7,870 tons
2014	6,191 tons	1,204 tons	7,669 tons

² US international Trade Commission.

https://dataweb.usitc.gov/scripts/tariff_current.asp?Phase=List_items&lookfor=481310. Accessed on January 29, 2016

³ Same as footnote 2.

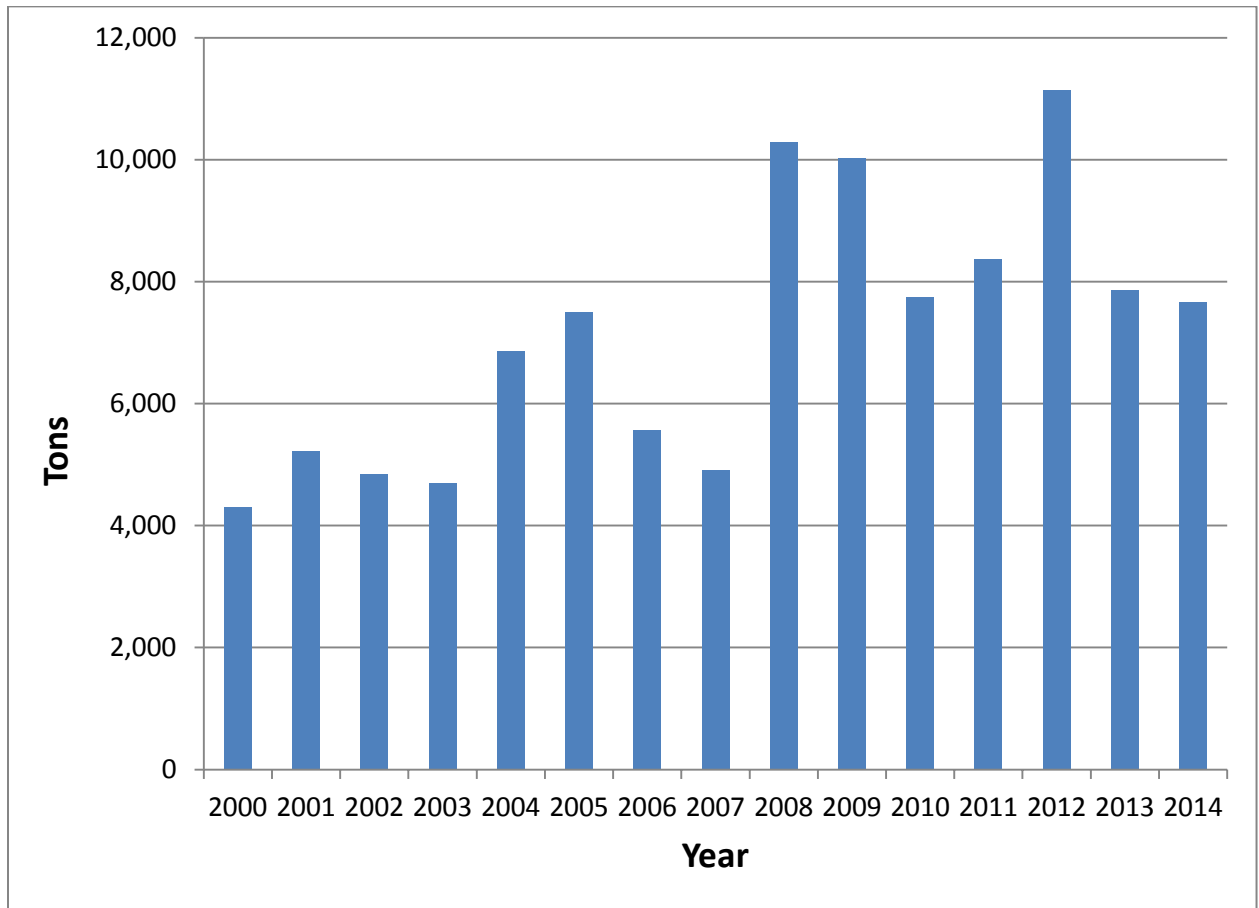
Figure 1 Cigarette Paper imported from the Philippines into the U.S. in 2000 - 2014



No environmental emission information on filtered cigarette tubes and cigarette booklet manufacture in the Philippines is available to the Agency.

Notably, a 56% increase (from 4,296 tons in 2000 to 7,669 tons in 2014) in tobacco product importation from the Philippines to the U.S. was estimated, as shown in Figure 2.

Figure 2. Total Tobacco Products Imported from the Philippines into the U.S. 2000 – 2014



5.1.2 Environmental Introduction from Manufacturing the New Products

Introduction from manufacturing new products in the proposed actions. The Agency anticipates the waste generated as a result of manufacturing the new products will be released to the environment, transferred to publicly owned treatment works (POTWs), and disposed of in landfills in the same manner as any other products manufactured in the same facility and in a similar manner to other filtered cigarette tubes manufactured in the Philippines. In addition, the new products are anticipated to compete with other filtered cigarette tubes and therefore, the Agency does not expect the introduction of the new product to notably affect the current manufacturing waste generated from the production of all filtered cigarette tubes.

Based on information in the SE Reports, the only difference between the new products and the predicate products are in name and package size. Therefore, the Agency does not anticipate any new substances or new type of emissions to be released into the environment as a result of manufacturing the new products.

To evaluate the environmental impact of the proposed action due to manufacturing of the new products, historic data regarding manufacturing of cigarette paper imported from the Philippines to the U.S from 2008 to 2014 was used. This was achieved by using one best-fit linear trend line with the R^2 value of 0.93 for the total cigarette paper imported from the Philippines to the U.S. Accordingly, the forecasted amounts of the total cigarette paper imported from the Philippines to the U.S. are estimated to be 1,525 and 2,302 tons in 2016 and 2020, respectively (Appendix 2).

The applicant provided the first- and fifth-year market volume projections for the new products (See Confidential Appendix 1). Comparing the projected market volumes of the new products with the forecasted market volumes of the total imported cigarette paper from the Philippines to the U.S. in 2016 and 2020, the individual and cumulative projected market volumes of the new products are miniscule fractions of the total forecasted market volumes in 2016 and 2020. (See Appendix 2 and Confidential Appendix 2). Therefore, no new control practices of air emission, water discharge, and solid waste disposal are needed.

Based on information in the SE Reports, the characteristics of the cigarette papers are within the traditional range found throughout the industry. Any differences between the new products and the predicate products are a direct result of the differences in packaging size. Therefore, the Agency does not anticipate any new substances or new type of emissions to be released into the environment as a result of manufacturing the new products.

Therefore, no new control practices of air emission, water discharge, and solid waste disposal are needed.

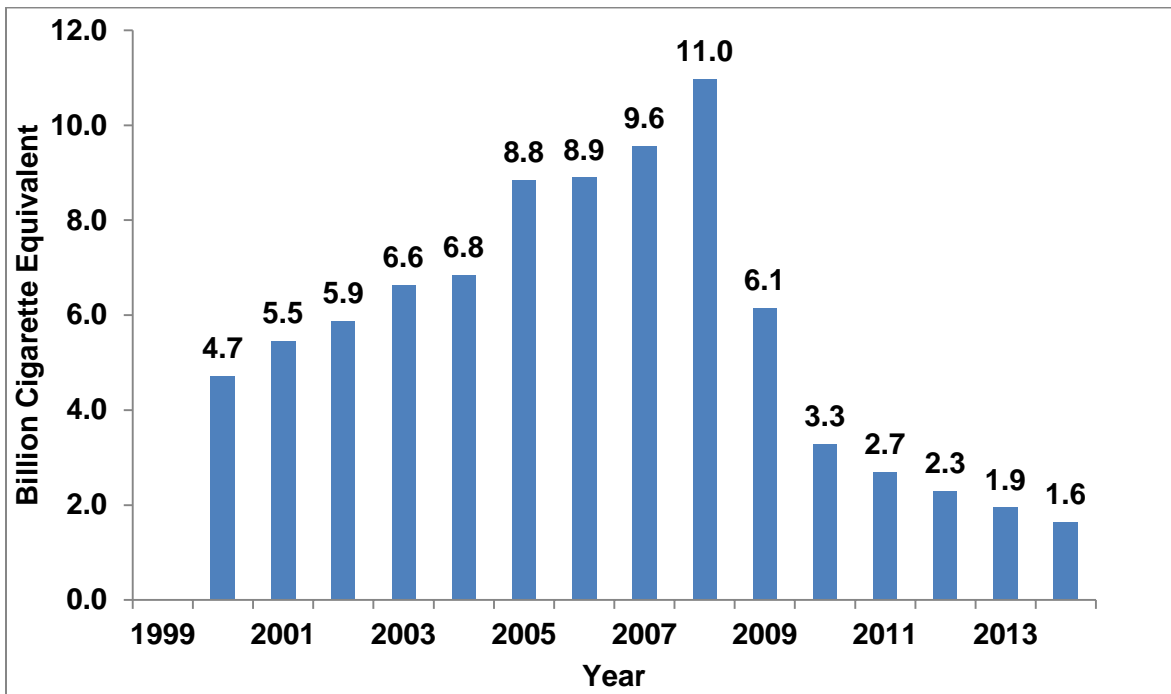
5.2. Environmental Introduction as a Result of Use of the New Products

5.2.1 Use of Filtered Cigarette Tubes

Data from the U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) statistics reports showed a gradual linear increase in the use of RYO tobacco in the U.S. from 4.7 billion cigarette-equivalents to 11 billion cigarette-equivalents during the years 2000 to 2008, respectively (Figure 3).⁴ This was followed by a sharp decline in its use to 3.3 billion cigarette-equivalents in 2010 and to 1.6 billion cigarette-equivalents in 2014.

⁴ 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 30, 2015.

Figure 3 Use of ROY in the U.S. in 2000 – 2014 in Billion Cigarette Equivalents



5.2.2 Environmental Introduction from Use of the New Products

As noted, the primary difference between the predicate and corresponding new tobacco products is in name and package size. During use, the new product is usually burned to ash, carbon dioxide, and water vapor, as well as products of incomplete combustion such as carbon monoxide. These combustion products from the new products are released in a similar manner to the predicate products and other filtered cigarette tubes. The released substances during use of the new products are negligible from the environmental viewpoint. Essentially, 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 already on the market and all other RYO cigarette tubes.

5.3. Environmental Introduction as a Result of Disposal Following Use in the U.S.

The waste that is generated following use of the new and predicate products consists of the disposed packaging materials and the discarded cigarette tube filter (tube butt). Although the paper board material is biodegradable, the filters can persist in the environment for an extensive time (see below).⁵

⁵ Novotny TE and Zhao F. Consumption and production waste: Another externality of tobacco use. Tobacco Control 1999; 8:75-80.

5.3.1 Disposal Following Use of Filtered Cigarette Tubes

a) Disposal of packaging material

Disposal of the packaging materials following use either would enter the recycling stream or would be disposed of in MSW landfills or as litter. In 2013, the amount of waste generated in the U.S. was approximately 254 million tons and approximately 87 million tons of this material was recycled and composted, equivalent to a 34.3% recycling rate (Figure 3 and Figure 4). The recovery of newspaper/mechanical papers was about 67% (5.7 million tons). On average, 4.40 pounds per person per day of waste was generated, of which 1.51 pounds was recycled and composted in the U.S. in 2013.⁶

Figure 3. Municipal Solid Waste (MSW) Generation Rates in the U.S, 1960 – 2013

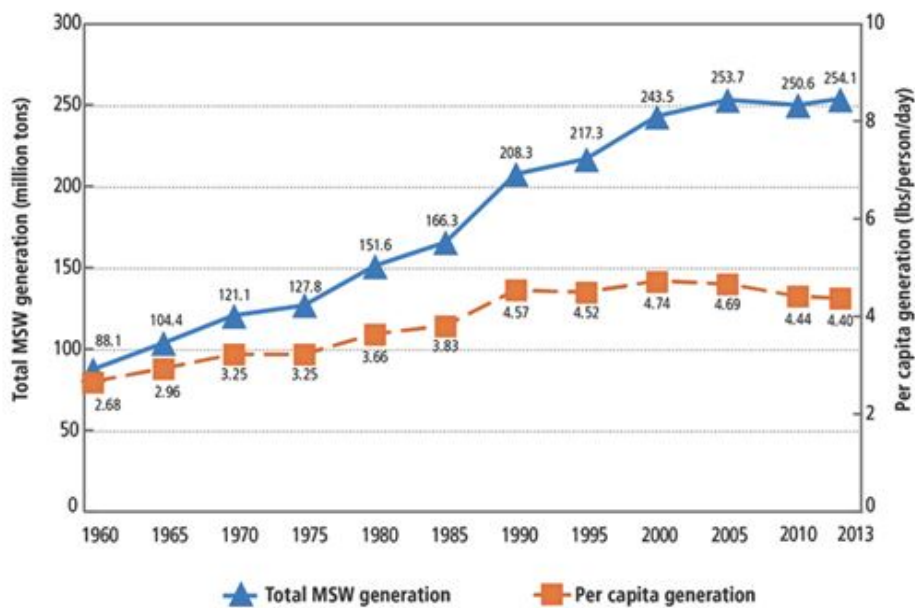
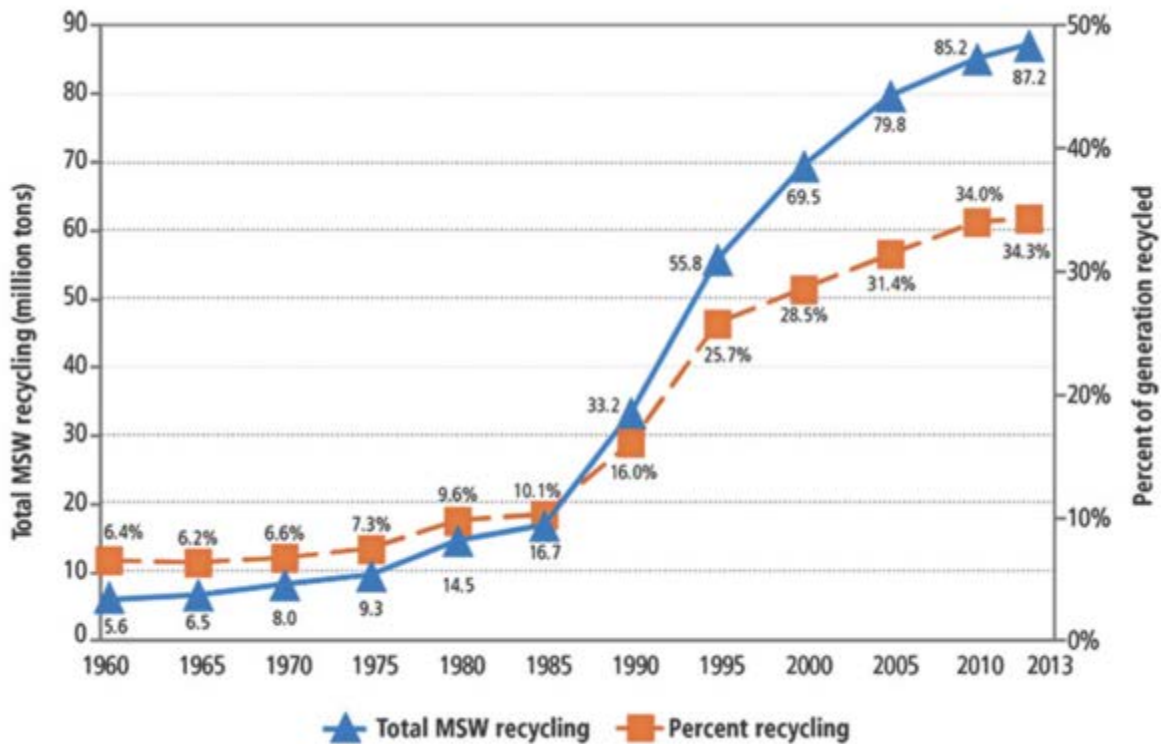


Figure 4. MSW Recycling Rates in the U.S.

⁶ EPA. Wastes - Non-Hazardous Waste - Municipal Solid Waste. Available at: <http://www.epa.gov/waste/nonhaz/municipal/>. Accessed January 26, 2016.



b) Disposal of cigarette tube filters following use

A major existing environmental consequence of use of filtered cigarette tubes is the waste disposal of the filters (cigarette butts). Evidence has shown that cigarette butts are the most prevalent items discarded into roads and streets in urban areas. Once dumped onto city streets, they move through the storm drains to streams, into the ocean, and back onto the beaches, while leaching toxicants into the environment along the way. Discarded filters are found to be the most collected item in beach clean-ups and litter surveys. An estimated 30% of the total waste (by count) on the U.S. shorelines, waterways and land is cigarette filter waste.⁷

Cigarette tube filters most commonly contain cellulose diacetate, which may persist under normal environmental conditions for 18 months to 10 years.^{8,9} Cigarette filters were found to be a source for metal contamination, based on research done investigating the gradual release of multiple metals from the filter over a 34-day study

⁷ Tobacco Control Legal Consortium. Policy Tools for Minimizing Public Health and Environmental Effects of Cigarette Waste. March 2014. Available at: <http://publichealthlawcenter.org/sites/default/files/resources/tclc-guide-cigarette-waste-2014.pdf>. March 27, 2015.

⁸ US Department of Health and Human Services. Reducing the health consequences of smoking: 25 years of progress. A report of the Surgeon General, 1989. Rockville, Maryland: Public Health Service, Centers for Disease Control, Office on Smoking and Health, 1989. (DHHS Publication No (CDC) 89-8411.).

⁹ Ach A. Biodegradable plastics based on cellulose acetate. *Journal of Macromolecular Science: Pure and Applied Chemistry* 1993; A30:733-40.

period.¹⁰ In addition, cigarette filters were found to be a source for nicotine entering the environment according to research investigating the release of nicotine from smoked cigarette butts over a 24-hour simulated rainfall event.¹²

5.3.2 Environmental introduction of disposal following use of the new products

The Agency believes that the disposal of the new products will be similar to the disposal conditions of other filtered cigarette tube products that are currently being marketed. After using the new product, the users may dispose of or recycle the packaging paper material. Users may also discard the cigarette tube filters and ashes as municipal solid waste (MSW) or as litter.

a) Disposal of packaging material

To determine the amount of waste from disposal of paper packaging material, in the worst case scenario, the Agency used the first- and fifth-year projected volumes of marketing the new and predicate products after issuance of the authorization orders for the new products (Confidential Appendix 4). The calculated cumulative waste of the paper packaging material is determined to be miniscule compared to the forecasted MSW to be generated in the U.S. In addition, paper components are more likely to be recycled; at least a portion of the waste is likely to be recycled.

b) Disposal of cigarette tube filters

To determine the amount of waste from disposal of cigarette tube filters, the Agency used the first- and fifth-year projected volumes of marketing the new and predicate products (Confidential Appendix 5). Although the waste generated from cigarette tube filters remains as an environmental concern, the calculated cumulative waste of the filters is determined to be miniscule compared to the forecasted MSW to be generated in the U.S.

As previously discussed, the new products will compete with other filtered tube tobacco products on the market. Due to that, plus the above information regarding waste, construction of new landfills is not anticipated due to the proposed action.

6. Fate of Materials Released into the Environment Due to the Proposed Action

The Agency does not anticipate that the proposed action will lead to the release of new chemicals into the environment because the predicate products (filtered cigarette tubes with the same attributes and characteristics as the new products) have been sold and continue to be sold in the U.S. The new products are anticipated to be manufactured the same way as other filtered cigarette tubes in the same facility. Therefore, the fate of any

¹⁰ Moerman, JW; Potts, GE. Analysis of metals leached from smoked cigarette litter. *Tobacco Control*. 2011; 20(Suppl. 1):I30-I35.

¹² Roder Green, AL; Putschew, A; Nehls, T. Littered cigarette butts as a source of nicotine in urban waters. *Journal of Hydrology*. 2014; 519:3466-3474.

materials emitted is anticipated to be the same as other products manufactured in the facility. No new types of materials are anticipated to be emitted since the new products are identical to the predicate products and will be made using the same materials and processes as for the predicate products.

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

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

Furthermore, as discussed above, the amount of materials anticipated to enter the environment due to manufacturing and use of the new products are small fractions when compared to that of the RYO cigarette papers imported in the U.S. In addition, the amount of materials anticipated to enter the environment due to disposal following use of the new products occupies a small fraction of the total forecasted MSWs in the U.S. Consequently, no new environmental effects are anticipated due to the new products.

8. Use of Resources and Energy

The new products will compete with other currently marketed tobacco products. The applicant stated that the paper used to manufacture the filtered cigarette tubes are from sustainable sources. Furthermore, comparing the projected market volumes of the new products with the forecasted market volumes of the total imported cigarette papers to the U.S., as well as the total cigarette paper use in 2016 and 2020, the individual and cumulative projected market volumes of the new products are miniscule fractions of the total forecasted market volumes in 2016 and 2020. Accordingly, no additional use of resources and energy is anticipated.

9. Mitigation

During our review of the available data and information, we did not identify adverse environmental effects for the new products and their proposed use as filtered cigarette tubes. Therefore, no mitigation measures are discussed.

10. Alternatives to the Proposed Action

Alternative A (No-action alternative): The no-action alternative is to not allow the marketing of the new tobacco products in the U.S. The environmental impact of this action would not change the existing condition of the manufacturing, use, and disposal following use of the tobacco products as the predicate products, as well as many other RYO cigarette paper products, will continue to be marketed.

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

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

11. List of Preparers:

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

Mehran Niazi, PhD, Center for Tobacco Products

Education: PhD, in Environmental Science

Experience: 12 years in Environmental Fate and Transport and Environmental Modeling

Expertise: Environmental Risk Assessment, Water Quality Modeling, Environmental Fate & Transport

12. Appendix List

Appendix 1: List of Submission Tracking Numbers for the SE Reports with Names and Package Size of the New and Predicate Products, and Related Amendments that are Covered Under this Programmatic Environmental Assessment (PEA)

Appendix 2: Forecast of Manufactured RYO Cigarette.

Appendix 3: Projected Use of RYO Tobacco Products in the U.S.

13. Confidential Appendix

Confidential Appendix 1: The First- and Fifth-Year Market Volume Projections of the New Products and the Corresponding Predicate Products

Confidential Appendix 2: Percentage of the Projected Total RYO Cigarette Paper Importation from the Philippines Occupied by the New and Predicate Products in 2016 and 2020 (First and Fifth Year of Marketing the New Products)

Confidential Appendix 3: The Percentages of the Projected Total RYO Cigarette Paper Market in the U.S. Occupied by the New and Predicate Products Market Occupied the Cigarette Paper Use in the U.S. in 2016 and 2020 (the First and Fifth Year Marketing of Marketing the New Products)

Confidential Appendix 4: The First- and Fifth-Year Projections of Paper Box Waste of Packaging Materials Associated with Marketing the Products

Confidential Appendix 5: The First- and Fifth-Year Market Projections of Disposed Tube Filters Associated with Marketing the Products

APPENDIX 1

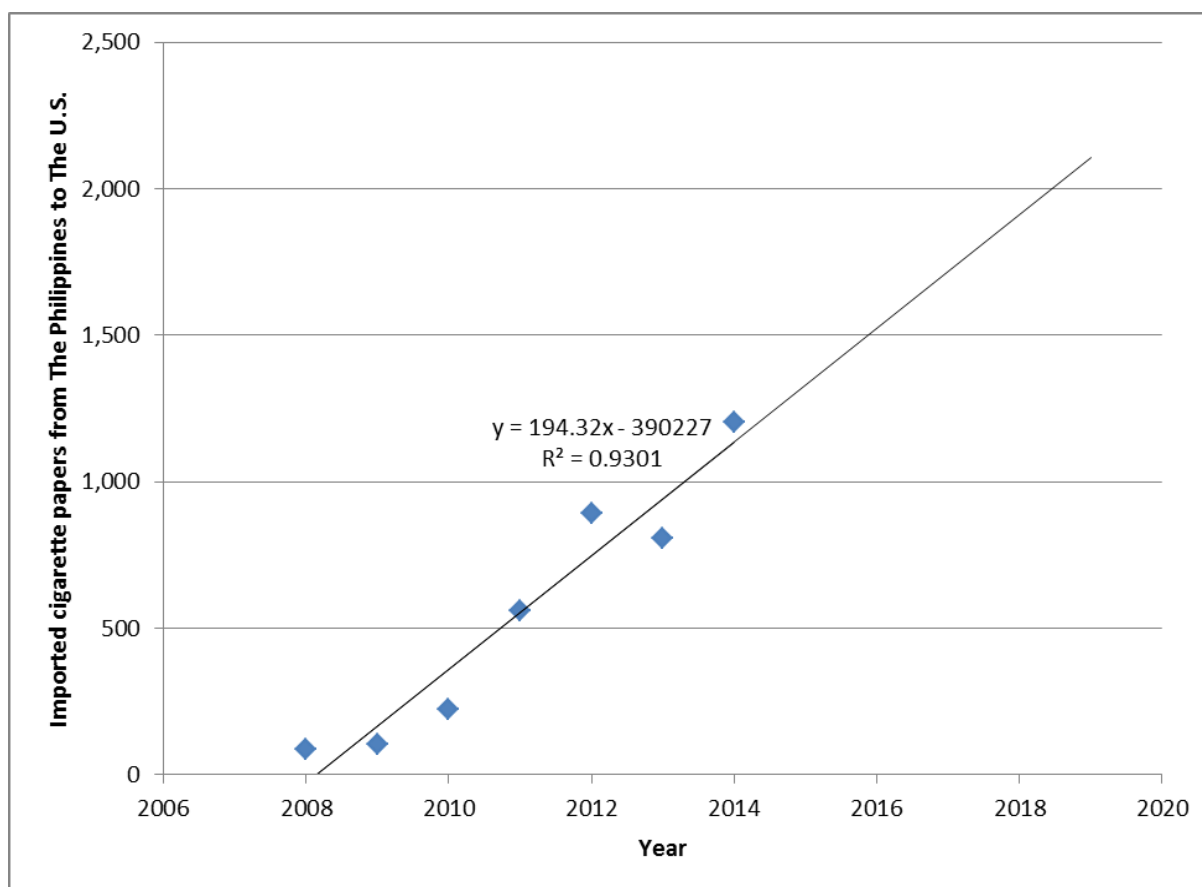
List of Submission Tracking Numbers for the SE Reports with Names and Package Size of the New and Predicate Products, and Related Amendments that are Covered Under this Programmatic Environmental Assessment (PEA)

STN	New Product	Package Size	Predicate Product	Package size	Amendments
SE0002200	Vera Cruz Nocturne King Size Slim	200 per box	Zen Full Flavor Cigarette Tubes King Size	250 per box	SE0012358, SE0011031, SE0010768, SE0010776, SE0010788, SE0010547, SE0009085, SE0011838, SE0011748
SE0002202	Vera Cruz Midnight King Size Slim	200 per box	Zen Full Flavor Cigarette Tubes King Size	250 per box	SE0012358, SE0011031, SE0010768, SE0010776, SE0010788, SE0010547, SE0009087, SE0011838, SE0011748
SE0002220	Vera Cruz Elegante King Size Slim	200 per box	Zen Light Cigarette Tubes King Size	250 per box	SE0012358, SE0011031, SE0010768, SE0010776, SE0010788, SE0010547, SE0009087, SE0011838, SE0011748

APPENDIX 2

Forecast of Manufactured RYO Cigarette

To evaluate the environmental impact of the proposed action due to manufacturing of the new products, historic data regarding imported cigarette papers from the Philippines to the U.S. from 2008 to 2014 was used to forecast the manufacturing of cigarette papers. This was achieved by using one best-fit power trend line with the R^2 value of 0.93. Accordingly, the forecasted amount of imported cigarette paper from the Philippines is estimated to be 1,525 tons in 2016 and 2,302 tons in 2020.



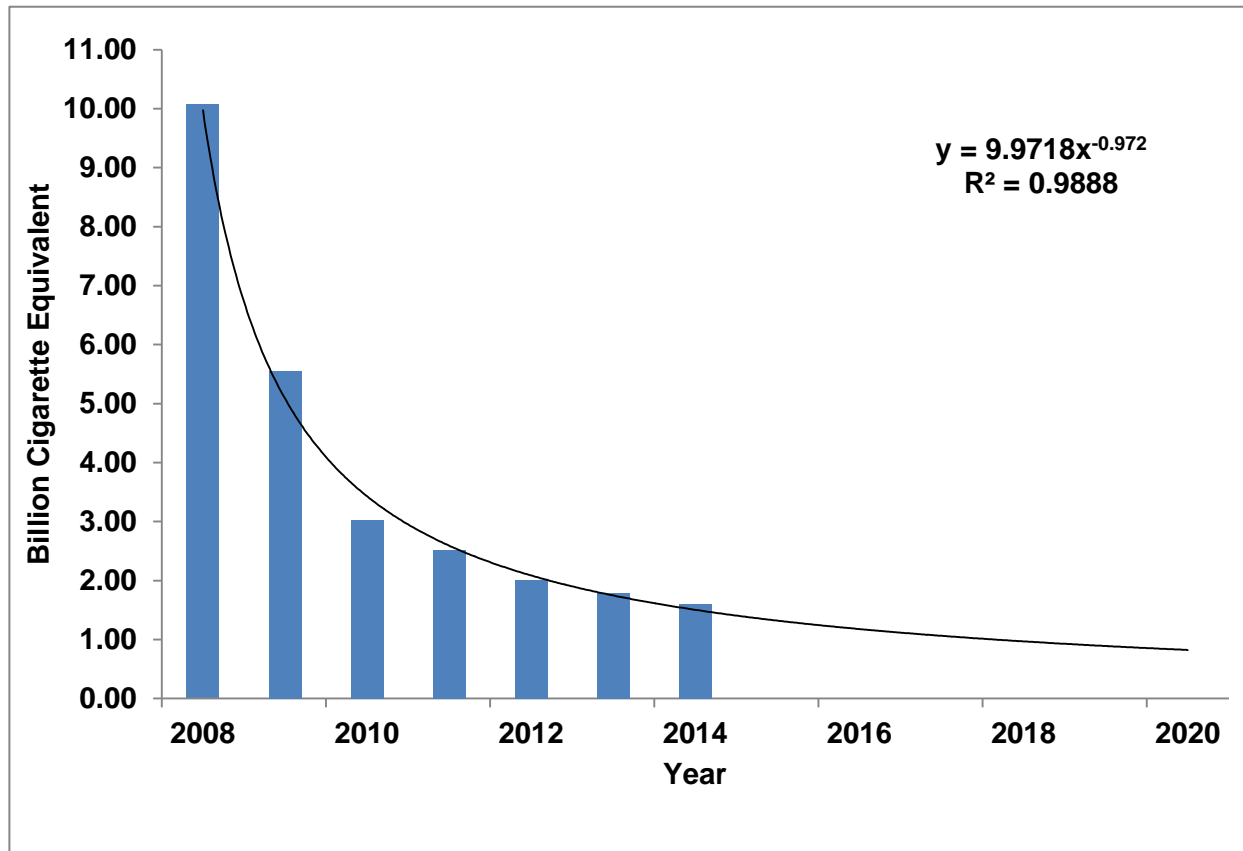
APPENDIX 3

Projected Use of RYO Tobacco Products in the U.S.

To evaluate the environmental impact of the proposed action due to use of the new products, historic data regarding use of RYO from 2008 to 2014 was used to mathematically estimate the forecast of the use of RYO in the U.S. This was achieved by using one best-fit power trend line with the R^2 value of 0.9888 (Figure 5).

Accordingly, the forecasted amount of RYO papers that will be used in the U.S. is estimated to be 1.26 billion in 2016 and 0.87 billion in 2020.

Figure 5. Forecast of Use of RYO Paper Products in the U.S.



CONFIDENTIAL APPENDIX 1

The First- and Fifth-Year Market Volume Projections of the New Products and Corresponding Predicate Products

STN	Product Name	1st-Year Projected Market Volume (# of Tubes)	1st-Year Projected Market Volume (Tons)	5th-Year Projected Market Volume (# of Tubes)	5th-Year Projected Market Volume (Tons)
SE0002200	Vera Cruz Nocturne King Size Slim	(b) (4)			
SE0002202	Vera Cruz Midnight King Size Slim				
SE0002220	Vera Cruz Elegante King Size Slim				
Predicate	Zen Full Flavor Cigarette Tubes King Size				
Predicate	Zen Light Cigarette Tubes King Size				
Total Projected Market Volume of the New Products					
Total Projected Market Volume of Predicate Products					
Total Projected Market Volume of New and Predicate Products					

CONFIDENTIAL APPENDIX 2

Percentage of the Projected Total RYO Cigarette Paper Importation from the Philippines Occupied by the New and Predicate Products in 2016 and 2020 (First and Fifth Year of Marketing the New Products)

Year	Weight of Cigarette Paper Forecasted to be Imported from the Philippines (tons)	New Products		Predicate Products		Total New and Predicate Products	
		Weight (tons)	Percent of Total RYO Cigarette Paper Imported from the Philippines	Weight (tons)	Percent of Total RYO Cigarette Paper Imported from the Philippines	Weight (tons)	Percent of Total RYO Cigarette Paper Imported from the Philippines
2016 (1 st Year of Marketing New Products)	(b)(4)						
2020 (5 th Year of Marketing New Products)							

The projected market volume for the new products is (b)(4) in both 2016 and 2020. Compared to the forecasted volume for RYO cigarette papers imported from the Philippines in 2016 and 2020, the first- and fifth-year market volume of the new products would occupy (b)(4) of the total market of RYO papers imported from the Philippines, respectively (see section 5.1.1).

The projected market volume for the predicate products is (b)(4) in 2016 and (b)(4) in 2020. Compared to the forecasted volume for RYO imported cigarette papers from the Philippines in 2016 and 2020, the first- and fifth-year market volume of the predicate products would occupy (b)(4) of the total market of RYO papers imported from the Philippines, respectively.

CONFIDENTIAL APPENDIX 3

Percentage of the Projected Total RYO Cigarette Paper Market in the U.S. Occupied by the New and Predicate Products in 2016 and 2020 (First and Fifth Year of Marketing the New Products)

Year	Projected Cigarette Paper Use in the U.S. (# of tubes in million)	New Products		Predicate Products		Total New and Predicate Products	
		Projected # of Tubes (million)	Percent of Total Cigarette Paper use	Projected # of Tubes (million)	Percent of Total Cigarette Paper Use	Projected # of Tubes (million)	Percent of Total Cigarette Paper Use
2016 (1 st Year of Marketing the New Products)	(b)(4)	(b)(4)					
2020 (5 th Year of Marketing the New Products)	(b)(4)						

The projected market volume for the new products (b)(4) in both 2016 and 2020. Compared to the number of RYO products projected to be used in the U.S., the new products would occupy (b)(4) of the total market of RYO papers in 2016 and 2020, respectively (see section 5.1.1).

The projected market volume for the predicate products is (b)(4) in 2016 and (b)(4) in 2020. Compared to the number of RYO products projected to be used in the U.S., the predicate products would occupy (b)(4) of the total market of RYO papers in 2016 and 2020, respectively.

CONFIDENTIAL APPENDIX 4

The First- and Fifth-Year Projections of Paper Box Waste of Packaging Materials Associated with Marketing the Products

The Agency estimated the first- and fifth-year weights of the packaging materials waste (in tons) that would be generated from disposal after use of the new products as follows:

A= (B / C) x D x E, where

- A= Projected packaging material waste (tons)
- B= Projected number of manufactured tubes*
- C= Number of tubes per box, 200
- D= Weight of the packaging material (grams/box) **
- E= 10⁻⁶ (tons/gram)

* From column 3 and 5 in table below.

**The paper box weights for the new products and predicate products are 20.7 and 40.5 grams, respectively.

STN	Product Name	1 st -Year Projected Market Volume (# of Tubes)	1 st -Year Projected Paper Box Waste (Metric Tons)	5 th -Year Projected Market Volume (# of Tubes)	5 th -Year Projected Paper Box Waste (Metric Tons)
SE0002200	Vera Cruz Nocturne King Size Slim	(b) (4)			
SE0002202	Vera Cruz Midnight King Size Slim				
SE0002220	Vera Cruz Elegante King Size Slim				
Predicate	Zen Full Flavor Cigarette Tubes King Size				
Predicate	Zen Light Cigarette Tubes King Size				
Total Projected Market Volume of the New Products					
Total Projected Market Volume of Predicate Products					
Total Projected Market Volume of New and Predicate Products					

Paper Waste. Estimation for generated total paper waste for the new products is (b)(4) metric tons in the first and the fifth years. A portion of the generated paper waste is likely to be recycled with an overall recycling rate for paper products at 70% in the U.S.

according to US EPA¹¹. Therefore, if 30% of the box is disposed of as waste based on the 2013 waste generation data in the U.S., the estimated cumulative cardboard waste will be [REDACTED] metric tons in the first and fifth years of marketing the new products.

If the entire packaging cardboard is disposed of as waste, in the worst case scenario, the projected cumulative cardboard waste in the first and fifth years of marketing the products is [REDACTED] metric tons. This is a negligible fraction of the 254 million tons of total waste reported in the U.S. in 2013.

Estimation for generated total paper waste for the predicate products is [REDACTED] metric tons in the first year and [REDACTED] metric tons in the fifth year. A portion of the generated paper waste is likely to be recycled with an overall recycling rate for paper products at 70% in the U.S. according to US EPA¹². Therefore, if 30% of the box is disposed of as waste based on the 2013 waste generation data in the U.S., the estimated cumulative cardboard waste will be [REDACTED] and [REDACTED] metric tons in the first and fifth years of marketing the predicate products, respectively.

If the entire packaging cardboard is disposed of as waste, in the worst case scenario, the projected cumulative cardboard waste in the first and fifth years of marketing the products is [REDACTED] metric tons, respectively. Even this worst case scenario projection is a negligible fraction of the [REDACTED] million tons of total waste reported in the U.S. in 2013.

¹¹ EPA. Wastes - Non-Hazardous Waste - Municipal Solid Waste. Available at: <http://www.epa.gov/waste/nonhaz/municipal/>. Accessed January 29, 2016

¹² EPA. Wastes - Non-Hazardous Waste - Municipal Solid Waste. Available at: <http://www.epa.gov/waste/nonhaz/municipal/>. Accessed January 29, 2016

CONFIDENTIAL APPENDIX 5

The First- and Fifth-Year Market Projections of Disposed Tube Filters Associated with Marketing the Products

The Agency estimated the first- and fifth-year projected weights of the cigarette tube filter (in tons) that is generated from disposal after use of the new and predicate products as follows:

A= (B x C) / D, where

A= Projected waste (tons)

B= Weight of each cigarette tube filter (grams)*

C= Projected market volume of the product**

D=10⁻⁶ (tons/gram)

* From column 6 in table below

** From last 3 rows in table below

STN	Product Name	1 st -Year Projected Market Volume (# of Tubes)	1 st -Year Projected Filter Waste (Tons)	5 th -Year Projected Market Volume (# of Tubes)	Filter weight (grams)	5 th -Year Projected Filter Waste (Tons)
SE0002200	Vera Cruz Nocturne King Size Slim	(b) (4)				
SE0002202	Vera Cruz Midnight King Size Slim	(b) (4)				
SE0002220	Vera Cruz Elegante King Size Slim	(b) (4)				
Predicate	Zen Full Flavor Cigarette Tubes King Size	(b) (4)				
Predicate	Zen Light Cigarette Tubes King Size	(b) (4)				
Total Projected Market Volume of the New Products		(b) (4)				
Total Projected Market Volume of Predicate Products		(b) (4)				
Total Projected Market Volume of New and Predicate Products		(b) (4)				

The waste of cigarette tube filters can end up in landfills, but they can also be discarded on streets and roadsides where they may move via storm drains into surface waters. When the tube filters enter the environment, ultimately, they can move into the ocean and back onto the beaches. Moreover, potentially toxic residues from littered filters may leach into the environment via storm water runoff.

The projected cumulative waste of cigarette tube filters in the first year and the fifth year of marketing the new products is [REDACTED]. This is a miniscule fraction of the 254 million tons of total waste reported in the U.S. in 2013.

The projected cumulative waste of cigarette tube filters in the first year and the fifth year of marketing the predicate products is [REDACTED] and [REDACTED] tons, respectively. These are miniscule fractions of the 254 million tons of total waste reported in the U.S. in 2013.