

Programmatic Environmental Assessment for Market Authorizations of “1839 Regular 100mm 200 Count, 1839 Smooth 100mm 200 Count, Hot Rod Regular 100mm 200 Count, Great Choice Regular 100mm 200 Count, Great Choice Smooth 100mm 200 Count, Kentucky Select Regular 100mm 200 Count, Kentucky Select Smooth 100mm 200 Count, Wild Bill’s Regular 100mm 200 Count, Wild Bill’s Smooth 100mm 200 Count, Wild Horse Regular 100mm 200 Count, Wild Horse Smooth 100mm 200 Count and Hot Rod Smooth 100mm 200 Count” With Same Characteristics as Their Respective Predicate Products, “Cheap Tobacco Regular 100mm 200 Count and Cheap Tobacco Smooth 100mm 200 Count”

Prepared by Center for Tobacco Products U.S.

Food and Drug Administration

August 28, 2015

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This programmatic environmental assessment (PEA) is for the market authorizations of multiple Roll-Your-Own (RYO) tobacco filtered cigarette tubes manufactured by “Midwest Tobacco Tube 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

Midwest Tobacco Tube Inc.

2. Address

10825 Medallion Drive,
Cincinnati, Ohio 45241

3. Manufacturer

Midwest Tobacco Tube 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 multiple new Roll-Your-Own (RYO) tobacco filtered cigarette tubes into interstate commerce. These authorizations are based on the finding that these new products are substantially equivalent to their respective predicate products that were on the market as of February 15, 2007. The applicant stated that the predicate products will continue to be marketed after the new products are authorized.

4.1. Requested Action

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

4.2. Need for Action

Midwest Tobacco Tube Inc. submitted SE Reports SE0010959-10961, SE0010965-10966, SE0010975-10976, SE00109980-10981, SE0010985-10986, and SE0010988 seeking marketing authorizations for the introduction of their new products (as described) into interstate commerce. The requested action is a finding that the new products are substantially equivalent to their respective predicate products (see Appendix 1).

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

4.4.2. Product Names and Their Original Submission Tracking Numbers (STNs)

STNs	New Products
SE0010959	1839 Regular 100mm 200 Count
SE0010960	1839 Smooth 100mm 200 Count
SE0010961	Hot Rod Regular 100mm 200 Count
SE0010965	Great Choice Regular 100mm 200 Count
SE0010966	Great Choice Smooth 100mm 200 Count
SE0010975	Kentucky Select Regular 100mm 200 Count
SE0010976	Kentucky Select Smooth 100mm 200 Count
SE0010980	Wild Bill's Regular 100mm 200 Count
SE0010981	Wild Bill's Smooth 100mm 200 Count
SE0010985	Wild Horse Regular 100mm 200 Count
SE0010986	Wild Horse Smooth 100mm 200 Count
SE0010988	Hot Rod Smooth 100mm 200 Count

Also see a list of names of the new products and the predicate products is provided in Appendix 1.

4.4.3. Description of the Product Package

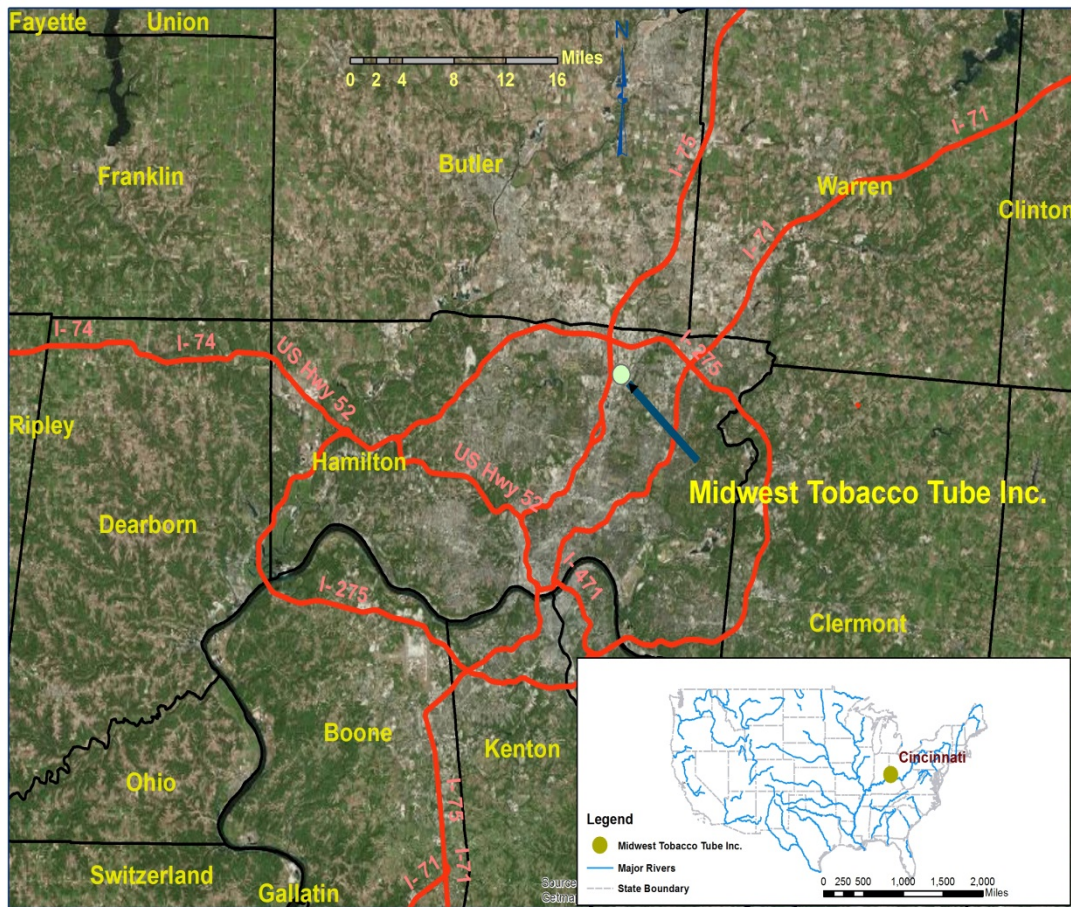
The new products are RYO tobacco filtered cigarette tubes. Two hundred tubes are contained in a solid bleached sulfate (SBS) paper board and 50 boxes are contained in a case.

4.4.4. Location of Manufacturing

The manufacturer is located at 10825 Medallion Drive, Cincinnati, Ohio 45241 (see Figure 1). The facility is located in a mixed use commercial area consisting of office buildings, warehouses, small businesses, rail yards, and light and heavy manufacturing facilities.¹

¹ Land use reconnaissance via aerial photo, Google Earth. Accessed 8/3/2015.

Figure 1. Location of the Manufacture and Major Cities



4.4.5 Location of Use

Midwest Tobacco Tube Inc. intends to distribute and sell the new tobacco products to U.S. consumers in the U.S.

4.4.6 Location of Disposal

The used and unused filtered cigarette tubes will be disposed of in municipal solid waste (MSW) landfills or as litter, in the same manner as any other marketed filtered cigarette tubes. Following use, the packaging materials would either 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 the new products contain the same components, packaging materials, and ingredients and are made to the same specifications with the exception of changes in product names (see Appendix 1).

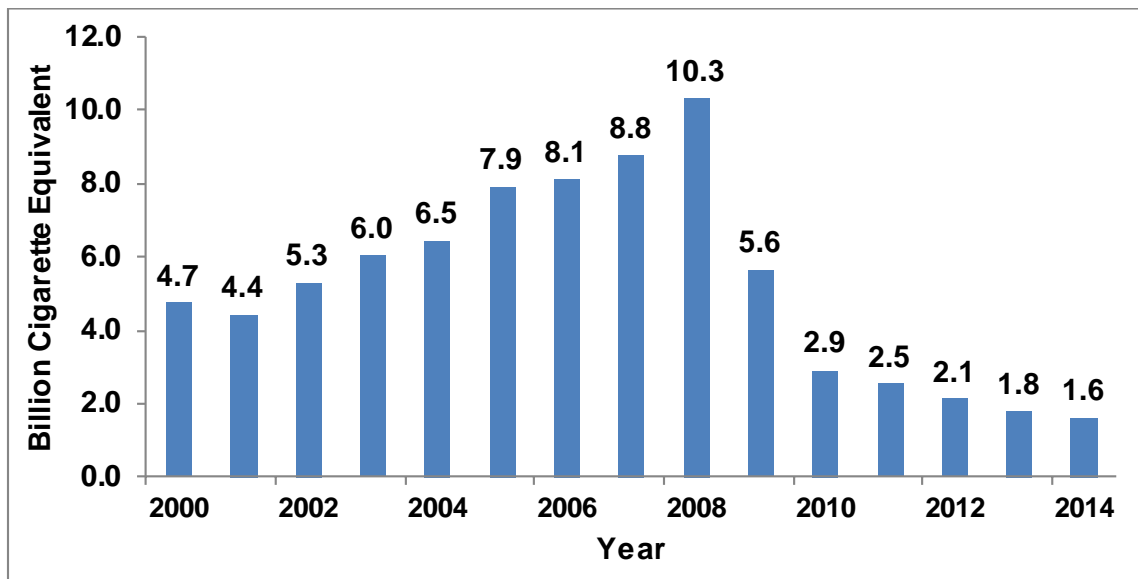
5. Environmental Introduction Due to the Proposed Action

5.1. Introduction as a Result of Manufacturing the New Products

5.1.1 Manufacturing filtered cigarette tubes

Data from the U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) statistics reports² showed a gradual linear increase in the manufacturing of RYO tobacco in the U.S. from 4.7 billion cigarette equivalents³ to 10.3 billion cigarette equivalents during the years 2000 to 2008, respectively (Figure 2). This was followed by a sharp decline in its manufacturing to 5.6 billion cigarette equivalents in 2009 and to 1.6 billion cigarette equivalents in 2014.

Figure 2. Manufactured RYO in the U.S. in 2000 – 2014 in Billion Cigarette Equivalent



² 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.

³ The calculated cigarette equivalence data is based on the conversion rate in the Master Settlement Agreement as follows:

$$A = (B \times C/D) \times E, \text{ where}$$

A = Billion cigarette equivalents

B = RYO tobacco (lbs; TTB statistics reports)

C = 453.59 (g/lb)

D = 0.9 (g tobacco/cigarette)

E = 10^{-9}

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 March 30, 2015

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 U.S. In addition, the new products are anticipated to compete with other filtered cigarette tubes on the market 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 is a change in name. 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.

The first year projected market volume for the new products is a small portion of the forecasted manufactured cigarette equivalent of RYO tobacco in the U.S. in the same year. In addition, the fifth year projected market volume for the new product is a small portion of the forecasted manufactured cigarette equivalent of RYO tobacco in the U.S. in the same year. (see Confidential Appendix 1).

Introduction from manufacturing new products in other reasonably foreseeable future actions. The environmental effects of market authorizations of the new products in this PEA (see Appendix 1) must be considered for cumulative effects along with those of other products from the same manufacturer, receiving authorizations at the same time (SE0010989-10997 and SE0011004) for two reasons: (1) the market authorizations are determined based on the comparisons to the same predicate products; and (2) the new products in this PEA, as well as in the PEA for the aforementioned SE Reports, due to the potential for concurrent marketing of the products (see Confidential Appendix 4).

Cumulative introduction of the new products. The only difference between the new products (referenced here and in SE0010989-10997 and SE0011004) and predicate products are in name. Furthermore, according to the applicant, the new products and the predicate products are manufactured in the same way, therefore, no new types of emitted constituents are expected. The quantity of emissions, however, would be expected to change once the new products are manufactured because of the potential for concurrent manufacturing of the predicate and new products.

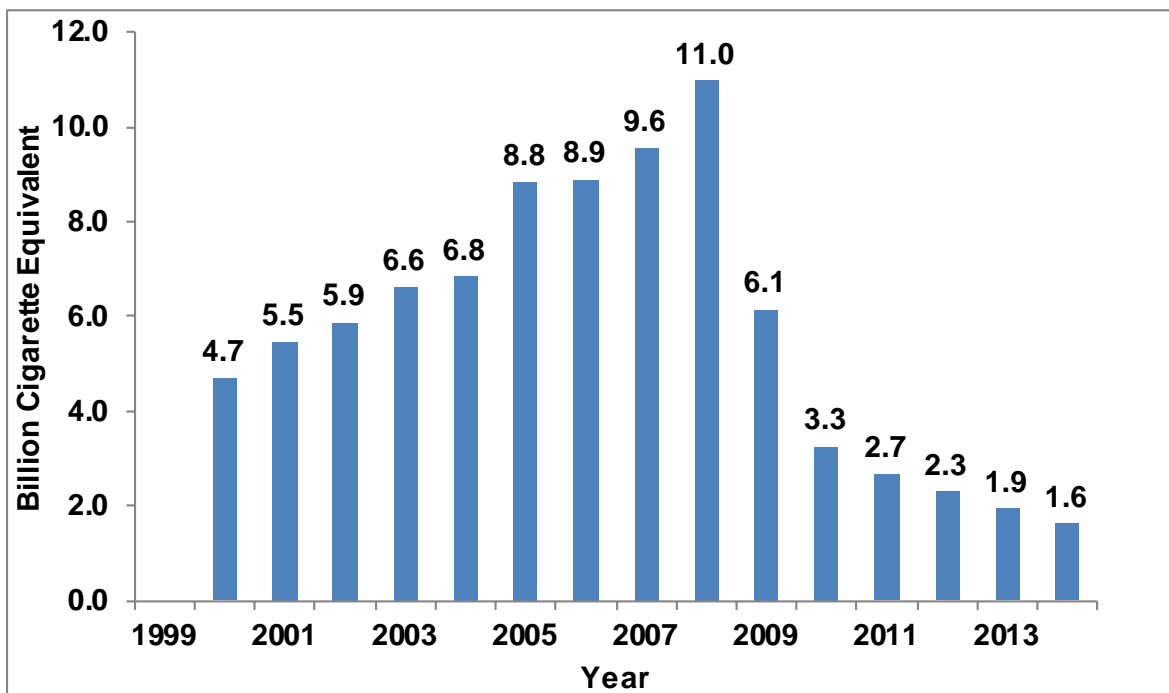
5.2. Environmental Introduction as a Result of Use of the New Products

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.

Figure 3. Use of RYO 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 products and corresponding new tobacco products is related to name changes. 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 product are released in a similar manner to those from its predicate product and other filtered cigarette tube products. The substances released 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.

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.

5.3. Environmental Introduction as a Result of Disposal Following Use

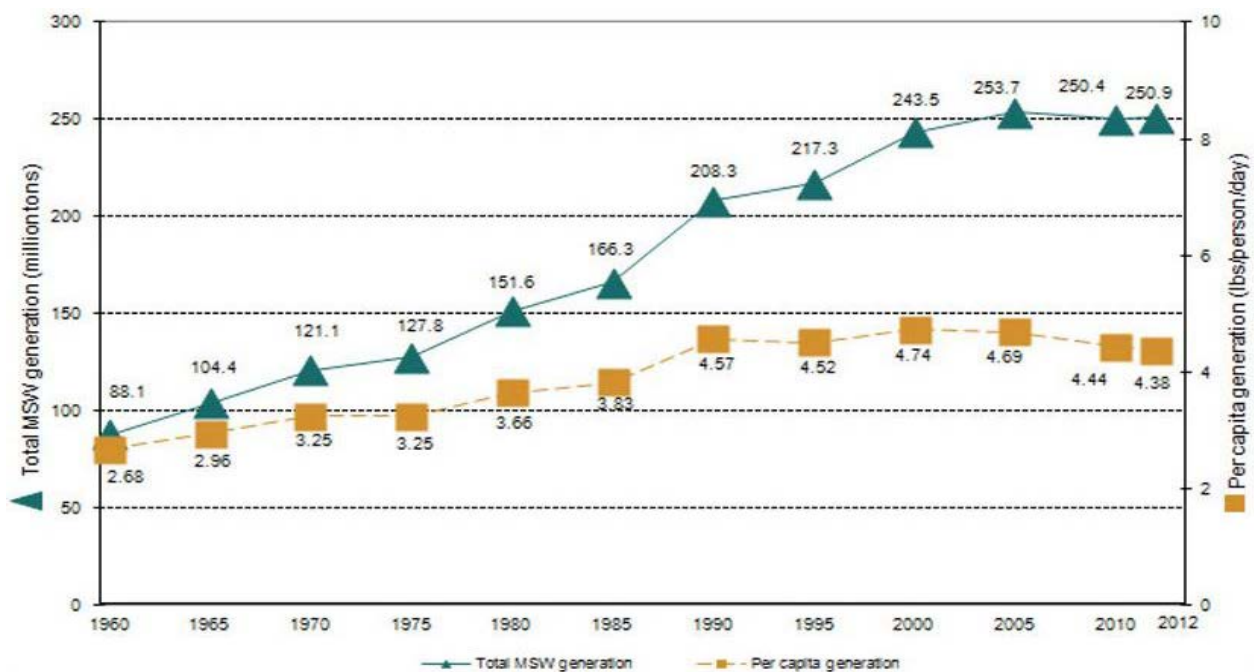
The waste that is generated following use of the new and predicate products consists of the disposed packaging materials and the discarded cigarette tube filter (tube butt). Although the paper board material is biodegradable, the filters can persist in the environment for more than 10 years.⁵

5.3.1 Disposal following use of filtered cigarette tubes

a) Disposal of packaging material

As noted above, the used filtered cigarette tubes will be disposed of in MSW landfills or as litter. Disposal of the packaging materials following use would either enter the recycling stream or be disposed of in MSW landfills or as litter. In 2012, the amount of waste generated in the U.S. was approximately 251 million tons and approximately 87 million tons of this material was recycled and composted, equivalent to a 34.5 percent recycling rate (Figure 3 and Figure 4). The recovery of newspaper/mechanical papers was about 70 percent (5.9 million tons). On average, 4.38 pounds per person per day of waste was generated, of which 1.51 pounds was recycled and composted in the U.S. in 2012.⁶

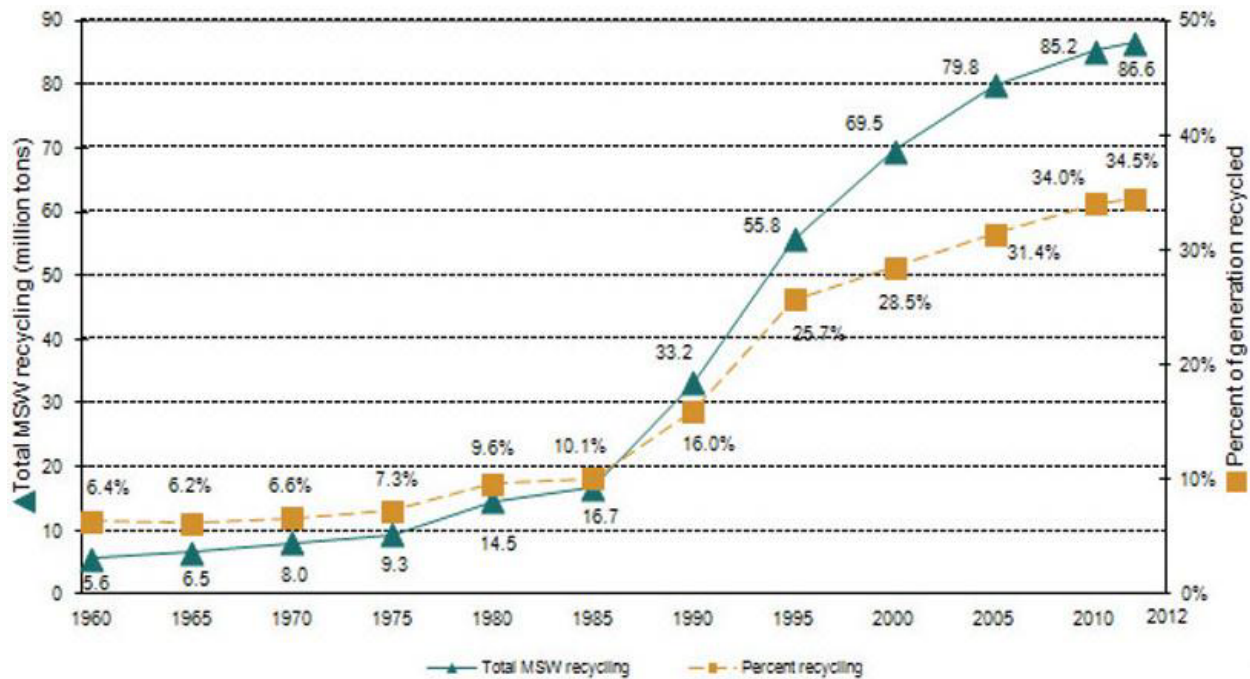
Figure 3. Municipal Solid Waste (MSW) Generation Rates in the U.S., 1960 – 2012



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

⁶ EPA. Wastes - Non-Hazardous Waste - Municipal Solid Waste. Available at: <http://www.epa.gov/waste/nonhaz/municipal/>. Accessed March 27, 2015.

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



b) Disposal of cigarette tube filters following use

A major existing environmental consequence of the 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 percent of the total waste (by count) on 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 point 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 point source for nicotine based on 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 filtered cigarette tubes

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 MSW or as litter.

a) Disposal of packaging material

The agency assumes that all packaging material of the new products will be disposed of as MSW. However, paper products are more likely to be recycled. According to the information presented in the SE Reports, the predicate products and the new products are packed the same. To determine the amount of waste from disposal of paper packaging material, the agency used the first and fifth year projected volumes of marketing the new and predicate products (Confidential Appendix 1 and 2). The calculated cumulative waste of the paper packaging material is miniscule compared to all municipal solid waste generated and 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 1 and 3). Although the waste generated from cigarette tube filters remains as an environmental concern, the calculated cumulative waste of the filters from these new products is a miniscule fraction of the 251 million tons of total waste reported in the U.S. in 2012.

Furthermore, the anticipated release of new substances into the environment as a result of disposal of the new products is miniscule compared to that of all tobacco products that are already on the market.

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 products in the same facility. Therefore, the fate of additional 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.

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.

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 expected not to exceed what is allowed to be introduced to the environment under relevant environmental laws.

Consequently, the environmental effects of the materials released due to the manufacturing of the new products are anticipated to be no more than the potential maximum effects to the environment due to the manufacturing facility. Environmental protection laws generally are based on risk to sensitive populations and threshold limits are set using safety factors to address uncertainty. Therefore, if the manufacturer remains in compliance with the existing laws, the environmental effects are expected to be below the level that would cause harm and no substantial effects are anticipated.

Furthermore, as outlined above, the amount of materials anticipated entering the environment due to use and disposal following use of the new products is negligible. Therefore, the environmental effects of the materials released due to the use and disposal following use of the new products are negligible.

8. Use of Resources and Energy

The applicant stated that the paper used to manufacture the filtered cigarette tubes is from sustainable sources and their manufacture does not appear to threaten any endangered species or critical habitat. The applicant reported that the trees used to make the wood pulp for the paper are protected by the Brazilian Forestry Sector Association and other world organizations.

Based on the information provided by the applicant (see Confidential Appendix 4), the increase in use of energy due to the proposed action is anticipated not to be substantial.

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 not substantial.

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.

Gregory G. Gagliano, MS, Center for Tobacco Products

Education: MS in Environmental Science

Experience: 32 years in environmental toxicology and risk assessment

Expertise: NEPA analysis, environmental risk assessment, endocrine disruption

12. Appendix List

Appendix 1: List of SE Reports and Related Amendments that are Covered Under this Programmatic Environmental Assessment (PEA).

Appendix 2: Appendix 2 Forecast of Manufactured RYO Cigarette Equivalents in the U.S.

13. Confidential Appendix

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

Confidential Appendix 2: The First and Fifth Year Projections of Waste of Packaging Materials Associated with Marketing the Products.

Confidential Appendix 3: The First and Fifth Year Projections of Disposed Tube filters Associated with Marketing the Products.

Confidential Appendix 4: Cumulative First and Fifth Year Market Projections of New and Predicate Products that are Addressed in Two PEAs Relevant to Multiple SE Reports from the Same Manufacturer (SE0010959-10961, SE0010965-10966, SE0010975-10976, SE00109980-10981, SE0010985-10986, and SE0010988 from one PEA, and SE0010989-10997 and SE0011004 from the second PEA).

APPENDIX 1

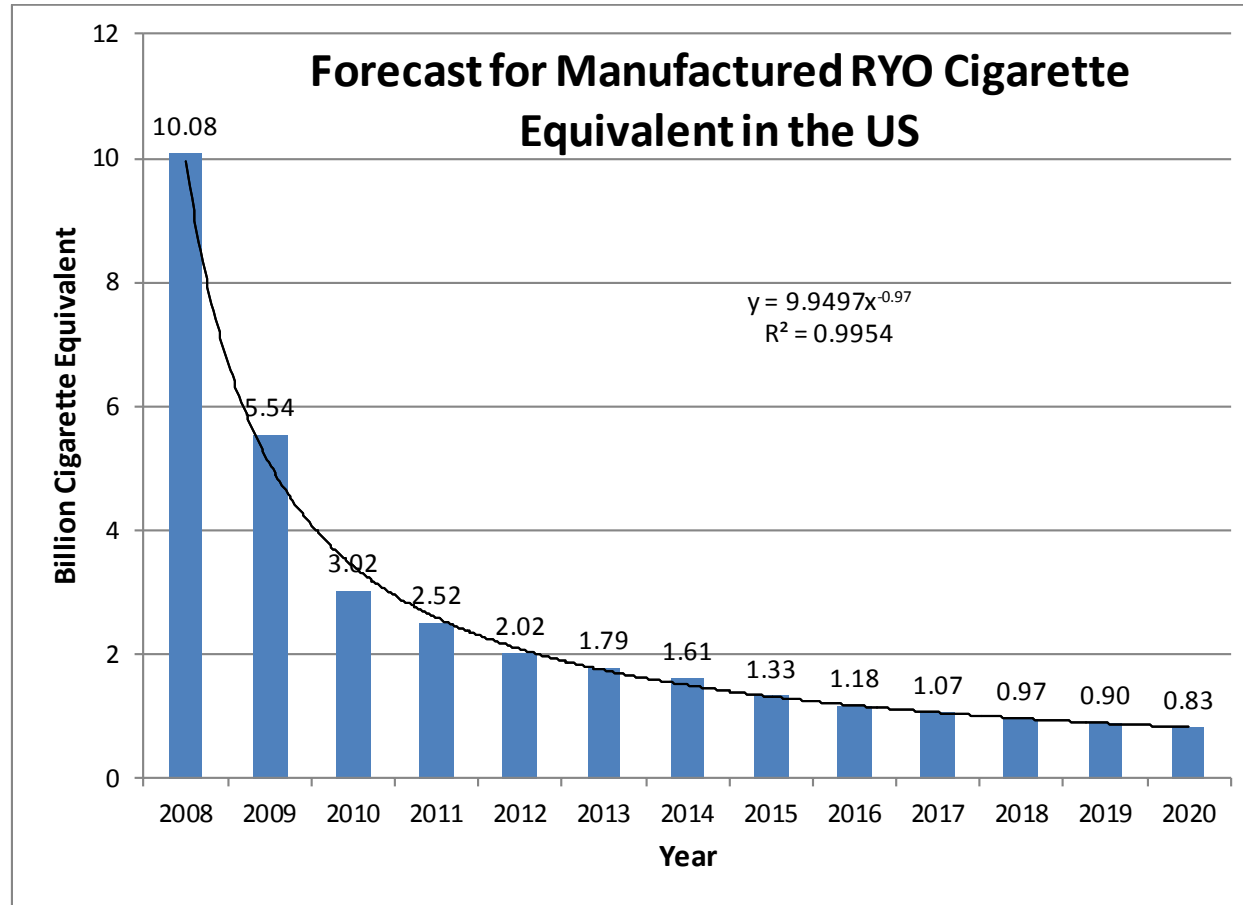
List of SE Report Submission Tracking Numbers with Names of the New and Predicate Products, and Related Amendments that are Covered Under this Programmatic Environmental Assessment (PEA)

STN	New Product	Predicate Product	Amendments
SE0010959	1839 Regular 100mm 200 Count	Cheap Tobacco Regular 100mm 200 Count	SE0011712 SE0011851
SE0010960	1839 Smooth 100mm 200 Count	Cheap Tobacco Smooth 100mm 200 Count	SE0011712 SE0011851
SE0010961	Hot Rod Regular 100mm 200 Count	Cheap Tobacco Regular 100mm 200 Count	SE0011712 SE0011851
SE0010965	Great Choice Regular 100mm 200 Count	Cheap Tobacco Regular 100mm 200 Count	SE0011712 SE0011851
SE0010966	Great Choice Smooth 100mm 200 Count	Cheap Tobacco Smooth 100mm 200 Count	SE0011712 SE0011851
SE0010975	Kentucky Select Regular 100mm 200 Count	Cheap Tobacco Regular 100mm 200 Count	SE0011712 SE0011851
SE0010976	Kentucky Select Smooth 100mm 200 Count	Cheap Tobacco Smooth 100mm 200 Count	SE0011712 SE0011851
SE0010980	Wild Bill's Regular 100mm 200 Count	Cheap Tobacco Regular 100mm 200 Count	SE0011712 SE0011851
SE0010981	Wild Bill's Smooth 100mm 200 Count	Cheap Tobacco Smooth 100mm 200 Count	SE0011712 SE0011851
SE0010985	Wild Horse Regular 100mm 200 Count	Cheap Tobacco Regular 100mm 200 Count	SE0011712 SE0011851
SE0010986	Wild Horse Smooth 100mm 200 Count	Cheap Tobacco Smooth 100mm 200 Count	SE0011712 SE0011851
SE0010988	Hot Rod Smooth 100mm 200 Count	Cheap Tobacco Smooth 100mm 200 Count	SE0011712 SE0011851

APPENDIX 2

Forecast of Manufactured RYO Cigarette Equivalents in the US

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 2020 was used to forecast the use of RYO. This was achieved by using one best-fit power trend line with the R^2 value of 0.9854. Accordingly, the forecasted amounts of cigarette equivalent use in the U.S. are estimated to be 1.18 billion cigarette equivalents in 2016 and 0.83 billion cigarette equivalents in 2020.



CONFIDENTIAL APPENDIX 1

The First and Fifth Year Market Volume Projections of the New Products and the Respective 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)
SE0010959	1839 Regular 100mm 200 Count	(b) (4)			
SE0010960	1839 Smooth 100mm 200 Count				
SE0010961	Hot Rod Regular 100mm 200 Count				
SE0010965	Great Choice Regular 100mm 200 Count				
SE0010966	Great Choice Smooth 100mm 200 Count				
SE0010975	Kentucky Select Regular 100mm 200 Count				
SE0010976	Kentucky Select Smooth 100mm 200 Count				
SE0010980	Wild Bill's Regular 100mm 200 Count				
SE0010981	Wild Bill's Smooth 100mm 200 Count				
SE0010985	Wild Horse Regular 100mm 200 Count				
SE0010986	Wild Horse Smooth 100mm 200 Count				
SE0010988	Hot Rod Smooth 100mm 200 Count				
Predicate	Cheap Tobacco Regular 100mm				
Predicate	Cheap Tobacco Smooth 100mm				

Total Projected Market Volume of the New Products	(b) (4)
Total Projected Market Volume of Predicate Products	
Total Projected Market Volume of New and Predicate Products	

Compared to the forecasted manufactured RYO cigarette equivalents in the U.S. in 2016 and 2020, 1.1 billion and 0.83 billion equivalents, the first and fifth year market volume projections occupy (b) (4) and (b) (4) of the forecasted market volume in the U.S., respectively.

CONFIDENTIAL APPENDIX 2

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 projected packaging materials waste (in tons) that is 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 (28.8 grams/box)
- E= 10^{-6} (tons/gram)

STN	Product Name	1st Year Projected Market Volume (# of Tubes)	1st Year Projected Paper Box Waste (Metric Tons)	5th Year Projected Market Volume (# of Tubes)	5th Year Projected Paper Box Waste (Metric Tons)
SE0010959	1839 Regular 100mm 200 Count	(b) (4)			
SE0010960	1839 Smooth 100mm 200 Count				
SE0010961	Hot Rod Regular 100mm 200 Count				
SE0010965	Great Choice Regular 100mm 200 Count				
SE0010966	Great Choice Smooth 100mm 200 Count				
SE0010975	Kentucky Select Regular 100mm 200 Count				
SE0010976	Kentucky Select Smooth 100mm 200 Count				
SE0010980	Wild Bill's Regular 100mm 200 Count				
SE0010981	Wild Bill's Smooth 100mm 200 Count				
SE0010985	Wild Horse Regular 100mm 200 Count				

SE0010986	Wild Horse Smooth 100mm 200 Count
SE0010988	Hot Rod Smooth 100mm 200 Count
Predicate	Cheap Tobacco Regular 100mm
Predicate	Cheap Tobacco Smooth 100mm
Total Projected Market Volume of the New Products	
Total Projected Market Volume of Predicate Products	
Total Projected Market Volume of New and Predicate Products	

(b) (4)

Paper Waste. Estimation for generated total paper waste is (b) (4) metric tons in the first year and (b) (4) 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 EPA¹¹. Therefore, if 30% of the box is disposed of as waste based on the 2012 waste generation data in the U.S., the estimated cumulative cardboard waste will be (b) (4) metric tons in the first year of marketing the products (b) (4) metric tons from the new products and (b) (4) metric tons from the predicate products). The estimated cumulative cardboard waste will be (b) (4) metric tons in the fifth year of marketing the products, (b) (4) metric tons from the new products and (b) (4) metric tons from the predicate products.

If the entire packaging cardboard is disposed of as waste, in the worst case scenario, the projected cumulative cardboard waste in the first year of marketing the products is (b) (4) metric tons (b) (4) metric tons from the new products and (b) (4) metric tons from the predicate products. In the fifth year of marketing the products, the worst case scenario for the projected cumulative cardboard waste is (b) (4) metric tons of total cardboard waste, (b) (4) metric tons from the new products and (b) (4) metric tons from the predicate products). This is a negligible fraction of the 251 million tons of total waste reported in the U.S. in 2012.

¹¹ EPA. Wastes - Non-Hazardous Waste - Municipal Solid Waste. Available at: <http://www.epa.gov/waste/nonhaz/municipal/>. Accessed January 20, 2015

CONFIDENTIAL APPENDIX 3

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 (0.2 grams for Regular filters, 0.21 grams for Smooth filters)

C= Projected market volume of the product

D=10⁻⁶ (tons/gram)

STN	Product Name	1st Year Projected Market Volume (# of Tubes)	1st Year Projected Filter Waste (Tons)	5th Year Projected Market Volume (# of Tubes)	5th Year Projected Filter Waste (Tons)
SE0010959	1839 Regular 100mm 200 Count	(b) (4)			
SE0010960	1839 Smooth 100mm 200 Count				
SE0010961	Hot Rod Regular 100mm 200 Count				
SE0010965	Great Choice Regular 100mm 200 Count				
SE0010966	Great Choice Smooth 100mm 200 Count				
SE0010975	Kentucky Select Regular 100mm 200 Count				
SE0010976	Kentucky Select Smooth 100mm 200 Count				
SE0010980	Wild Bill's Regular 100mm 200 Count				
SE0010981	Wild Bill's Smooth 100mm 200 Count				

SE0010985	Wild Horse Regular 100mm 200 Count	(b) (4)
SE0010986	Wild Horse Smooth 100mm 200 Count	
SE0010988	Hot Rod Smooth 100mm 200 Count	
Predicate	Cheap Tobacco Regular 100mm	
Predicate	Cheap Tobacco Smooth 100mm	
Total Projected Market Volume of the New Products		
Total Projected Market Volume of Predicate Products		
Total Projected Market Volume of New and Predicate Products		

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. The projected cumulative waste of cigarette tube filters in each of the first year and the fifth year of marketing the products is (b) (4) and (b) (4) tons, respectively. This is a miniscule fraction of the 251 million tons of total waste reported in the U.S. in 2012. When entering 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.

CONFIDENTIAL APPENDIX 4

Cumulative First and Fifth Year Market Projections of New and Predicate Products that are Addressed in Two PEAs Relevant to Multiple SE Reports from the Same Manufacturer (SE0010959-10961, SE0010965-10966, SE0010975-10976, SE00109980-10981, SE0010985-10986, and SE0010988 from one PEA, and SE0010989-10997 and SE0011004 from the second PEA).

	1st Year Projected Market Volumes (In Tubes)	5th Year Projected Market Volumes (In Tubes)
New Products	(b) (4)	
Predicate Products		

The cumulative projected first year market volumes represent (b) (4) and (b) (4) of the estimated total U.S. RYO market¹² (cigarette equivalents) for the new products and predicate products, respectively. The cumulative projected fifth year market volumes represent (b) (4) and (b) (4) of the estimated total U.S. RYO market (cigarette equivalents) for the new products and predicate products, respectively.

The applicant stated that the overall use trend for smoking is on the decline, the trend for RYO products has increased slightly since 2011 and the marketing forecasts do not account for the potential decline in the number of smokers. Specially, in the SE Reports the applicant said, “While the overall smoking rate is down from the last time we introduced a new brand (2010-2011), per numbers released by the U.S. Dept. of Treasury, TBB, show that the percentage of smokers who ‘roll their own’ have increased since 2010-2011.” The applicant’s interpretation of the TBB contradicts the agency’s interpretation that RYO use has been on the decline. However, the applicant also stated that historic sales data for previously introduced new products were considered for the market projection estimates. The differing interpretations of the TBB information does not change the environmental effect analysis as the trend of RYO manufacture in the U.S. has declined from 2008 to 2014 and the agency has no reason to expect that this trend will not continue. The applicant further added that the manufacturing facility has a (b)(4) and this (b)(b)(4) is expressed in the 2020 market projections. Therefore, this represents the worst case scenario.

¹² The estimated RYO market is presented in Appendix 2.