Programmatic Environmental Assessment for Market Authorizations of:

"Riverside Blue 100's, Riverside Blue Kings, Riverside Blue Kings Box, Riverside Filter 100's, Riverside Filter Kings, Riverside Filter Kings Box, Riverside Menthol 100's, Riverside Menthol Kings, Riverside Menthol Kings Box, Riverside Silver 100's, Riverside Silver Kings, Riverside Teal Menthol 100's, Riverside Teal Menthol Kings, Valu Time Filter Kings, Valu Time Filter Kings Box, Valu Time Gold 100's, Valu Time Gold Kings Box, Valu Time Menthol 100's, Valu Time Menthol Kings Box, Valu Time Silver 100's, and Valu Time Teal Menthol 100's" Found Substantially Equivalent to Their Respective Predicate Products From the Tahoe Cigarette Product Line

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

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This programmatic environmental assessment (PEA) is for the marketing authorizations "Riverside Blue 100's, Riverside Blue Kings, Riverside Blue Kings Box, Riverside Filter 100's Riverside Filter Kings, Riverside Filter Kings, Riverside Filter Kings, Riverside Menthol Kings, Riverside Menthol Kings, Riverside Silver 100's, Riverside Silver Kings, Riverside Teal Menthol 100's, Riverside Teal Menthol Kings, Valu Time Filter 100's, Valu Time Filter Kings, Valu Time Filter Kings Box, Valu Time Gold 100's, Valu Time Gold Kings Box, Valu Time Menthol 100's, Valu Time Menthol Kings Box, Valu Time Silver 100's, and Valu Time Teal Menthol 100's". Information presented in the PEA is based on the submissions referenced in Appendix 1, unless noted or referenced otherwise. Products described in SE0010338-SE0010359 are products with an alternative Fire Standard Compliant (FSC) cigarette paper supplier, which would not be used in the manufacturing process simultaneously with FSC paper used in the products describe in SE0003503-SE0003524.

This PEA has been prepared in accordance with 21 CFR 25.40 as part of submissions under section 905(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

1. Name of Applicant

S&M Brands, Inc.

2. Address

3662 Ontario Road, Keysville, VA 23947

3. Manufacturer

S&M Brands, Inc.

4. Description of the Proposed Action

The proposed action is to issue a market authorization under section 910(a)(2) of the FD&C Act for the introduction of the following new cigarette products, "Riverside Blue 100's, Riverside Blue Kings, Riverside Blue Kings Box, Riverside Filter 100's, Riverside Filter Kings, Riverside Filter Kings Box, Riverside Menthol 100's, Riverside Menthol Kings, Riverside Menthol Kings, Riverside Silver 100's, Riverside Silver Kings, Riverside Teal Menthol 100's, Riverside Teal Menthol Kings, Valu Time Filter 100's, Valu Time Filter Kings, Valu Time Filter Kings Box, Valu Time Gold 100's, Valu Time Gold Kings Box, Valu Time Menthol 100's, Valu Time Menthol Kings Box, Valu Time Silver 100's, and Valu Time Teal Menthol 100's" into interstate commerce. This authorization is based on the finding of "Substantial Equivalence" for the new products, in reference to products that were on the market as of February 15, 2007 ("predicate products").

4.1. Requested Action

Orders finding that "Riverside Blue 100's, Riverside Blue Kings, Riverside Blue Kings Box, Riverside Filter 100's Riverside Filter Kings, Riverside Filter Kings Box, Riverside Menthol 100's, Riverside Menthol Kings, Riverside Menthol Kings Box, Riverside Silver 100's, Riverside Silver Kings, Riverside Teal Menthol 100's, Riverside Teal Menthol Kings, Valu Time Filter 100's, Valu Time Filter Kings, Valu Time Gold Kings Box, Valu Time Menthol 100's, Valu Time Menthol Kings Box, Valu Time Silver 100's, and Valu Time

Teal Menthol 100's" tobacco products are substantially equivalent to predicate Tahoe products. Several of the Tahoe products were used as predicates to more than one of the new products. The Tahoe products that were identified as the predicates are: "Tahoe Light 100's, Tahoe Light Kings, Tahoe Light Kings Box, Tahoe Full Flavor 100's, Tahoe Full Flavor Kings, Tahoe Full Flavor Kings, Tahoe Menthol 100's, Tahoe Menthol Kings, Tahoe Ultra Light Kings, Tahoe Menthol Light 100's, and Tahoe Menthol Light Kings".

4.2. Need for Action

S&M Brands, Inc. is a tobacco product manufacturer located in Keysville, Virginia that manufactures cigarettes under the brands Bailey's, Tahoe, Riverside, and Valu Time. The company wishes to introduce into interstate commerce in the U.S. new Riverside and Valu Tobacco products by replacing the tobacco blends and the conventional cigarette paper in these product lines with the FSC paper and tobacco blend used in its current Tahoe brand line. The predicate products use the "Light", "Ultra Light", "Full Flavor", and "Menthol Light" descriptor in the name and S&M Brands, Inc. claims that the predicate products were commercially marketed in the United States as of February 15, 2007. The agency issued determination letters that the predicate products qualify for grandfathered status and are not subject to the premarket review requirements set forth in section 910(a)(2) of FD & C Act, as amended by the Family Smoking Prevention and Tobacco Control Act. S&M Brands, Inc. also claims that the new products and the corresponding predicate products are substantially equivalent.

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

4.3.1 Type of Tobacco Products

Conventional filtered cigarettes

4.3.2 Trade Names and UPC Numbers of Tobacco Products

A list of the new products and the predicate grandfathered (GF) products along with the grandfathered submission numbers and date of FDA GF determination is provided in Appendix 2.

4.3.3 Description of the Product Package

The packaging materials include plastic wrap, laminated paper foil, and paper cardboard that are identical for both the predicate and the new product except for the names of the product on the packaging paper. The company uses industry standard soft packs, boxes, cartons, and cases to package the products.

Each pack of cigarettes consists of twenty cigarettes and each carton consists of 10 packs. The packaging process involves loading the finished cigarettes onto the packaging machines that will wrap units of 20 cigarettes in foil and surround them by a pack paper wrap. The packs are then enclosed in polypropylene with a piece of tear tape attached. Groups of ten finished packs are automatically inserted into cartons, which are then hand packed into shipping cases and placed on pallets ready for shipping. A detailed description of the packaging materials is included in

Confidential Appendix 1.

4.3.4 Location of Manufacturing

3662 Ontario Road, Keysville, VA 23947

4.3.5 Location of Use

S&M Brands, Inc. intends to distribute and sell the new tobacco products to consumers in the United States (U.S.). Based on the CDC analysis of the National Adult Tobacco Survey and the agency calculation, the distribution of any tobacco product users matches the population distribution in the U.S.¹ For instance, there are likely more tobacco users in densely populated regions than in less populated areas.

4.3.6 Location of Disposal

Disposal of the used new cigarette products will be through deposit in municipal solid waste (MSW) landfills or as litter, in the same manner as any other marketed cigarette. Disposal of the packaging materials following use will either enter the recycling stream or be deposited in MSW landfills or as litter. The distribution of waste from disposal after use should correspond to the pattern of product use, which matches the population distribution in the U.S.

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

S&M Brands, Inc. is making certain ingredient changes in its Riverside and Valu Time brand product lines (the new products) by replacing its current components and tobacco blend with the identical components and tobacco blend used in the company's Tahoe brand line (the predicates). While the new and predicate tobacco products will have the same components and tobacco blend, they will differ in the name and use of FSC cigarette papers. Therefore, the new tobacco products will be branded as either Riverside or Valu Time and include FSC cigarette paper. Additional information on the modifications in the new products compared with the predicate products is provided in the Confidential Appendix 2 attached to this PEA.

5. Environmental Introduction Due to the Proposed Action

5.1. Introduction as a Result of Manufacturing the New Products

5.1.1 Existing condition of cigarette manufacturing

As of February 2014, a total of seventy-three tobacco production establishments are registered under 905(b) of the FD&C Act. These manufacturers produced cumulatively 580.62 million pounds of cigarettes (292.63 billion cigarettes or 14.63 billion packs of 20 cigarettes each) in 2013.^{2,3} According to the Attorney General of Virginia, there are 29 different tobacco

¹ King B.A., Dube, S.R., and Tynan, M.A., 2012 "Current Tobacco Use Among Adults in the United States: Findings from the National Adult Tobacco Survey," American Journal of Public Health. The tobacco products in this survey include cigarettes, chewing tobacco, snuff, dip, snus, cigars, cigarillos, small cigars, water pipes, or pipes.

² The calculated cumulative tobacco includes cigarettes, larges cigars, cigarillos, pipe, snuff, and chewing tobacco, assuming that each cigarette or cigarillos contains 0.9 grams tobacco and the large cigar 14.175 grams (a half

manufacturers registered in the State of Virginia as of March 2014. However, only ten facilities report toxic substance release to the Environmental Protection Agency (EPA). This is due to the fact that the EPA's Toxic Substance Release Inventory (TRI) database only includes toxic release data of facilities that (1) fall within a TRI-reportable industry sector or are federally-owned or operated; (2) has 10 or more full-time (or equivalent) employees; and (3) manufactures, processes or otherwise uses (MPOU) a TRI-listed chemical in an amount above the TRI reporting threshold during a calendar year. A search of the EPA's databases, including TRI database, did not show any reported toxic substance release by S&M Brands, Inc. indicating that the manufacturer does not fall within this category of reporting.

Based on the reports from facilities that have solid waste management permits in the state of Virginia, a total of 20,255,675.15 tons of solid waste was received at these facilities during calendar year 2012. Of this total, 14,877,701.90 tons originated in the Commonwealth and 5,377,973.25 tons originated from other jurisdictions. Municipal solid waste (MSW) constituted 11,929,167.91 tons of the total amount of solid waste received during calendar year 2012. Of the total MSW received, 8,268,439.89 tons originated in the Commonwealth and 3,660,728.02 tons originated from other jurisdictions (Table 1).

Table 1. Waste, in Tons, Reported by Facilities with Solid Waste Management Permits in the State of Virginia in 2012

Type of Waste	Tons
Total Solid Waste Received by Facilities	20,255,675
Waste Originated in the Commonwealth	14,877,702

ounce equivalent) based on information on the American Cancer Society website. Cigar smoking. Available at http://www.cancer.org/acs/groups/cid/documents/webcontent/002965-pdf.pdf. Accessed May19, 2014.

http://www.deq.state.va.us/Portals/0/DEQ/Land/SolidWaste/2013_Annual_Solid_Waste_Report.pdf. Accessed May 22, 2014.

³ Department of the Treasury Alcohol and Tobacco Tax and Trade Bureau: Statistical Report – Tobacco for December 2013. Issued February 2014. Available at: http://www.ttb.gov/statistics/2013/201312tobacco.pdf. Accessed on May 19, 2014.

⁴ Virginia.gov. Tobacco Product Manufacturer Requirements and Resources: Virginia Tobacco Directory. Available at: http://www.ag.virginia.gov/Opinions%20and%20Legal%20Resources/Tobacco/VA_Directory/. Accessed May 20, 2014.

⁵ U.S. Environmental Protection Agency (EPA). Toxics Release Inventory (TRI). Available at: http://www.epa.gov/enviro/facts/tri/form_ra_download.html. Accessed May 20, 2014.

⁶ The EPA TRI is a database that allows user 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 tobacco manufacture industry is retrieved by using North American Industry Classification System (NAICS) codes beginning with 3122. Available at: http://www2.epa.gov/toxics-release-inventory-tri-program/learn-about-toxics-release-inventory. Accessed May 22, 2014.

Virginia Department of Environmental Quality. Solid waste managed in Virginia during calendar year 2012. June, 2013. Available at:

Waste Originated from Other Jurisdiction	5,377,973
Total Municipal Solid Waste (MSW)	11,929,167
MSW Originated in the Commonwealth	8,268,439
MSW Originated from Other Jurisdiction	3,660,728

5.1.2 Environmental introduction from manufacturing the new products

The agency anticipates the waste generated as a result of manufacturing the new products to be released to the environment, transferred to Publicly Owned Treatment Works (POTWs), and disposed of in landfills in the same manner as the other products manufactured in the same facility and products manufactured by other industries. The applicant stated that the predicate is a non-FSC cigarette that is no longer being manufactured and cannot be sold in interstate commerce. However, the company continues to manufacture its Tahoe brand line with FSC paper, as these products were commercially marketed after February 15, 2007 but before March 22, 2011. The applicant provided the amount of the annual solid waste generated from manufacturing its Riverside, Valu Time and FSC Tahoe products. Compared to the 2012 data of solid waste received by facilities with solid waste permits in the state of Virginia, the individual and cumulative solid waste generated by the manufacturing is negligible (Confidential Appendix 5). Since the new product is replacing the predicate product, the FDA does not anticipate the solid waste to significantly increase due to the manufacturing of the new products.

Based on information in the SE Reports, any differences between the new products and the predicate products are a direct result of the differences between the conventional cigarette paper and FSC cigarette paper used in these products. The majority of the increases in ingredients seen in the new cigarette at levels below 0.06% are a result of various organic salts, which are characteristics of FSC cigarette paper that is commonly used in the tobacco industry. Therefore, the FDA 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.

Furthermore, the individual and cumulative projected market volumes in the first and fifth years of marketing the new products, including the Tahoe product line with FSC cigarette paper, are less than 1% of the 292.63 billion cigarettes that are manufactured in the U.S. in 2013 (Confidential Appendix 3). Therefore, the amount of the release of material mass into the environment as a result of manufacturing the products is negligible compared to that of all tobacco products manufactured in the U.S.

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

5.2.1 Existing condition of cigarette use

Total consumption of cigarettes continued to decline in the U.S. and was estimated at 277.83 billion cigarettes in 2013 (13.89 billion packs equivalent to 551.26 million pounds) and the per capita consumption was 920 cigarettes (46 packs).⁸

⁸ Department of the Treasury Alcohol and Tobacco Tax and Trade Bureau: Statistical Report – Tobacco for

When using cigarettes, the users inhale the main stream smoke and they also release tobacco specific nitrosamines through excretion into the water. Cigarette users also release environmental tobacco smoke (secondhand smoke) to the environment. Secondhand smoke (SHS) is classified as a "known human carcinogen" by EPA, the U.S. National Toxicology Program, and the International Agency for Research on Cancer (IARC – a branch of the World Health Organization (WHO)). SHS has been linked to lung cancer with some evidence suggesting it might be linked to other forms of cancer in children and cancers of the larynx, pharynx (throat), nasal sinuses, brain, bladder, rectum, stomach, and breast in adults. About 40 percent of all children are regularly exposed to SHS at home, and almost a third of the deaths attributable to SHS are in children. A recent study found SHS led to a thickening of children's artery walls, adding some 3.3 years to the age of blood vessels by adulthood.

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 a change from non-FSC to FSC cigarette paper. The differences in the tar, nicotine, and carbon monoxide (TNCO) yields between the new and predicate tobacco products were negligible from the environmental perspective (Confidential Appendix 2).

Moreover, the predicate product is no longer on the market. Assuming that all manufactured products will be used in the U.S, the individual and cumulative projected volumes of consumption in the first and fifth years of marketing the new products, including the Tahoe product line with FSC cigarette paper, are less than 1% of the 277.83 billion cigarettes consumed in the U.S. in 2013 (Confidential Appendix 4). Therefore, the amount of the release of material mass into the environment as a result of use of the products is negligible.

5.3. Environmental Introduction as a Result of Disposal Following Use

The waste that is generated due to cigarette consumption consists of cigarette butts (filters), packages, cellophane wrappers, and cartons. Although the paper and tobacco components are

December 2013. Issued February 2014. Available at: http://www.ttb.gov/statistics/2013/201312tobacco.pdf. Accessed on May 22, 2014.

⁹ Andra S and Makris KC. Tobacco-specific nitrosamines in water: An unexplored environmental health risk. Environmental International. 2011; 37(2):412-417.

¹⁰ International Agency for Research on Cancer (IARC). Second-Hand Tobacco Smoke Monograph. Available at: http://monographs.iarc.fr/ENG/Monographs/vol100E/mono100E-7.pdf. Accessed May 20, 2014.

¹¹ EPA. Health effects of exposure to second hand smoke. Available at: http://www.epa.gov/smokefree/healtheffects.html. Accessed May 20, 2014

¹² World Health Organization (WHO). Tobacco Facts Sheet. July 2013. Available at: http://www.who.int/mediacentre/factsheets/fs339/en/. Accessed May 20, 2014

¹³ Gall S, Huynh QH, Magnussen GC, Juonala M, Viikari J S-A, Kähönen M, Dwyer T, Raitakari OT, and Venn A. Exposure to parental smoking in childhood or adolescence is associated with increased carotid intima-media thickness in young adults: Evidence from the cardiovascular risk in young Finns study and the childhood determinants of adult health study. *European Heart Journal*. Advance Access May 20, 2014.

biodegradable, the filters and plastic wrappers can persist in the environment for more than 10 years. ¹⁴

5.3.1 Existing condition of disposal following cigarettes use

a) Disposal of packaging material

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 1 and Figure 2). The recovery of newspaper/mechanical papers was about 70 percent (5.9 million tons) and recovery for polypropylene waste was 30.8%. 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 2012.¹⁵

¹⁴ Novotny TE and Zhao F. Consumption and production waste: Another externality of tobacco use. Tobacco Control 1999;8:75-80.

¹⁵ EPA. Wastes - Non-Hazardous Waste - Municipal Solid Waste. Available at: http://www.epa.gov/waste/nonhaz/municipal/. Accessed May 23, 2014.

Figure 1. Municipal Solid Waste (MSW) Generation Rates in the U.S, 1960 - 2012

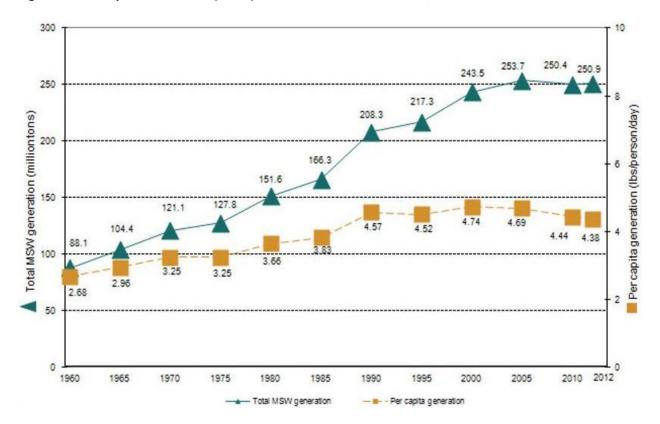
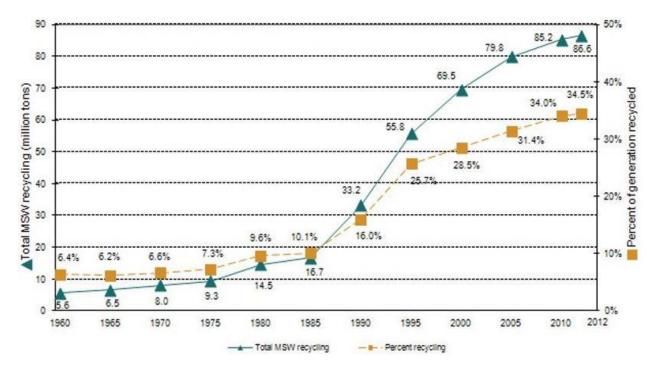


Figure 2. MSW Recycling Rates in the U.S.



b) Disposal of cigarette butts following use

A major existing environmental consequence of cigarette use is the waste disposal of discarded cigarette filters, as an estimated 4.5 trillion cigarette butts are thrown away every year worldwide and 1.69 billion pounds of cigarette butts are disposed of as toxic trash each year. 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 cigarette 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 waste. 18

Cigarette filters most commonly contain cellulose acetate and may persist under normal environmental conditions for 18 months to 10 years. ^{19,20} Cigarette filters were found to be a point source for metal contamination, based on a research done to allow a gradual release of multiple metals from the cigarette filter over the full 34-day study period. ²¹

5.3.2 Environmental introduction of disposal following cigarettes use

After using the new product, the users may dispose of or recycle the packaging paper material. Users may also discard the cigarette butts and ashes as municipal solid waste (MSW) or as litter.

a) Disposal of packaging material

According to the information presented in the SE Reports, the predicate products and the new products are packed similarly. 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 products. The calculated cumulative waste of foil and polypropylene wrap is negligible compared to the amount of municipal solid waste generated in 2012 (Confidential Appendix 6). Likewise, the waste generated from the paper packaging material is miniscule compared to all municipal solid waste generated and is likely to be recycled.

¹⁶ Novotny TE, Hardin SN, Hovda LR, Novonty DJ, McLean MK, Khan S. Tobacco and Cigarette Butt Consumption in Humans and Animals. *Tobacco Control* 2011;20(Suppl. 1):i17-i20. Available at: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3088460/. Accessed May 22, 2014.

¹⁷ Smith, EA and Novotny, TE. Whose butt is it? Tobacco industry research about smokers and cigarette butt waste. *Tobacco Control* 2011;20(Suppl. 1):i2-i9.

¹⁸ 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/tclcguide-cigarette-waste-2014.pdf. Accessed May 22, 2014.

¹⁹ 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.).

²⁰ Ach A. Biodegradable plastics based on cellulose acetate. *Journal of Macromolecular Science: Pure and Applied Chemistry* 1993;A30:733–40.

²¹ Moerman, JW; Potts, GE. Analysis of metals leached from smoked cigarette litter. *Tobacco Control*. 2011;20(Suppl. 1):I30-I35.

b) Disposal of cigarette butts

To calculate the weight of cigarette butts generated from the 277.83 billion cigarettes consumed in the U.S. in 2013, the agency assumed that the weight of a cigarette butt is 20% of the weight of a cigarette, the consumed cigarettes were of the 100's type, and the weight of each cigarette is 1.2 grams. Based on these assumptions, the agency estimated that cigarette consumption in the U.S generated 66.68 billion tons of cigarette butt waste in 2013. Although cigarette butt waste remains as an environmental concern, the agency estimated the amount of waste generated from disposal of cigarette butts after use of the new products to be negligible in the first and fifth years of marketing the new products, with a projected cumulative amount less than 1% of the total cigarette butt waste generated in the U.S. in 2013 (Confidential Appendix 6).

Furthermore, the new products have a change to FSC paper and substitution of certain ingredients that are commonly used in another product line. The anticipated release of new substances into the environment as a result of disposal of the products is minuscule compared to that of all tobacco products used in the U.S.

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

The new products have a change to FSC paper and substitution of certain ingredients that are commonly used in another product line; therefore, the agency does not anticipate the proposed action to release new chemicals into the environment.

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

The environmental effects of the materials released due to the manufacturing, use, and disposal following use are negligible compared to those of marketed cigarettes since the amount of materials anticipated to enter the environment due to the proposed action is miniscule, if any.

8. Use of Resources and Energy

The agency anticipates the new products to replace the predicate and compete with other tobacco products currently on the market, as noted. Furthermore, the market volumes of the new products are a negligible fraction of the total cigarettes consumed in the U.S. in 2013. Accordingly, the use of resources and energy due to the proposed action is negligible.

9. Mitigation

No adverse environmental effects are identified based upon the agency's review of the available data and information for the new products and their proposed use. 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 tobacco products to be marketed in the U.S. The environmental impact of this action would not change the existing condition due to the manufacture, use, and disposal from use of the tobacco products.

Alternative B (Proposed action): There is virtually no 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. Appendix List

- Appendix 1: List of SE Reports and Related Amendments that are Covered Under this Programmatic Environmental Assessment (PEA)
- Appendix 2: List of Submissions by SE Numbers, Trade Names and UPC Numbers of New Products and Predicate Products.

12. Confidential Appendix

- Confidential Appendix 1: Identity of the Packaging Materials Used in the New and Predicate Products
- Confidential Appendix 2: SE Numbers, Trade Names, and UPC Numbers for New Products and Trade Names, UPC Numbers and Grandfathered Determination Information for Respective Predicate Products
- Confidential Appendix 3: Percentage of the First and Fifth Year Market Volume Projections of the Manufactured New Products in Relation to the 2013 Market Volume of the Total Manufactured Cigarettes in the U.S.
- Confidential Appendix 4: Percentage of the First and Fifth Year Market Volume Projections of Use of the Product Lines in Relation to the 2013 Total Number of Used Cigarettes in the U.S.
- Confidential Appendix 5: Percentage of Solid Waste of the New Manufactured Product Lines in Relation to the Total Solid Waste Received by Facilities with Solid Waste Management Permits in the Commonwealth of Virginia in 2012
- Confidential Appendix 6: The First and Fifth Year Market Projections of Waste Associated with Marketing the New Products

APPENDIX 1

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

SE#	SE # for Same Product with (b) (4)	New Product	Amendments
0003503	0010338	Riverside Blue 100's	SE0010478, SE0010378, SE0010286, SE0010201, SE0009623, SE0008151, SE0004152, SE0004185, SE0005332
0003504	0010339	Riverside Blue Kings	SE0010478, SE0010378, SE0010286, SE0010201, SE0009623, SE0008151, SE0004152, SE0005335
0003505	0010340	Riverside Blue Kings Box	SE0010478, SE0010378, SE0010286, SE0010201, SE0009623, SE0008151, SE0004152, SE0004127, SE0005346
0003506	0010341	Riverside Filter 100's	SE0010478, SE0010378, SE0010286, SE0010201, SE0009623, SE0008151, SE0004152, SE0004078, SE0005333
0003507	0010342	Riverside Filter Kings Box	SE0010478, SE0010378, SE0010286, SE0010201, SE0009623, SE0008151, SE0004152, SE0004184, SE0005341, SE0007808
0003508	0010343	Riverside Filter Kings	SE0010478, SE0010378, SE0010286, SE0010201, SE0009623, SE0008151, SE0004152, SE0004182, SE0005336, SE0007809
0003509	0010344	Riverside Menthol 100's	SE0010478, SE0010378, SE0010286, SE0010201, SE0009623, SE0008151, SE0004152, SE0004160, SE0005331
0003510	0010345	Riverside Menthol Kings	SE0010478, SE0010378, SE0010286, SE0010201, SE0009623, SE0008151, SE0004152, SE0004161, SE0005339
0003511	0010346	Riverside Menthol Kings Box	SE0010478, SE0010378, SE0010286, SE0010201, SE0009623, SE0008151, SE0004152, SE0004181, SE0005334
0003512	0010347	Riverside Silver 100's	SE0010478, SE0010378, SE0010286, SE0010201, SE0009623, SE0008151, SE0004152, SE0004553, SE0005329
0003513	0010348	Riverside Silver Kings	SE0010478, SE0010378, SE0010286, SE0010201, SE0009623, SE0008151, SE0004152, SE0004551, SE0005345

²²(b) (4)

SE#	SE # for Same Product with	New Product	Amendments
	(b) (4)		
0003514	0010349	Riverside Teal Menthol	SE0010478, SE0010378, SE0010286,
		100's	SE0010201, SE0009623, SE0008151,
			SE0004152, SE0004552, SE0005330
0003515	0010350	Riverside Teal Menthol	SE0010478, SE0010378, SE0010286,
		Kings	SE0010201, SE0009623, SE0008151,
			SE0004152, SE0004555, SE0005340
0003516	0010351	Valu Time Filter 100's	SE0010478, SE0010378, SE0010286,
			SE0010201, SE0009623, SE0008151,
			SE0004152, SE0004554, SE0005338
0003517	0010352	Valu Time Filter Kings	SE0010478, SE0010378, SE0010286,
			SE0010201, SE0009623, SE0008151,
			SE0004152, SE0004556, SE0005354,
27			SE0007810
0003518	0010353	Valu Time Filter Kings	SE0010478, SE0010378, SE0010286,
111		Box	SE0010201, SE0009623, SE0008151,
			SE0004152, SE0004151, SE0005353,
			SE0007811
0003519	0010354	Valu Time Gold 100's	SE0010478, SE0010378, SE0010286,
			SE0010201, SE0009623, SE0008151,
			SE0004152, SE0004079, SE0005342
0003520	0010355	Valu Time Gold Kings	SE0010478, SE0010378, SE0010286,
	The Control of the Co	Box	SE0010201, SE0009623, SE0008151,
			SE0004152, SE0004080, SE0005352
0003521	0010356	Valu Time Menthol 100's	SE0010478, SE0010378, SE0010286,
			SE0010201, SE0009623, SE0008151,
			SE0004152, SE0004129, SE0005356
0003522	0010357	Valu Time Menthol Kings	SE0010478, SE0010378, SE0010286,
1011	11	Box	SE0010201, SE0009623, SE0008151,
			SE0004152, SE0004126, SE0005355
0003523	0010358	Valu Time Silver 100's	SE0010478, SE0010378, SE0010286,
		manufactures of the second of	SE0010201, SE0009623, SE0008151,
			SE0004152, SE0004128, SE0005343
0003524	0010359	Valu Time Teal Menthol	SE0010478, SE0010378, SE0010286,
Constitution of the state of th		100's	SE0010201, SE0009623, SE0008151,
			SE0004152, SE0004150, SE0004183,
			SE0005344

APPENDIX 2

SE Numbers, Trade Names, and UPC Numbers for New Products and Trade Names, UPC Numbers and Grandfathered Determination Information for **Respective Predicate Products**

SE#	New Product, UPC #	Non-FSC Predicate Product, 23	GF Submission #
		UPC#	and Date of GF
			Determination
0003503,	Riverside Blue 100's,	Tahoe Light 100's,	GF1200053;
0010338	000710405096	000710200066	6/20/2012
0003504,	Riverside Blue Kings,	Tahoe Light Kings,	GF1200046;
0010339	000710400022	000710200011	8/27/2012
0003505,	Riverside Blue Kings Box,	Tahoe Light Kings,	GF1200051;
0010340	000710400039	000710200011	6/11/2012
0003506,	Riverside Filter 100's,	Tahoe Full Flavor 100's,	GF1200052;
0010341	000710405089	00071020059	8/27/2012
0003507,	Riverside Filter Kings Box,	Tahoe Full Flavor Kings,	GF1200050;
0010342	000710400015	000710200004	11/15/2012
0003508,	Riverside Filter Kings, 00071	Tahoe Full Flavor Kings,	GF1200045;
0010343	0400008	000710200004	8/27/2012
0003509,	Riverside Menthol 100's,	Tahoe Menthol 100's,	GF1200055;
0010344	000710405102	000710200073	6/20/2012
0003510,	Riverside Menthol Kings,	Tahoe Menthol Kings,	GF1200048;
0010345	000710400060	00710200028	8/27/2012
0003511,	Riverside Menthol Kings Box,	Tahoe Menthol Kings, 0071	GF1200048;
0010346	000710400053	0200028	8/27/2012
0003512,	Riverside Silver 100's,	Tahoe Ultra Light 100's,	GF1200054;
0010347	000710405126	00710200042	6/25/2012
0003513,	Riverside Silver Kings,	Tahoe Ultra Light Kings,	GF1200047;
0010348	000710400077	00710200042	6/25/2012
0003514,	Riverside Teal Menthol 100's,	Tahoe Menthol Light 100's,	GF1200056;
0010349	000710405119	000710200080	6/25/2012
0003515,	Riverside Teal Menthol Kings,	Tahoe Menthol Light Kings,	GF1200049;
0010350	000710400060	000710200035	6/25/2012
0003516,	Valu Time Filter 100's,	Tahoe Full Flavor 100's,	GF1200052;
0010351	011225070310	00071020059	8/27/2012
0003517,	Valu Time Filter Kings,	Tahoe Full Flavor Kings,	GF1200045;
0010352	011225070242	000710200004	8/27/2012
0003518,	Valu Time Filter Kings Box,	Tahoe Full Flavor Kings Box,	GF1200050;
0010353	011225070440	000710200103	11/15/2012
0003519,	Valu Time Gold 100's,	Tahoe Light 100's, 00071	GF1200053;
0010354	011225070327	0200066	6/20/2012
0003520,	Valu Time Gold Kings Box,	Tahoe Light Kings Box,	GF1200051;

²³ Tahoe predicate product lines with non-Fire Safe Cigarette (FSC) papers

SE#	New Product, UPC #	Non-FSC Predicate Product, ²³ UPC #	GF Submission # and Date of GF Determination
0010355	011225070471	000710200110	6/11/2012
0003521,	Valu Time Menthol 100's,	Tahoe Menthol 100's,	GF1200055;
0010356	011225070358	000710200073	6/20/2012
0003522,	Valu Time Menthol Kings Box,	Tahoe Menthol Kings,	GF1200048;
0010357	011225070501	00710200028	8/27/2012
0003523,	Valu Time Silver 100's,	Tahoe Ultra Light 100's,	GF1200054;
0010358	011225070419	00710200042	6/25/2012
0003524,	Valu Time Teal Menthol	Tahoe Menthol Light 100's,	GF1200056;
0010359	100's, 011225070389	000710200080	6/25/2012

Identity of the Packaging Materials Used in the New and Predicate Products

All products are packaged in soft packs unless box is listed in the product name. For the grandfathered products, all products listed are soft pack unless crush proof box (CPB) is listed in the product name.

In addition to paper and cardboard, the packaging material consists of:

<u>Laminated Paper Foil:</u> Outside structure schematic consists	of (b) (4)
(b) (4)	
(b) (4)••	
Film: Made of polypropylene with (b) (4)	
<u>Tear Tape:</u> the total thickness of the (b) (4)	
	.24 The product complies with the Packaging
(Essential Requirements) Regulations 1998. It is recyclable.	

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 $^{^{24}\} http://legacy.library.ucsf.edu/documentStore/k/j/f/kjf51c00/Skjf51c00.pdf$

Weight of Packaging Material:

The applicant provided the weight of each packaging material and the dimensions of each cigarette pack. The agency utilized the weight of the wrap of the pack and the ratio of surface area of the carton to the pack (calculated using the dimensions) to estimate the weight of polypropylene wrap around the carton. The agency estimated the total weight of polypropylene wrap and paper for the carton and 10 packs, as follows:

 $A = [B \times C] + D$, where

A= Total weight of the packaging material for 10 cigarette packs and a 10-pack Carton (grams)

B = Weight of the packaging material of the individual pack (grams)

C= 10 (number of packs/carton)

D= Weight of packaging material of the 10-pack carton (grams)

Product Type	Weight of Wrap of a Pack (gram)	Weight of Wrap of a 10- pack Carton (gram)	Total Weight of Wrap of 10 packs and a 10-Pack Carton (gram)	Weight of the Foil of a Pack (gram)	Weight of Paper of a Pack (gram)	Weight of Paper of a 10- Pack Carton (gram)	Total Weight of Paper of 10 Packs and a 10- Pack Carton (gram)
100's Soft Pack	0.42	1.79382	5.99382	1.2	1.35	19.92	33.42
King Soft Pack	0.35	1.5001	5.0001	1.05	1.67	18.02	34.72
King Box Riverside	0.38	1.62868	5.42868	1.05	4.38	18.79	62.59
King Box Valu		1.62868					
Time	0.38		5.42868	1.05	4.38	18.79	62.59
King Box Tahoe	0.38	1.62868	5.42868	1.05	5.24	18.79	71.19

Modifications in the New Products Compared to the Grandfathered Predicate Products

- New Product contains additiona (b) (4) (paper burn additive) and has higher porosity cigarette paper due to use of fire safe (FSC) cigarette paper.
- Percent change in other attributes and constituents are presented in this table:

SE#	New Product Name	Puff C	Counts Filter Efficiency		Puff Counts		Filter Efficiency		Filter Efficiency		lainstream noke		otine in eam Smoke		onoxide in am Smoke
		ISO ²⁵	CI ²⁶	ISO	CI	ISO	CI	ISO	CI	ISO	CI				
0003503	Riverside Blue 100's	(b) (4)													
0003504	Riverside Blue Kings														
0003505	Riverside Blue Kings Box														
0003506	Riverside Filter 100's														
0003507	Riverside Filter Kings Box														
0003508	Riverside Filter Kings	Š													
0003509	Riverside Menthol 100's														
0003510	Riverside Menthol Kings														
0003511	Riverside Menthol Kings Box														
0003512	Riverside Silver 100's														
0003513	Riverside Silver Kings														
0003514	Riverside Teal Menthol 100's														
0003515	Riverside Teal Menthol Kings														
0003516	Valu Time Filter 100's														
0003517	Valu Time Filter Kings														
0003518	Valu Time Filter Kings Box														
0003519	Valu Time Gold 100's	S													
0003520	Valu Time Gold Kings Box														
0003521	Valu Time Menthol 100's														

²⁵ International Standards Organization (ISO) smoking regimen

²⁶ Health Canada Intense (CI) smoking regimen

²⁷ Not determined since it is similar to the product in SE0003504 but in a box in lieu of soft pack

SE#	New Product Name	Puff Counts	Filter Efficiency	Tar in Mainstream Smoke	Nicotine in Mainstream Smoke	Carbon Monoxide in Mainstream Smoke
0003522	Valu Time Menthol Kings Box	(b) (4)				
0003523	Valu Time Silver 100's					
0003524	Valu Time Teal Menthol 100's					

Percentage of the First and Fifth Year Market Volume Projections of the Manufactured New Products in Relation to the 2013 Market Volume of Total Manufactured Cigarettes in the U.S.²⁸

Product Name	First Year Market Volume (# of packs)	% of Total Manufactured Cigarettes in the U.S.	Fifth Year Market Volume (# of packs)	% of Total Manufactured Cigarettes in the U.S.
Riverside Blue 100's	(b) (4)			
Riverside Blue Kings				
Riverside Blue Kings Box				
Riverside Filter 100's				
Riverside Filter Kings Box				
Riverside Filter Kings				
Riverside Menthol 100's				
Riverside Menthol Kings				
Riverside Menthol Kings Box				
Riverside Silver 100's				
Riverside Silver Kings				
Riverside Teal Menthol 100's				
Riverside Teal Menthol Kings				
Valu Time Filter 100's				
Valu Time Filter Kings				
Valu Time Filter Kings Box				
Valu Time Gold 100's				
Valu Time Gold Kings Box				
Valu Time Menthol 100's	1			
Valu Time Menthol Kings Box				
Valu Time Silver 100's				
Valu Time Teal Menthol 100's				
Total Riverside & Valu Time Products				
Tahoe Filter 100's				

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²⁸ The Tahoe product lines with FSC cigarette papers were introduced or delivered for introduction into interstate commerce for commercial distribution in the United States between February 15, 2007 and March 22, 2011. In addition, these new products had 905(j) Reports submitted to FDA by March 22, 2011. As such, these products are legally marketed and may remain on the market unless FDA finds the products not substantially equivalent to the predicate.

Product Name	First Year Market Volume (# of packs)	% of Total Manufactured Cigarettes in the U.S.	Fifth Year Market Volume (# of packs)	% of Total Manufactured Cigarettes in the U.S.
Tahoe Filter Kings	(b) (4)			
Tahoe Filter Kings Box				
Tahoe Gold 100's				
Tahoe Gold Kings	72			
Tahoe Gold Kings Box				
Tahoe Menthol 100's				
Tahoe Menthol Kings				
Tahoe Sky Blue 100's				
Tahoe Sky Blue Kings				
Tahoe Evergreen Menthol 100's				
Tahoe Evergreen Menthol Kings				
Total Tahoe Products				
Total of all 3 Product Lines				

Percentage of the First and Fifth Year Market Volume Projections of Use of the Product Lines in Relation to the 2013 Total Number of Used Cigarettes in the U.S.²⁹

Product Name	First Year Market Volume (# of cigarettes)	% of Total Cigarettes Used in 2013 ³⁰	Fifth Year Market Volume (# of cigarettes)	% of Total Cigarettes Used in 2013
Riverside Blue 100's	(b) (4)			
Riverside Blue Kings				
Riverside Blue Kings Box				
Riverside Filter 100's				
Riverside Filter Kings Box	2			
Riverside Filter Kings	r G			
Riverside Menthol 100's				
Riverside Menthol Kings				
Riverside Menthol Kings Box				
Riverside Silver 100's				
Riverside Silver Kings				
Riverside Teal Menthol 100's				
Riverside Teal Menthol Kings				
Valu Time Filter 100's				
Valu Time Filter Kings				
Valu Time Filter Kings Box				
Valu Time Gold 100's	r			
Valu Time Gold Kings Box				
Valu Time Menthol 100's				
Valu Time Menthol Kings Box				
Valu Time Silver 100's	8			
Valu Time Teal Menthol 100's	·			
Total Riverside & Valu Time				
Products				
Tahoe Filter 100's				
Tahoe Filter Kings				
Tahoe Filter Kings Box				
Tahoe Gold 100's				

²⁹ Assuming that all manufactured new products will be used in the U.S.

 $^{^{\}rm 30}$ 277.83 billion cigarettes were used in the U.S. in 2013

Product Name	First Year Market Volume (# of cigarettes)	% of Total Cigarettes Used in 2013 ³⁰	Fifth Year Market Volume (# of cigarettes)	% of Total Cigarettes Used in 2013
Tahoe Gold Kings	(b) (4)			
Tahoe Gold Kings Box				
Tahoe Menthol 100's				
Tahoe Menthol Kings				
Tahoe Sky Blue 100's				
Tahoe Sky Blue Kings				
Tahoe Evergreen Menthol 100's				
Tahoe Evergreen Menthol Kings				
Total Tahoe Products Line				
Total of all 3 Products Lines				

Percentage of Solid Waste of the New Manufactured Product Lines in Relation to the Total Solid Waste Received by Facilities with Solid Waste Management Permits in the Commonwealth of Virginia in 2012

Name of Cigarette Product Line	Annual Tons of Total Solid Waste of Manufacture	% of Total Solid Waste Received in VA in 2012
Riverside	(b) (4)	
Valu Time		
Tahoe		

The First and Fifth Year Market Projections of Waste Associated with Marketing the New Products

The agency used the applicant's data of the first and fifth year projected market volumes for the manufactured new products to estimate the amount of waste generated from disposal of the consumed cigarettes. In worst case scenario, 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.

<u>Polypropylene Wrap</u>: The agency estimated the first and fifth year projected weights of the polypropylene wrap waste (in tons) that is generated from disposal after use of the new products as follows:

 $A = [B \times C \times D] / E$, where

A= Projected waste (tons)

B= Number of manufactured packs (packs)

C= Total weight of wrap of a 10-pack carton and the 10 packs (grams/carton)

D=10⁻⁶ (tons/gram)

E= 10 (number of packs/carton)

New Product	First Year Market Volume (# of packs)	First Year Projected Waste of Polypropylene (tons)	Fifth Year Market Volume (# of packs)	Fifth Year Projected Waste of Polypropylene (tons)
Riverside Blue 100's	(b) (4)			
Riverside Blue Kings				
Riverside Blue Kings Box				
Riverside Filter 100's	_			
Riverside Filter Kings Box				
Riverside Filter Kings				
Riverside Menthol 100's				
Riverside Menthol Kings				
Riverside Menthol Kings Box				
Riverside Silver 100's				
Riverside Silver Kings				
Riverside Teal Menthol 100's				
Riverside Teal Menthol Kings				
Valu Time Filter 100's				
Valu Time Filter Kings				
Valu Time Filter Kings Box				

New Product	First Year Market Volume (# of packs)	First Year Projected Waste of Polypropylene (tons)	Fifth Year Market Volume (# of packs)	Fifth Year Projected Waste of Polypropylene (tons)
Valu Time Gold 100's	(b) (4)			
Valu Time Gold Kings Box				
Valu Time Menthol 100's				
Valu Time Menthol Kings Box				
Valu Time Silver 100's				
Valu Time Teal Menthol 100's				
Total for Riverside & Valu Time Lines				
Tahoe Filter 100's				
Tahoe Filter Kings				
Tahoe Filter Kings Box				
Tahoe Gold 100's				
Tahoe Gold Kings				
Tahoe Gold Kings Box				
Tahoe Menthol 100's				
Tahoe Menthol Kings				
Tahoe Sky Blue 100's				
Tahoe Sky Blue Kings				
Tahoe Evergreen Menthol 100's				
Tahoe Evergreen Menthol Kings				
Total for Tahoe Products Line				
Total of all 3 product Lines				

The projected cumulative wrap waste is (b) (4) tons and (b) (4) tons in the first and fifth years, respectively, of marketing the new products (Riverside, Valu Time and Tahoe products). However, based on EPA's data in 2012, 34.5% of the polypropylene is estimated to be recycled; therefore, 64.5% of the polypropylene is estimated to actually be waste that is disposed of in landfills. The agency then estimated (b) (4) tons of the polypropylene will be disposed of as waste in the first year and (b) (4) tons in the fifth years of marketing the products. Therefore, the estimated amount of wrap waste is a miniscule fraction of the 251 million tons of total waste reported in the U.S. in 2012.

<u>Waste of Laminated Paper Foil</u>: The agency estimated the first and fifth year projected weights of the foil waste (in tons) that is generated from disposal after use of the new products as follows:

 $A = B \times C \times D$, where

A= Projected waste (tons)

B= Number of manufactured packs (packs)

C= Total weight of the foil of a pack (grams/pack)

D=10⁻⁶ (tons/gram)

New Product	First Year Market Volume (# of packs)	First Year Projected Foil Waste (tons)	Fifth Year Market Volume (# of packs)	Fifth Year Projected Foil Waste (tons)
Riverside Blue 100's	(b) (4)			
Riverside Blue Kings				
Riverside Blue Kings Box				
Riverside Filter 100's				
Riverside Filter Kings Box				
Riverside Filter Kings				
Riverside Menthol 100's				
Riverside Menthol Kings				
Riverside Menthol Kings Box				
Riverside Silver 100's				
Riverside Silver Kings				
Riverside Teal Menthol 100's				
Riverside Teal Menthol Kings				
Valu Time Filter 100's				
Valu Time Filter Kings				
Valu Time Filter Kings Box				
Valu Time Gold 100's				
Valu Time Gold Kings Box				
Valu Time Menthol 100's				
Valu Time Menthol Kings Box				
Valu Time Silver 100's				
Valu Time Teal Menthol 100's				
Total for Riverside & Valu Time Lines				
Tahoe Filter 100's				
Tahoe Filter Kings				
Tahoe Filter Kings Box				

New Product	First Year Market Volume (# of packs)	First Year Projected Foil Waste (tons)	Fifth Year Market Volume (# of packs)	Fifth Year Projected Foil Waste (tons)
Tahoe Gold 100's	(b) (4)			
Tahoe Gold Kings	_			
Tahoe Gold Kings Box				
Tahoe Menthol 100's				
Tahoe Menthol Kings	-			
Tahoe Sky Blue 100's				
Tahoe Sky Blue Kings				
Tahoe Evergreen Menthol 100's				
Tahoe Evergreen Menthol Kings				
Total for Tahoe Products Line				
Total of all 3 product Lines		-		

The projected total foil waste is (b) (4) tons and (b) (4) tons in the first and fifth years, respectively, of marketing the new products (Riverside, Valu Time and Tahoe products). However, based on EPA's data in 2012, 34.5% of the foil is estimated to be recycled; therefore, 64.5% of the foil is estimated to actually be waste that is disposed of in landfills. The agency estimated (b) (4) tons of the foil will be disposed of as waste in the first year and (b) (4) tons in the fifth years of marketing the products. Therefore, the estimated amount of foil waste is a miniscule fraction of the 251 million tons of total waste reported in the U.S. in 2012.

<u>Disposal of Paper Packaging Material</u>: The agency estimated the first and fifth year weights of the projected paper waste (in tons) that is generated from disposal after use of the new products as follows:

 $A = B \times C \times D / E$, where

A= Projected waste (tons)

B= Number of manufactured packs (packs)

C= Total weight of paper of a 10-pack carton and the 10 packs (grams/carton)

D=10⁻⁶ (tons/gram)

E= 10 (number of packs/carton)

New Product	First Year Market Volume (# of packs)	First Year Projected Paper Waste (tons)	Fifth Year Market Volume (# of packs)	Fifth Year Projected Paper Waste (tons)
Riverside Blue 100's	(b) (4)		14 14 14 14 14 14 14 14 14 14 14 14 14 1	
Riverside Blue Kings				
Riverside Blue Kings Box	Ţ			
Riverside Filter 100's				
Riverside Filter Kings Box				
Riverside Filter Kings	Ī			Ĭ
Riverside Menthol 100's				
Riverside Menthol Kings	Ţ			
Riverside Menthol Kings Box	Ī			
Riverside Silver 100's	Ī			*
Riverside Silver Kings	Ī			
Riverside Teal Menthol 100's	Ī			
Riverside Teal Menthol Kings				
Valu Time Filter 100's	Ţ			
Valu Time Filter Kings				
Valu Time Filter Kings Box	Ī			
Valu Time Gold 100's	Ī			
Valu Time Gold Kings Box	Ţ			
Valu Time Menthol 100's	Ţ			
Valu Time Menthol Kings Box	Ī			
Valu Time Silver 100's	Ī			
Valu Time Teal Menthol 100's				
Total for Riverside & Valu Time Lines				
Tahoe Filter 100's				
Tahoe Filter Kings				

New Product	First Year Market Volume (# of packs)	First Year Projected Paper Waste (tons)	Fifth Year Market Volume (# of packs)	Fifth Year Projected Paper Waste (tons)
Tahoe Filter Kings Box	(b) (4)			
Tahoe Gold 100's				
Tahoe Gold Kings				
Tahoe Gold Kings Box				
Tahoe Menthol 100's				
Tahoe Menthol Kings				
Tahoe Sky Blue 100's				
Tahoe Sky Blue Kings				
Tahoe Evergreen Menthol 100's				
Tahoe Evergreen Menthol Kings				
Total for Tahoe Products Line				
Total of all 3 product Lines		-	2	

The projected cumulative paper waste is (b) (4) tons and (b) (4) tons in the first and fifth years, respectively, of marketing the new products (Riverside, Valu Time and Tahoe products). The generated paper waste is most likely to be recycled. In the worst case scenario, if 20% of the paper is disposed of as waste, the projected amount of waste will be (b) (4) tons and (b) (4) tons in the first and fifth years of marketing the products, respectively; a minute fraction of the 251 million tons of total waste reported in the U.S. in 2012.

<u>Disposal of Cigarette Butts</u>: According to the information presented in the SE Reports, the weight of the filter, including the tipping paper, for the 100's cigarette products is 0.2197 grams and for the Kings products 0.1794 grams. Knowing that the cigarette weight for the 100's is 1.2 gram and for the Kings is 1.0 grams, the weight ratio of cigarette butt to the cigarette is 0.1831 and 0.1794, respectively.

To calculate the weight of cigarette butts generated from the 277.83 billion cigarettes consumed in the U.S. in 2013, the agency assumed that:

- · the weight of cigarette butt is 20% of the weight of cigarette;
- · the consumed cigarettes were of the 100's type; and
- the weight of each cigarette is 1.2 grams, similar to the weight of the 100's type cigarettes in the SE applications

Based on these assumptions, the estimated cumulative weight of cigarette butts generated in the U.S. in 2013 was 66,679 million tons.

The agency estimated the first and fifth year projected weights of cigarette butt waste (in tons) that is generated from disposal after use of the new products as follows:

 $A=(B) \times (C)$, where

A= Projected waste (tons)

B= Weight of manufactured cigarettes (tons)

C= the weight ratio of cigarette butt to the cigarette

New Product	First Year Market Volume (tons of cigarettes)	First Year Projected Cigarette Butt Waste (tons)	Fifth Year Market Volume (tons of cigarettes)	Fifth Year Projected Cigarette Butt Waste (tons)
Riverside Blue 100's	(b) (4)			
Riverside Blue Kings				
Riverside Blue Kings Box				
Riverside Filter 100's	_			
Riverside Filter Kings Box				
Riverside Filter Kings				
Riverside Menthol 100's				
Riverside Menthol Kings				
Riverside Menthol Kings Box				
Riverside Silver 100's				
Riverside Silver Kings				
Riverside Teal Menthol 100's				
Riverside Teal Menthol Kings				
Valu Time Filter 100's				
Valu Time Filter Kings				
Valu Time Filter Kings Box				

New Product	First Year Market Volume (tons of cigarettes)	First Year Projected Cigarette Butt Waste (tons)	Fifth Year Market Volume (tons of cigarettes)	Fifth Year Projected Cigarette Butt Waste (tons)
Valu Time Gold 100's	(b) (4)			
Valu Time Gold Kings Box	Control of a			
Valu Time Menthol 100's				
Valu Time Menthol Kings Box				
Valu Time Silver 100's				
Valu Time Teal Menthol 100's				
Total for Riverside & Valu Time Lines				
Tahoe Filter 100's				
Tahoe Filter Kings				
Tahoe Filter Kings Box				
Tahoe Gold 100's				
Tahoe Gold Kings				
Tahoe Gold Kings Box				
Tahoe Menthol 100's				
Tahoe Menthol Kings				
Tahoe Sky Blue 100's				
Tahoe Sky Blue Kings				
Tahoe Evergreen Menthol 100's				
Tahoe Evergreen Menthol Kings				
Total for Tahoe Products Line				
Total of all 3 product lines				

The projected cumulative cigarette butt waste is (b) (4) tons and (b) (4) tons in the first and fifth years, respectively, of marketing the new products (Riverside, Valu Time and Tahoe products). The first year and fifth year projected amount of cigarette butt waste is (b) (4) and (b) (4), respectively, of the estimated cigarette butts generated in 2013. The cigarette butt waste may end up in landfills; filters discarded on streets may move through the storm drains to streams, into the ocean, and back onto the beaches.