Programmatic Environmental Assessment for Marketing Orders for Twelve New Cigarettes by Susan Jesmer dba Native Trading Associates

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

July 26, 2018

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1. Applicant and Manufacturer Information

Applicant Name:	Susan Jesmer dba Native Trading Associates
Applicant Address:	442 Frogtown Road Hogansburg, NY 13655
Manufacturer Name:	Native Trading Associates
Address Where the Product is Manufactured:	442 Frogtown Road Hogansburg, NY 13655

2. Product Information

New Product Names, Submission Tracking Numbers (STN), and Predicate Product Names

New Product	STN	Corresponding Predicate Products
Native 100's hard pack (Blue) (2017)	SE0014352	Native Full Flavor 100's hard pack
Native 100's Soft (Blue) (2017)	SE0014353	Native Full Flavor 100's soft pack
Native King hard pack (Blue) (2017)	SE0014354	Native Full Flavor King hard pack
Native King Soft (Blue) (2017)	SE0014355	Native Full Flavor King soft pack
Native 100's hard pack (Ultra) (2017)	SE0014356	Native Full Flavor 100's hard pack
Native 100's Soft (Ultra) (2017)	SE0014357	Native Full Flavor 100's soft pack
Native King hard pack (Ultra) (2017)	SE0014358	Native Full Flavor King hard pack
Native King Soft (Ultra) (2017)	SE0014359	Native Full Flavor King soft pack
Native Menthol 100's hard pack (Green) (2017)	SE0014360	Native Menthol 100's hard pack
Native Menthol 100's Soft (Green) (2017)	SE0014361	Native Menthol 100's soft pack
Native Menthol King hard pack (Green) (2017)	SE0014362	Native Menthol King hard pack
Native Menthol King Soft (Green) (2017)	SE0014363	Native Menthol King soft pack

Product Identification

Product Type	Cigarettes
Product Sub-Category	Combusted Filtered
Product Number per Retail Unit	20 cigarettes per package

3. The Need for the Proposed Actions

The proposed actions, requested by the applicant, are for FDA to issue marketing orders under the provisions of sections 910 and 905(j) of the Federal Food, Drug, and Cosmetic Act, after finding the new tobacco products substantially equivalent to the corresponding predicate products. The applicant wishes to introduce the new tobacco products into interstate commerce for commercial distribution in the United States.

The Agency shall issue marketing orders if, after considering the substantial equivalence (SE) reports and amendments submitted by the applicant, the new products are found substantially equivalent to the predicate products. The predicate products were on the market as of February 15, 2007, but are not currently on the market.

The applicant claimed that the new products differ from the corresponding predicate products in product components and composition; including changes to the cigarette paper, plug wrap and tipping paper (Confidential Appendix 1).

4. Alternative to the Proposed Actions

The no-action alternative is FDA does not authorize the marketing of the new tobacco products in the United States.

5. Potential Environmental Impacts of the Proposed Actions and Alternative –Manufacturing the New Products

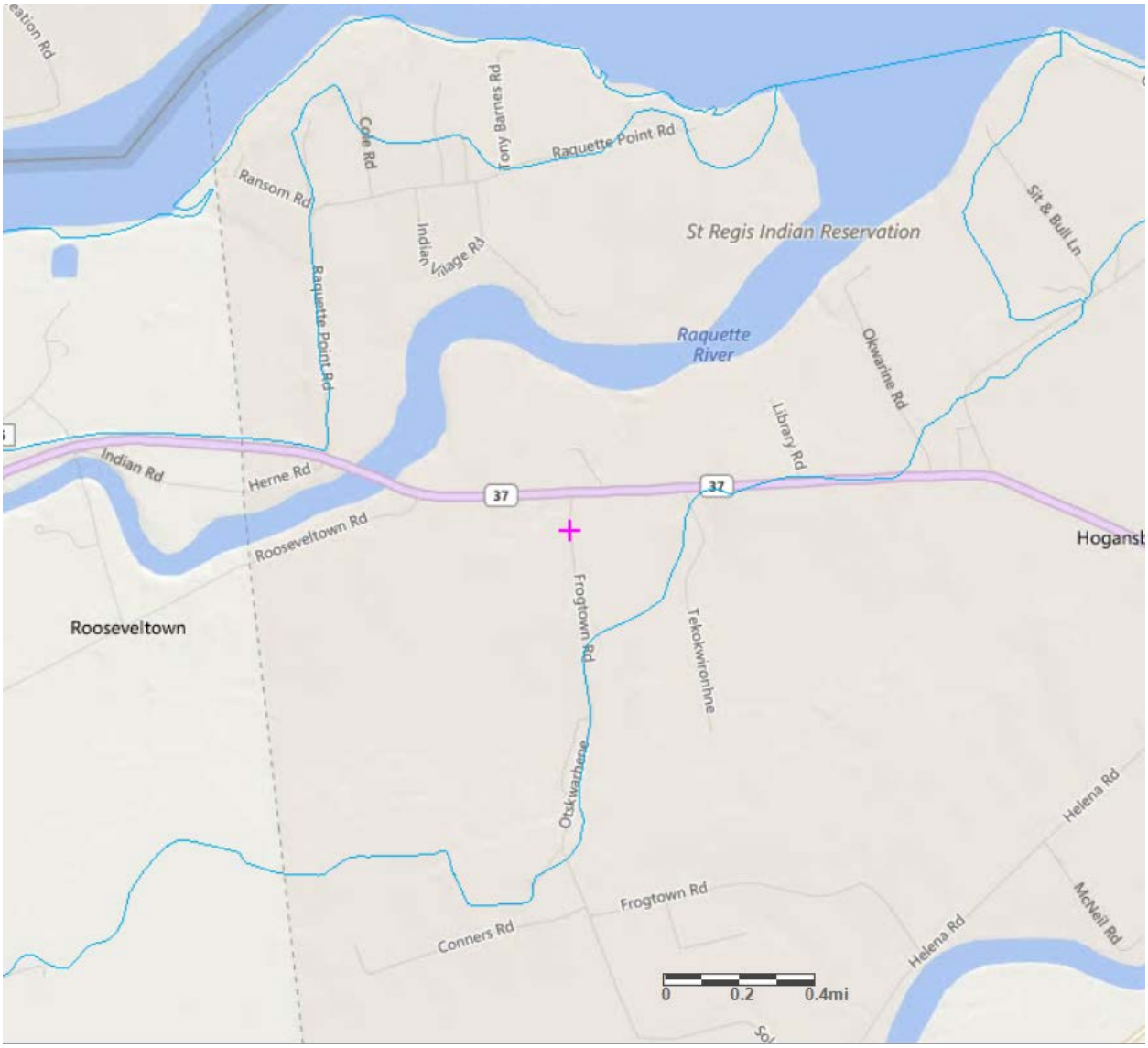
The Agency considered potential impacts to resources in the environment that may be affected by manufacturing the new products and found no significant impacts.

5.1 Affected Environment

The new and predicate products are manufactured at 442 Frogtown Road, Hogansburg, NY 13655 (Figure 1). The facility is in the St. Regis Indian Reservation. The area is a mixed-use area, surrounded by industrial and commercial land, as well as residential development to the east and west. Raquette River is immediately north and St. Regis River is south east of the facility.[1] The facility is in the Hutchins Creek-Raquette (HUC12) watershed.

[1] *Map of* 442 Frogtown Road, Hogansburg, NY. Retrieved from EPA's NEPA Assist: https://nepassisttool.epa.gov/nepassist/nepamap.aspx (Retrieved May 22, 2018).

Figure 1. Location of the Manufacturer (crosshairs) in relation to the Hutchins Creek-Raquette watershed (outline).



5.2 Air Quality

The applicant stated that manufacturing the new products would not produce any unique air emissions which are not already addressed by federal, tribal and state emission requirements. Additionally, the applicant stated that the new products would replace similar products that are currently being manufactured at the applicant's facility that have the same market volume projections (Confidential Appendix 2), therefore, no increase in manufacturing is anticipated.

5.3 Water Resources

The applicant stated that the facility where the new products would be manufactured does not generate industrial waste water. Therefore, the Agency does not anticipate any impacts on water resources.

5.4 Land Use and Zoning

No facility construction or expansion would occur because of manufacturing the new products, thus no land conversion of prime farmland, unique farmland, or farmland of statewide importance to non-agricultural use is expected. Also, because no construction would occur, no change of zoning for land needed for a new or expanded facility would occur.

5.5 Biological Resources

The applicant stated that manufacturing the new products would not impact any threatened or endangered species or critical habitat. No facility expansion is expected, so no effect on listed species or their habitat would occur. No impacts on biological resources are anticipated.

5.6 Geological Features and Soils

No facility expansion is expected, so no effect on geological features or soils would occur.

5.7 Socioeconomic Conditions

No facility expansion is anticipated. Therefore, no impacts are expected on employment; state or municipal revenue and taxes; or demand on community, municipal, and state resources, such as police force and fire department resources.

5.8 Solid Waste and Hazardous Materials

The applicant stated that manufacturing the new products would replace the manufacturing of currently marketed products, therefore, no impact on municipal solid waste (MSW) generation is expected. Compliance by the manufacturer with applicable laws, regulations, and local ordinances for solid waste and hazard materials management is assumed to indicate that no significant impacts would occur.

5.9 Floodplains, Wetlands, and Coastal Zones

No facility expansion would occur, so no effects to floodplains, wetlands, or coastal zones are anticipated.

5.10 Environmental Justice

Because no significant environmental impacts were identified, there would be no disproportionate impacts to environmental justice populations near the manufacturing facility.

5.11 Regulatory Compliance

The applicant stated that they are in compliance with all applicable federal, tribal and state environmental laws and regulations.

5.12 Cumulative Impacts

No actions were identified that would lead to cumulative impacts due to the proposed actions.

5.13 Impacts from No Action Alternative

The environmental impact of the no-action alternative would not change the existing condition of the manufacturing cigarettes, as many other similar tobacco products would continue to be marketed and therefore manufactured.

6. Potential Environmental Impacts of the Proposed Actions and Alternative – Use of the New Products

The Agency considered potential impacts to resources in the environment that may be affected by use of the new products and found no significant impacts.

6.1. Affected Environment

The affected environment is the entire United States because the marketing orders would allow for the new tobacco products to be sold to consumers nationwide. The new products are combusted, filtered cigarettes that are intended to be smoked. Users may smoke cigarettes indoors or outside, as the law permits.

6.2. Air Quality

The new products do not contain any materials not commonly found in cigarettes currently on the market. Therefore, the Agency does not anticipate that using the new products would lead to the release of new chemicals into the air, as compared to the corresponding predicate products or combusted cigarettes currently on the market.

6.3. Environmental Justice

The new products would be used by the same consumers that use the predicate products. Therefore, no change in impacts to environmental justice populations is expected.

6.4. Cumulative Impacts

When burned, cigarettes produce environmental tobacco smoke or secondhand smoke (SHS). Particles emitted by smoking may remain on surfaces, be re-emitted back into the gas phase, or react with oxidants and other compounds in the environment to yield secondary pollutants. The mixture of these pollutants, called thirdhand smoke (THS), coexists in the environment alongside SHS (Burton, 2011; Matt et al., 2011).

The impacts from use of cigarette products include exposure to SHS and THS. There is no safe level of exposure to SHS (U.S. Department of Health and Human Services, 2006a and 2006b). Even low levels of SHS can harm children and adults in many ways, including the following:

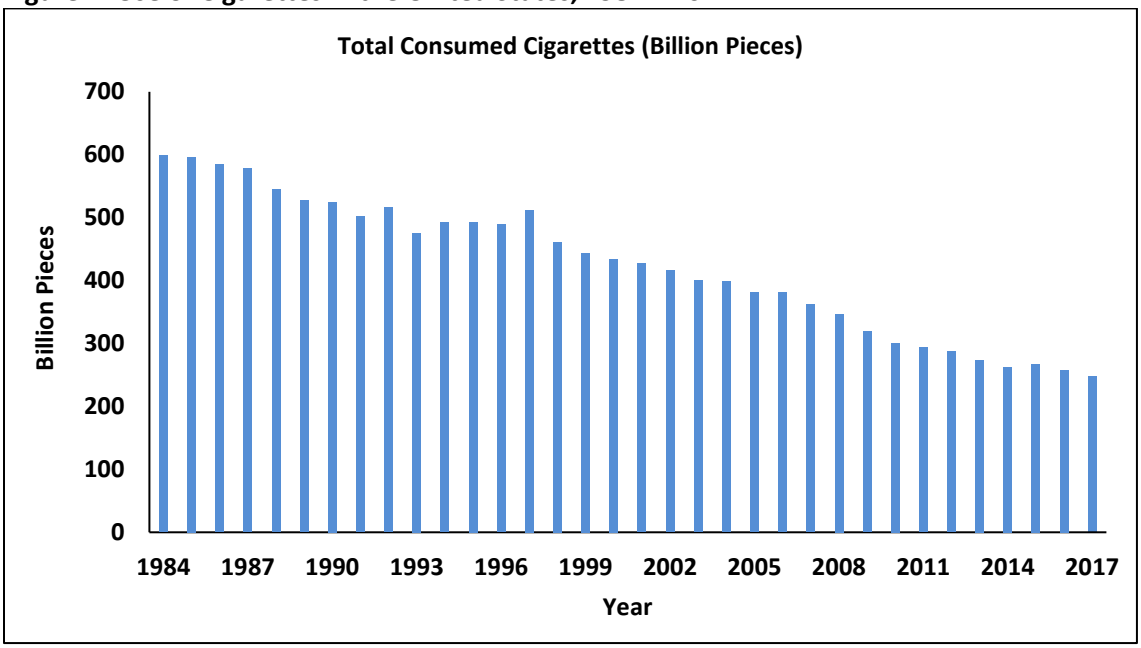
- The U.S. Surgeon General estimates that living with a smoker increases a nonsmoker's chances of developing lung cancer by 20 to 30% (U.S. Department of Health and Human Services, 2014).
- Exposure to SHS increases school children's risk for ear infections, lower respiratory illnesses, more frequent and more severe asthma attacks, and slowed lung growth, and it can cause coughing, wheezing, phlegm, and breathlessness (U.S. Department of Health and

Human Services, 2006a and 2006b).

- SHS causes more than 40,000 deaths a year (U.S. Department of Health and Human Services, 2014).

Per the U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) Statistical Release reports, the use of cigarettes in the United States is declining (Figure 2).[2]

Figure 2. Use of Cigarettes in the United States, 1984 – 2017



Several studies have been conducted to assess the levels of SHS exposure in children and nonsmokers living at homes of smokers (Homa et al., 2015; Yao et al., 2016; other studies). Although these studies found considerable ethnic and racial disparities in SHS exposure in vulnerable populations, there was a clear decline in exposure among children and adults for all population subgroups. Data from the National Health and Nutrition Examination Survey showed a decline in SHS exposure from 1999-2000 to 2011-2012 with the highest prevalence of exposure among non-Hispanic subpopulations (46.8%), compared to Mexican Americans (23.9%) and non-Hispanic whites (21.8%) in 2011-2012 (Homa et al., 2015). There were also significant declines in SHS exposure prevalence noted in the 2000 and 2010 National Health Interview Survey Cancer Control Supplements. The SHS exposure declined in Hispanics from 16.3% in 2000 to 3.1% in 2010, non-Hispanic Asians from 13.4% in 2000 to 3% in 2010, and non-Hispanic blacks from 31.2% in 2000 to 11.5% in 2010 as compared to exposures in non-Hispanic whites, which declined from 25.8% in 2000 to 9.7% in 2010 (Yao et al., 2016).

As of December 2015, 26 states and the District of Columbia have implemented comprehensive smoke-free laws (Tynan, Holmes, Promoff, Hallett, Hopkins, & Frick, 2016). Such laws are expected to reduce the levels of non-users' exposure to SHS and THS.

[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 15, 2018.

6.5. Impacts from No Action Alternative

The environmental impact of the no-action alternative would not change the existing condition of the use of cigarettes, as many other similar tobacco products would continue to be marketed and therefore used.

7. Potential Environmental Impacts of the Proposed Actions and Alternative – Disposal of the New Products

The Agency has considered potential impacts to resources in the environment that may be affected by disposal of the new products and found no significant impacts.

7.1. Affected Environment

The affected environment is the entire United States because the marketing orders would allow for the new tobacco products to be sold to consumers nationwide Consumers would dispose of the used product and packaging via MSW landfills, recycling centers, or as litter.

7.2. Air Quality

The Agency does not anticipate disposal of the new products or the packaging material would lead to the release of new or increased chemicals into the air.

No changes in air quality are anticipated from disposal of the cigarette butts of the new products. The chemicals in the used new products, or the cigarette butts, are commonly used in currently marketed cigarettes. Because the new products are anticipated to compete with or replace currently marketed cigarettes, the butt waste generated from the new products would replace the same type of waste (Confidential Appendix 3). Therefore, the fate and effects of any materials emitted into the air from disposal of the new products is anticipated to be the same as any materials from other cigarettes disposed of in the United States.

No changes in air quality from disposal of the package materials would be expected from the new products because; (1) the paper and plastic components of the packages are more likely to be recycled or at least a portion of the packaging waste is likely to be recycled, (2) the packaging materials are commonly used in the United States, and (3) the waste generated due to disposal of the new products' packaging is a miniscule portion of the municipal solid waste, per FDA's experience in evaluating the packaging waste generated from cigarettes.

7.3. Biological Resources

Proper disposal of the used new products and packaging in the municipal solid waste stream would not affect biological resources. Improper disposal could occur in undeveloped areas and wildlife habitats. However, because introducing the new products into the U.S. market is not expected to increase the nationwide use of cigarettes, it is not expected that the amount of littering would change from the current amount due to existing products. Thus, this impact would not be significant.

7.4. Environmental Justice

Because no significant environmental impacts were identified, there would be no disproportionate impacts to environmental justice populations from disposal of the used products and packaging waste from the new products.

7.5. Water Resources and Water Quality

Proper disposal of used products and packaging from the new products in the municipal solid waste stream would not affect water resources. Improper disposal could occur in or near surface water. However, because introducing the new products into the U.S. market is not expected to increase the nationwide use of cigarettes, it is not expected that the amount of littering would change from the current amount due to existing products. Thus, this impact would not be significant.

7.6. Regulatory Compliance

It is assumed that the portion of product and packaging waste from the new products that is disposed of by users, despite littering ordinances, would be no greater than the current tobacco product littering rates.

7.7. Cumulative Impacts

A major existing environmental consequence of the use of the new products, as well as other conventional cigarettes, is littering of discarded cigarette filters or butts, which can persist in the environment for more than 10 years (Novotny and Zhao, 1999). Cigarette butts are some of the most common forms of litter found on beaches (Claereboudt, 2004; Smith, Livingston and Doolittle, 1997), near streams, night clubs (Becherucci and Pon, 2014), bus stops (Wilson, Oliver, and Thomson, 2014), roads, and streets (Healton, Cummings, O'Connor and Novotny, 2011; Patel, Thomson and Wilson, 2013). Cigarette butts have been found at densities averaging more than four cigarette butts m^2 in urban environments (Seco Pon and Becherucci, 2012).

The environmental toxicity of cigarette butts due to air emissions is not well studied. The chemicals in cigarette butts can be the original chemicals in the unsmoked cigarettes or the pyrolysis and distillation products deposited in the cigarette butts. Airborne emissions of discarded cigarette butts depend on the environmental conditions and the chemicals in the butt which are influenced by the cigarette brand, cigarette length, filter material, types of tobacco, ingredients in the cigarette and tobacco fillers, smoking method, number of butts, and the mass transfer behavior of combustion products along the cigarette.[3]

However, the decline in cigarette use in the United States would result in decreased cigarette butt waste and, therefore, decreased cumulative impact from cigarette butts on the environment.

7.8 Impacts from No Action Alternative

[3] NIST Technical Report 8147 available at: http://dx.doi.org/10.6028/NIST.IR.8147. Accessed April 24, 2018.

The environmental impact of the no-action alternative would not change the existing condition of the disposal of cigarettes, as many similar tobacco products would continue to be marketed.

8. List of Preparers

The following individuals were primarily responsible for preparing and reviewing this EA:

Preparers:

Shannon K. Hanna, Ph.D., Center for Tobacco Products
Education: Ph.D. in Environmental Science and Management
Experience: Four years in environmental science, three years in toxicology
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Reviewer:

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Education: M.S. in Environmental Science and Ph.D. in Biochemistry
Experience: 9 years in FDA-related NEPA review
Expertise: NEPA analysis, environmental risk assessment, wastewater treatment

9. A Listing of Agencies and Persons Consulted

Not applicable.

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Wilson, N., J., Oliver, and G. Thomson. (2014). Smoking close to others and butt littering at stops: Pilot observational study. *PeerJ* 2:e272.

Yao, T., Sun, H.Y., Wang, Y., Lightwood, J., and W. Max. (2016). Sociodemographic differences among U.S. children and adults exposed to secondhand smoke at home: National Health Interview Surveys 2000 and 2010. *Public Health Reports*, *131*, 357-366.

Confidential Appendix 1. Comparison Between the New Products and Predicate Products

Component	New	Predicate
Cigarette Paper	Fire standard compliant (FSC); higher permeability	Non-fire standard compliant (non-FSC); lower permeability
Plug Wrap	(b) (4)	(b) (4)
Tipping Paper	(b) (4) , (b) (4)	(b) (4)

Confidential Appendix 2. First- and Fifth-Year Market Volume Projections for the New Products and Percentage of Cigarette Use in the United States Projected to be Attributed to the New Products

First- and fifth-year market volume projections for the new products were compared to the total forecasted use of cigarettes in the United States.[4] The predicate products are not currently marketed and the applicant does not intend to market them after receiving marketing orders for the new products.

STN	Market Volume			
	First-Year		Fifth-Year	
	New Products (# of Cigarettes)	New Product as a Percent of Total Cigarettes Used[5]	New Products (# of Cigarettes)	New Product as a Percent of Total Cigarette Used[5]
SE0014352	(b) (4) [redacted]			
SE0014353				
SE0014354				
SE0014355				
SE0014356				
SE0014357				
SE0014358				
SE0014359				
SE0014360				
SE0014361				
SE0014362				
SE0014363				
Total				

[4] The Agency used historical data regarding total use of cigarettes from 2002 to 2017 to mathematically estimate the total amount of cigarettes used in the United States. Using the best-fit trend line with an R^2 value of 0.9786, the forecasted number of cigarettes that would be used in the United States is estimated at 236.26 billion cigarettes in the first year and 210.92 billion cigarettes in the fifth year of marketing the new products.

[5] Projected Market Occupation of the New Product in the United States (%)=

$$\frac{\text{Projected Market Volume of the New Products (cigarette } \textit{pieces}\text{)}}{\text{Projected Use of Cigarettes in United States (cigarette pieces)}} \; x \; 100$$

Confidential Appendix 3. Projected Calculated Waste of Cigarette Butts in the First and Fifth-Year of Marketing the New Products

$$\sum_{i=1}^{12} A_i = \sum_{i=1}^{12} (B_i \times C_i \times D_i \; X \; G)$$

$$D_i = \frac{E}{F_i}$$

A_i:	Projected waste generation of cigarette butts of the new product (metric tons)
B_i:	Projected market volume of the new product (number of individual cigarettes
C_i:	Weight of cigarette (gram)
D_i:	Cigarette butt ratio
E:	Cigarette butt length [6]
F_i:	Length of cigarette (millimeter)
G:	1.0 x 10^{-6} metric tons/gram

Projected Year	STN	*Market Volume (Pieces) B_i*	*Cigarette Weight (Grams) C_i*	*Cigarette Length (mm) F_i*	*Cigarette Butt Waste (Tons) A_i*
First-Year	SE0014352	(b) (4)	1.20	100	(b) (4)
	SE0014353		1.20	100	
	SE0014354		1.04	84	
	SE0014355		1.04	84	
	SE0014356		1.24	100	
	SE0014357		1.24	100	
	SE0014358		1.05	84	
	SE0014359		1.05	84	
	SE0014360		1.23	100	
	SE0014361		1.23	100	
	SE0014362		1.04	84	
	SE0014363		1.04	84	
	Total				
Fifth-Year	SE0014352		1.20	100	
	SE0014353		1.20	100	
	SE0014354		1.04	84	
	SE0014355		1.04	84	
	SE0014356		1.24	100	
	SE0014357		1.24	100	
	SE0014358		1.05	84	
	SE0014359		1.05	84	
	SE0014360		1.23	100	
	SE0014361		1.23	100	
	SE0014362		1.04	84	
	SE0014363		1.04	84	
	Total				

If all the projected cigarette butt waste generated from use of the new products is disposed of in landfills, the projected waste of (b) (4) metric tons and (b) (4) metric tons in the first and fifth year of marketing the new products, respectively, would be negligible fractions of the 234.47 million metric tons of yearly total waste, as reported in the United States in 2014 (U.S. EPA, 2016).

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