

**Programmatic Environmental Assessment for Marketing  
Orders for New Combusted Filtered Cigarettes Manufactured  
by Native Trading Associates, LLC**

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

October 8, 2020

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**1. Applicant and Manufacturer Information**

<b>Applicant Name:</b>	Native Trading Associates, LLC
<b>Applicant Address:</b>	442 Frogtown Road Hogansburg, New York 13655
<b>Manufacturer Name:</b>	Native Trading Associates
<b>Product Manufacturing Location:</b>	442 Frogtown Road Hogansburg, New York 13655

**2. Product Information**

**New Product (STNs), New Product Names, and Original Product Names**

<b>New Product STN</b>	<b>New Product Name</b>	<b>Original Product Name</b>
EX0001188	Native Menthol King hard pack	Native Methol King hard pack (2016)
EX0001190	Native Menthol King Soft	Native Menthol King soft pack (2016)
EX0001192	Native Menthol 100's hard pack (Green)	Native Menthol 100's hard pack (Green) (2017)
EX0001193	Native Menthol 100's Soft (Green)	Native Menthol 100's soft pack (Green) (2017)
EX0001194	Native Menthol 100's hard pack	Native Menthol 100's hard pack (2016)
EX0001195	Native Menthol King hard pack (Green)	Native Menthol King hard pack (Green) (2017)
EX0001196	Native Menthol 100's Soft	Native Menthol 100's soft pack (2016)
EX0001197	Native Full Flavor King hard pack	Native Full Flavor King hard pack (2016)
EX0001198	Native 100's Soft (Blue)	Native 100's soft pack (Blue) (2017)
EX0001199	Native 100's Soft (Ultra)	Native 100's soft pack (Ultra) (2017)
EX0001200	Native Full Flavor 100's Soft	Native Full Flavor 100's soft pack (2016)
EX0001203	Native King hard pack (Ultra)	Native King hard pack (Ultra) (2017)
EX0001204	Native King Soft (Ultra)	Native King soft pack (Ultra) (2017)
EX0001206	Native King hard pack (Blue)	Native King hard pack (Blue) (2017)
EX0001207	Native 100's hard pack (Blue)	Native 100's hard pack (Blue) (2017)

**Product Identification**

<b>Product Category</b>	Cigarette
<b>Product Subcategory</b>	Combusted filtered
<b>Product Number per Retail Unit</b>	20 cigarettes per pack with 10 packs per carton and 60 cartons per shipping case.
<b>Product Package</b>	EX0001188, EX0001192, EX0001194, EX0001195, EX0001197, EX0001203, EX0001206, and EX0001207: The hard pack consists of an aluminum foil liner, cardboard pack, polypropylene pack overwrap, polypropylene tear tape, cardboard carton, and cardboard shipping box.  EX0001190, EX0001193, EX0001196, EX0001198, EX0001199, EX0001200, and EX0001204 : The soft pack consists of an aluminum foil pack liner, paperboard pack, polypropylene pack overwrap, polypropylene tear tape, cardboard carton, and cardboard shipping box.

### **3. The Need for the Proposed Actions**

The proposed actions, requested by the applicant, are for the U.S. Food and Drug Administration (FDA) to issue exemptions from substantial equivalence (SE) reporting for marketing orders under section 905(j)(3) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for fifteen combusted, filtered cigarettes. A tobacco product that is modified by adding or deleting a tobacco additive, or increasing or decreasing the quantity of an existing tobacco additive, may be considered for exemption from demonstrating substantial equivalence if (1) the product is a modification of another tobacco product and the modification is minor, (2) the modifications are to a tobacco product that may be legally marketed under the FD&C Act, (3) an SE Report is not necessary to ensure that permitting the tobacco product to be marketed would be appropriate for the protection of public health, (4) the modified tobacco product is marketed by the same organization as the original product, and (5) an exemption is otherwise appropriate.

The applicant wishes to introduce the new tobacco products into interstate commerce for commercial distribution in the United States. The applicant must obtain written notification that FDA has granted the products exemptions from demonstrating substantial equivalence under section 905(j)(3) before submitting an abbreviated report. Ninety days after FDA receipt of the abbreviated report, the applicant may introduce or deliver for introduction into interstate commerce for commercial distribution the new products for which the applicant has obtained exemptions from demonstrating substantial equivalence.

The new products are made by modifying the corresponding original products, which were previously found substantially equivalent by FDA and received marketing orders. The new products differ from the original products in the ingredients in the cigarette paper (Confidential Appendix 1.).

### **4. Alternatives to the Proposed Actions**

The no-action alternative is FDA does not issue marketing orders for the new tobacco products.

### **5. Potential Environmental Impacts of the Proposed Actions and Alternatives – Manufacturing the New Products**

The Agency considered potential impacts to resources in the environment that could be affected by manufacturing the new products and found no significant impacts based on the Agency-gathered information and the following applicant-submitted information:

- Components of the cigarette paper are commonly used in other products manufactured at the facility.
- The new tobacco products are expected to replace portions of similar tobacco products currently manufactured at the facility.
- There will be no new or increased compounds emitted from the disposal of the new product
- No facility expansion or new construction is expected due to manufacturing the new products.

#### **5.1 Affected Environment**

The affected environment includes human and natural environments surrounding the facility. The new products would be manufactured at the address listed in section 1 of this document (Figure 1).

**Figure 1. Location of the Manufacturing Facility<sup>1</sup>**



The manufacturing facility is in Franklin County in the St. Lawrence River Watershed.<sup>2,3,4</sup> The facility is surrounded by woodlands and is located on the St. Regis Mohawk Reservation within a commercial area north of a church, fitness center and Mohawk International Raceway.

## **5.2 Air Quality**

The Agency does not anticipate that manufacturing the new products would cause the release of any new chemicals into the environment. The applicant stated that manufacturing the new products is not expected to result in changes in air emissions or require any additional environmental controls for air emissions.

## **5.3 Water Resources**

The Agency does not anticipate that manufacturing the new products would cause the discharge of any new chemicals into water. The applicant stated that manufacturing the new products would not require any additional environmental controls for water discharges.

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<sup>1</sup> Google Maps. 2020. Map of 442 Frogtown Road, Hogansburg, New York. Retrieved from Google Maps. Sept 24, 2020

<sup>2</sup> A watershed is an area of land where all bodies of water drain to a common outlet such as the outflow of a reservoir, mouth of a bay, or any point along a stream channel. Such bodies of water include the following: surface water from lakes, streams, reservoirs and wetlands; the underlying ground water; and rainfall. See <https://water.usgs.gov/edu/watershed.html>.

<sup>3</sup> New York State, Department of Environmental Conservation. St. Lawrence River Watershed. Available at: <https://www.dec.ny.gov/lands/48021.html>. Accessed Sept 24, 2020.

<sup>4</sup> USGS. National Water Information System: Mapper. Available at: <https://maps.waterdata.usgs.gov/mapper/index.html>. Accessed Sept 24, 2020.

#### **5.4 Soil, Land Use, and Zoning**

The Agency does not anticipate that manufacturing the new products would lead to changes in soil, land use, or zoning. The applicant stated there would be no expected facility expansion. Therefore, there would be no zone change or land conversion of prime farmland, unique farmland, or farmland of statewide importance to non-agricultural use.

#### **5.5 Biological Resources**

The Agency does not anticipate manufacturing the new products would jeopardize the continued existence of any listed species or result in the destruction or adverse modification of the habitat of any such species identified under the Endangered Species Act (ESA). The applicant stated that manufacturing the new products is not expected to threaten any endangered species or critical habitat because there would be no anticipated changes in air emission or waste generation.

#### **5.6 Regulatory Compliance**

The applicant stated that the manufacturing facility complies with all federal, state, and tribal environmental regulations, and ESA.

#### **5.7 Socioeconomics and Environmental Justice**

No changes on socioeconomics are anticipated due to manufacturing the new products. The Agency does not anticipate any impacts on employment revenue, or taxes because the new products are intended to compete with, or replace, other cigarettes manufactured at the facility.

Although the manufacturing facility is on Native Indian Land, no changes in impacts on minority populations would be expected due to manufacturing the new products because no new chemical releases to the environment from manufacturing the new products were identified.

#### **5.8 Solid Waste and Hazardous Materials**

The Agency does not foresee the introduction of the new products would noticeably affect the current manufacturing waste generated from the facility production of all combusted cigarettes. The Agency anticipates the waste generated due to manufacturing the new products would be released to the environment and disposed of in landfills in the same manner as any other waste generated from any other tobacco products manufactured in the same facility.

#### **5.9 Floodplains, Wetlands, and Coastal Zones**

There would be no anticipated facility expansion due to manufacturing the new products and the applicant did not propose any land disturbance; therefore, there would be no effects on floodplains, wetlands, or coastal zones.

#### **5.10 Impacts of the No-Action Alternative**

The environmental impacts of the no-action alternative would not change the existing condition of manufacturing cigarettes at the listed facility, as many similar tobacco products would continue to be manufactured.

## **6. Potential Environmental Impacts of the Proposed Actions and Alternatives – Use of the New Products**

The Agency considered potential impacts to resources in the environment that could be affected by use of the new products and found no significant impacts based on Agency-gathered information and the applicant's submitted information. Included in the information the Agency considered were the projected market volumes for the new products and the documented decline in cigarette use in the United States.

### **6.1. Affected Environment**

The affected environment includes human and natural environments in the United States because the marketing orders would allow for the new tobacco products to be sold to consumers in the United States.

### **6.2. Air Quality**

The impacts from use of combusted tobacco products include exposure to secondhand smoke (SHS) produced from burned cigarettes. 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, thirdhand smoke (THS). These pollutants coexist in mixtures in the environment alongside SHS (Burton, 2011; Matt et al., 2011).

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. 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).

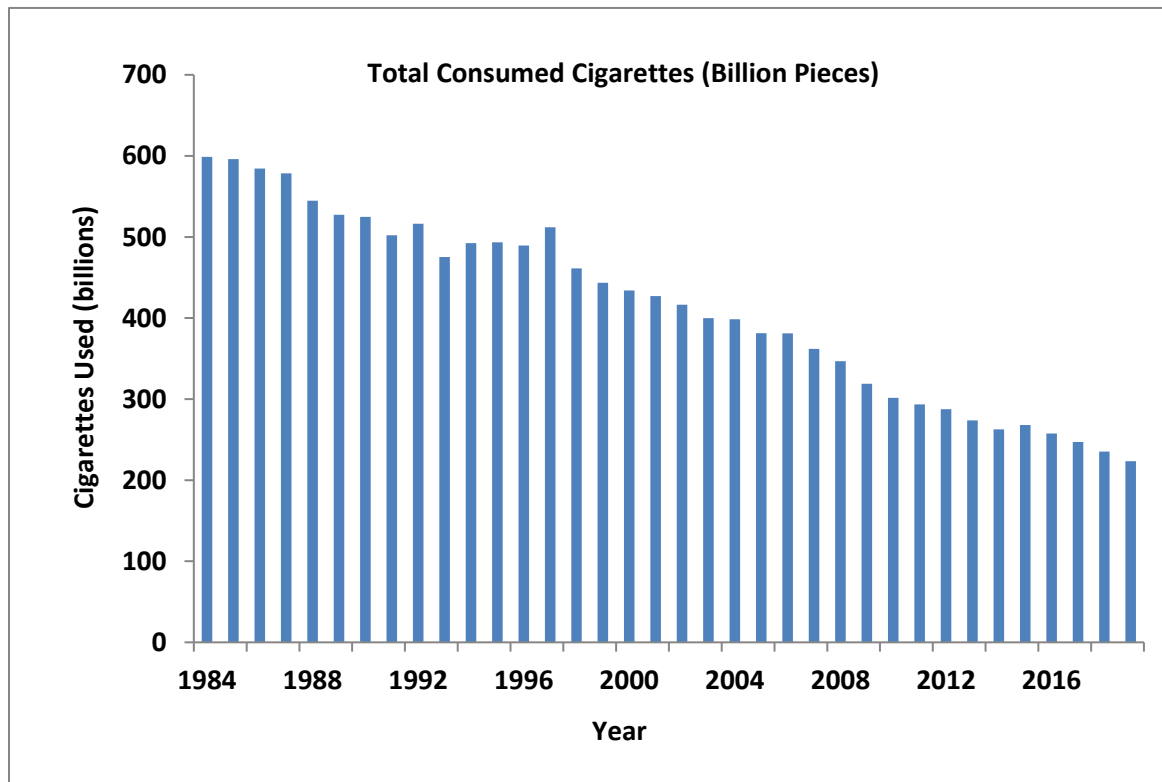
However, the use of cigarettes in the United States is declining, per the U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) Statistical Release reports (Figure 2).<sup>5</sup> This likely is responsible for the decline in SHS exposure observed in several studies that evaluated the levels of SHS exposure in children and nonsmokers living in homes of smokers (Homa et al., 2015; Yao et al., 2016). Despite the considerable ethnic and racial disparities in SHS exposure in vulnerable populations, 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. SHS exposure declined in Hispanics from 16.3% in 2000 to 3.1% in

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<sup>5</sup> U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) statistical data available at <https://www.ttb.gov/tobacco/tobacco-stats.shtml>. Accessed Sept 24, 2020.

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).

**Figure 2. Use of Cigarettes in the United States, 1984 – 2019**



As of March 10, 2020, 28 states and the District of Columbia have implemented comprehensive smoke-free laws (American Lung Association, 2020). Such laws are expected to reduce the levels of non-user exposure to SHS and THS.

The Agency does not anticipate new chemicals would be released into the environment as a result of use of the new products, relative to chemicals released into the environment due to use of other cigarettes already on the market because (1) the combustion products from the new products would be released in the same manner as the combustion products from the original products and any other marketed cigarettes, (2) the new products are expected to compete with, or replace, other currently marketed cigarettes, and (3) the ingredients in the new products are used in other currently marketed tobacco products.

### **6.3. Environmental Justice**

No new emissions are expected due to use of the new products. Therefore, there would be no disproportionate impacts on minority or low-income populations.

### **6.4. Impacts of the No-Action Alternative**

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



## **7. Potential Environmental Impacts of the Proposed Actions and Alternatives – Disposal of the New Products**

The Agency evaluated potential impacts to resources in the environment that may be affected by disposal of the new products. The Agency found no significant impacts based on publicly available information such as the documented continuous decline in use of cigarettes in the United States, and the applicant's submitted information, including the projected market volumes for the new products.

### **7.1. Affected Environment**

The affected environment includes human and natural environments in the United States because the marketing orders would allow for the new tobacco products to be sold to consumers in the United States.

### **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 cigarette butts are commonly used in other currently marketed cigarettes. Because the new products are anticipated to compete with, or replace, other currently marketed cigarettes, the butt waste generated from the new products would replace the same type of waste. Therefore, the fate and effects of any materials emitted into the air from disposal of the new products are 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 packaging materials of the new products would be expected 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 packaging is a minuscule portion of the municipal solid waste per FDA's experience in evaluating the packaging waste generated from cigarettes.

### **7.3. Biological Resources**

The proposed actions are not expected to change the continued existence of any endangered species or result in the destruction or adverse modification of the habitat of any such species, as prohibited under the U.S. ESA. Although disposal of smoldering cigarettes has been implicated in many fire incidents,<sup>6</sup> the new products are not expected to change the fire frequency as (1) the disposal of the new products would be the same as the disposal of cigarettes that are currently marketed in the United States, and (2) there would be no anticipated increase in number of cigarettes being disposed of because the new products are anticipated to compete with, or replace, other currently marketed cigarettes.

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<sup>6</sup> National Fire Protection Association. The smoking-material fire problem. Available at: <https://www.nfpa.org/News-and-Research/Data-research-and-tools/US-Fire-Problem/Smoking-Materials>. Accessed Sept 24, 2020.

#### **7.4. Water Resources**

No changes in impacts on water resources are expected due to disposal of the cigarette butts from the new products because the chemicals in the new products would be the same to chemicals in currently marketed cigarettes. The new products would replace similar products currently on the market.

#### **7.5. Solid Waste and Hazardous Materials**

A major existing environmental consequence of the use of the new products, as well as the original products and other conventional cigarettes, is littering of discarded cigarette filters or butts, which can persist in the environment for more than 18 months (Novotny and Zhao, 1999). Cigarette butts are among the most common forms of litter found on beaches (Claereboudt, 2004; Smith et al., 1997), near streams, night clubs (Becherucci and Pon, 2014), bus stops (Wilson et al., 2014), roads, and streets (Healton et al., 2011; Patel et al., 2013). Cigarette butts have been found at densities averaging more than four cigarette butts per meter squared of urban environments (Pon and Becherucci, 2012).

Compounds in cigarette butts can leach out into water, potentially threatening human health and the environment, especially marine ecosystems (Kadir and Sarani, 2015). 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 from cigarette butts after disposal depend on the environmental conditions and the chemicals in the butts. These emissions can be influenced by several factors, such as the cigarette brand, cigarette length, filter material, tobacco filler, ingredients in the cigarette, number of puffs, and the mass transfer behavior of combustion products along the cigarette.

The Agency does not foresee the introduction of the new products would notably affect the current cigarette butt waste generated from all combusted, filtered cigarettes. The waste generated due to disposal of the new products would be released to the environment and disposed of in landfills in the same manner as any other waste generated from any other combusted, filtered cigarettes in the United States. The number of cigarette butts generated is equivalent to the market projections (Confidential Appendix 1) and a portion of those would be littered.

#### **7.6. Socioeconomics and Environmental Justice**

The Agency does not anticipate changes in impacts on socioeconomic conditions or environmental justice from disposal of the new products. The waste generated due to disposal of the new products would be handled in the same manner as the waste generated from disposal of other cigarettes in the United States. No new emissions are expected due to disposal of the new products; therefore, there would be no disproportionate impacts on minority or low-income populations. Impacts of the No-Action Alternative

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

### **8. A Listing of Agencies and Persons Consulted**

Not applicable.

## **9. List of Preparers**

The following individuals were primarily responsible for preparing and reviewing this programmatic environmental assessment:

### **Preparer:**

Thomas E. Creaven, Ph.D., Center for Tobacco Products

Education: B.S. in Chemistry/Biology, Ph.D. in Biology/Neuroscience

Experience: Ten years in science education and three years in NEPA Review

Expertise: Physics, Chemistry, Biology education and NEPA Review

### **Reviewer:**

Rudaina Alrefai-Kirkpatrick, Ph.D., Center for Tobacco Products

Education: Ph.D. in Plant Molecular Biology and Virology

Experience: Forty-three years in various scientific activities including nine years in NEPA practice

Expertise: NEPA analysis, environmental risk assessment, evidence-based assessment of health technologies, NEPA Implementation

## 10. References

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

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

**CONFIDENTIAL APPENDIX 1: Modifications - The New Products Compared to the Corresponding Original Products**

The new products differ from the corresponding original products the deletion of Fire Standard Compliant (FSC) cigarette paper and the addition of alternate FSC cigarette paper leading to change in ingredients in the cigarette paper.

New Product STN	Component	Modification
EX0001188	Fiber	<ul style="list-style-type: none"> <li>• Increase in (b) (4)</li> </ul>
EX0001190	Filler	<ul style="list-style-type: none"> <li>• Decrease in (b) (4)</li> </ul>
EX0001192	Combustion modifier	<ul style="list-style-type: none"> <li>• Decrease in (b) (4),</li> </ul>
EX0001193		<ul style="list-style-type: none"> <li>and (b) (4)</li> </ul>
EX0001194	Binder	<ul style="list-style-type: none"> <li>• Decrease in (b) (4)</li> </ul>
EX0001195		<ul style="list-style-type: none"> <li>• Addition of (b) (4)</li> </ul>
EX0001196	Other	<ul style="list-style-type: none"> <li>• Addition of (b) (4)</li> </ul>
EX0001197	Processing aid	<ul style="list-style-type: none"> <li>• Addition of (b) (4)</li> </ul>
EX0001198		<ul style="list-style-type: none"> <li>• Decrease in (b) (4)</li> </ul>
EX0001199		
EX0001200		
EX0001203		
EX0001204		
EX0001206		
EX0001207		

**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.<sup>7</sup> The projected use of the new products account for a fraction of a percent of the forecasted cigarette use in the United States. The applicant stated that the new products are expected to replace the original products. The applicant also stated that the original products would not be manufactured or sold in the United States after the marketing orders are issued.

STN	Projected Market Volume			
	First Year		Fifth Year	
	New Product (# of Cigarettes)	New Product as a Percent of Total Cigarettes Used <sup>8</sup>	New Product (# of Cigarettes)	New Product as a Percent of Total Cigarettes Used <sup>9</sup>
EX0001188	(b) (4)			
EX0001190				
EX0001192				
EX0001193				
EX0001194				
EX0001195				
EX0001196				
EX0001197				
EX0001198				
EX0001199				
EX0001200				
EX0001203				
EX0001204				
EX0001206				
EX0001207				
<b>Total</b>				

<sup>7</sup> The Agency used historical data regarding total use of cigarettes from 2002 to 2019 to mathematically estimate the total number of cigarettes used in the United States. Using the best-fit trend line with an R<sup>2</sup> value of 0.9814, the forecasted number of cigarettes that would be used in the United States is estimated at 192.24 billion cigarettes in the first year and 145.78 billion cigarettes in the fifth year of marketing the new products.

<sup>8</sup> Projected Market Occupation of the New Product in the United States (%) =  $\frac{\text{Projected Market Volume of the New Products (cigarette pieces)}}{\text{Projected Use of Cigarettes in United States (cigarette pieces)}} \times 100$

<sup>9</sup> Ibid.