

**Programmatic Environmental Assessment for Marketing  
Orders for New Cigarettes Manufactured by Japan Tobacco  
International USA Inc.**

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

January 2, 2020

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### 1. Applicant and Manufacturer Information

<b>Applicant Name:</b>	Japan Tobacco International USA Inc.
<b>Applicant Address:</b>	500 Frank W. Burr Blvd., Suite 1601, Teaneck, NJ 07666
<b>Manufacturer Name:</b>	Japan Tobacco International
<b>Product Manufacturing Location:</b>	Tutlin Urunleri Sanayi, A.S. Copak Mahalles; No. 12 Torballi Izmir, Turkey

### 2. Product Information

#### New Product Names, Submission Tracking Numbers (STN), and Original Product Names

<b>New Product Name</b>	<b>STN</b>	<b>Original Product Name</b>
Wave Full Flavor 100s	EX0000736	Wave Full Favor 100s
Wave Blue 100s	EX0000737	Wave Blue 100s
Wave Silver 100s	EX0000738	Wave Silver 100s
Wave Full Flavor King Size	EX0000739	Wave Full Flavor King Size
Wave Blue King Size	EX0000740	Wave Blue King Size
Wave Menthol King Size	EX0000741	Wave Menthol King Size
Wave Menthol Green King Size	EX0000742	Wave Menthol Green King Size
Wave Silver King Size	EX0000743	Wave Silver King Size
Wave Menthol 100s	EX0000744	Wave Menthol 100s
Wave Menthol Green 100s	EX0000745	Wave Menthol Green 100s

#### Product Identification

<b>Product Category</b>	Cigarette
<b>Product Subcategory</b>	Combusted filtered
<b>Product Number per Retail Unit</b>	Twenty cigarettes per pack with ten packs per carton and shipped in boxes.
<b>Product Package</b>	The new and corresponding original products have identical packaging with hard packs consisting of cardboard, an aluminum foil liner, polypropylene outer wrap, and tear tape.

### 3. The Need for the Proposed Actions

The proposed actions, requested by the applicant, are for the 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 ten 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. These modifications are to the ingredients in the filter adhesive. (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 may be affected by manufacturing the new products and found no significant impacts based on the Agency-gathered information and the following applicant-submitted information:

- The new products are intended to compete with and eventually replace portions of similar tobacco products currently manufactured at the facility.
- No facility expansion or new construction is expected due to manufacturing the new products.
- No new compounds will be emitted, no additional environmental controls are needed and no expected increase in energy used as a result of manufacturing the new products

##### **5.1 Affected Environment**

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**



The manufacturing facility is surrounded by agricultural land to the north, east, and west; to the south is residential housing. To the west across a two-lane divided road sits a gas station and two auto repair shops.<sup>1</sup>

## **5.2 Air Quality**

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

## **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 new products are intended to replace similar tobacco products currently manufactured at the facility. The applicant also stated that manufacturing the new products would not require any additional environmental controls.

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<sup>1</sup> Google Earth. 2018. Map of Tutlin Urunleri Sanayi, A.S., Copak Mahalles; No. 12, Torbali Izmir, Turkey . Retrieved from Google Earth. November 27, 2018.

#### **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 that there would be no expected facility expansion or new construction due to manufacturing the new products. 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 that 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 the cigarette paper used to manufacture the new products is from sustainable sources and the manufacturing does not appear to threaten any endangered species or critical habitat. In addition, the applicant stated there are no plans of expanding the facility as a result of manufacturing the new products.

#### **5.6 Regulatory Compliance**

The applicant stated that the manufacturing facility is in compliance with applicable local and national environmental laws and regulations. The manufacturing facility is ISO 9001 (Quality Management Systems) and ISO 14001 (Environmental Management Systems) certified. The applicant stated that the facility complies with the ESA and the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES).

#### **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 replace similar tobacco products currently manufactured at the facility.

No changes in impacts on environmental justice are anticipated. The applicant stated manufacturing of the new products would not require expansion or new construction of the facility. Also, as discussed, the emissions and discharges from the facility are not expected to change because of manufacturing the new products.

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

The Agency does not foresee that the introduction of the new products would notably affect the current manufacturing waste generated from the facility production of all combusted, filtered 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 products manufactured in the same facility. Furthermore, the applicant stated the waste generated due to manufacturing the new products would be handled in the same manner as any other waste generated from any other products manufactured in the same.



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

There would be no 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 Cumulative Impacts**

The Agency does not anticipate the proposed actions to incrementally increase or change the chemicals released to the air from the facility due to the tobacco manufacturing. The applicant stated no new compounds would be emitted, no additional environmental controls would be needed and there would be no expected increase in energy used as a result of manufacturing the new products.

The applicant stated the new and corresponding products are essentially the same, so no changes in waste from manufacturing are expected.

## **5.11 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 Agency does not anticipate that 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 of 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. Cumulative Impacts

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).

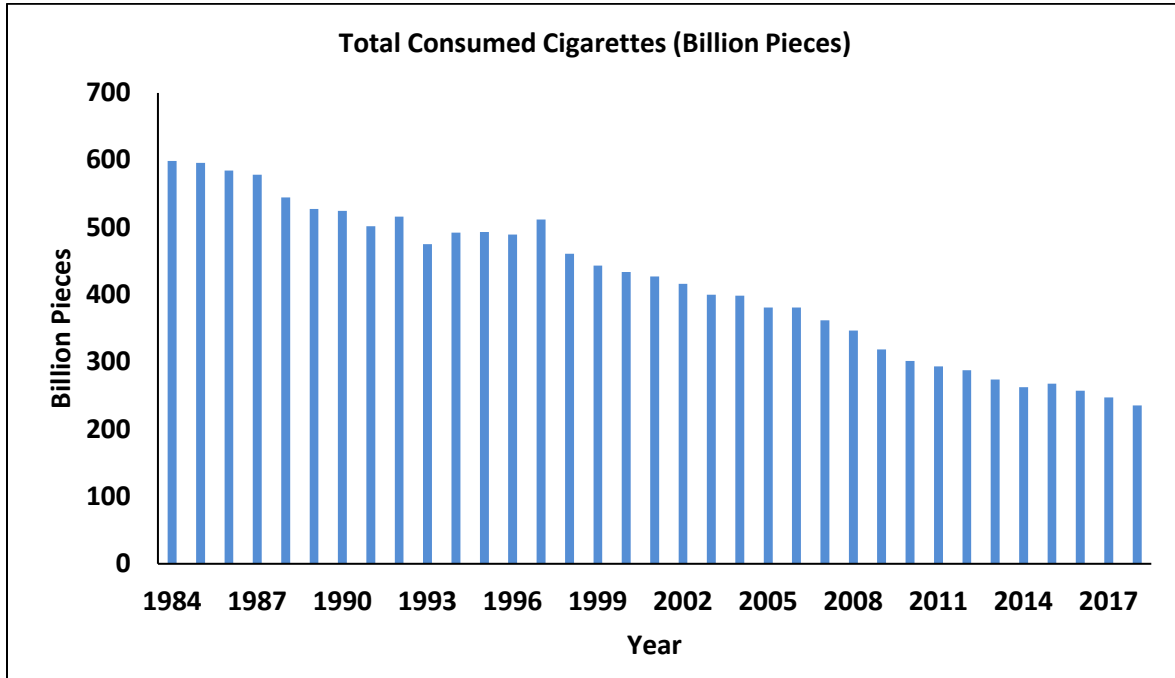
However, the use of cigarettes in the United States is declining, per the U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) Statistical Release reports, (Figure 2).<sup>2</sup> This likely is responsible for the decline in SHS exposure observed in several studies that evaluated the levels of SHS exposure 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 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).

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<sup>2</sup> U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) statistical data available at: <https://www.ttb.gov/tobacco/tobacco-stats.shtml>. Accessed March 7, 2018.



**Figure 2. Use of Cigarettes in the United States, 1984 – 2018**



As of March 2019, 28 states and the District of Columbia have implemented comprehensive smoke-free laws (American Lung Association, 2019). Such laws are expected to reduce the levels of non-user exposure to SHS and THS.

### **6.5. 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 used in the United States.

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

The Agency considered potential impacts to resources in the environment that may be affected by disposal of the new products. Based on publicly available information such as the documented continuous decline of cigarette use in the United States, and the applicant’s submitted information, including market volume projections for the new products, the Agency found no significant impacts.

### **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 new products' 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 new products' package materials 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 new products' packaging is a minuscule portion of the municipal solid waste per FDA's experience in evaluating the packaging waste generated from cigarettes. The applicant stated the new and corresponding original products packaging are identical.

### **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>3,4</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 as the new products are anticipated to replace similar marketed cigarettes.

### **7.4. Water Resources**

No changes in any impacts on water resources are expected due to disposal of the cigarette butts and packaging from the new products because the chemicals and packaging materials in the new products would be used in currently marketed cigarettes. Furthermore, the new products would compete with or replace other cigarettes currently on the market.

### **7.5. Solid Waste**

The Agency does not foresee that the introduction of the new products would notably affect the current cigarette butt and packaging 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 cigarettes marketed in the United States. The number of cigarette butts generated would be equivalent to the market projections (Confidential Appendix 2) and a portion of those would be littered.

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<sup>3</sup> National Fire Protection Association. The smoking-material fire problem. Available at: <https://www.nfpa.org/News-and-Research/Fire-statistics-and-reports/Fire-statistics/Fire-causes/Smoking-Materials>. Accessed May 22, 2018.

<sup>4</sup> UC Davis Health News. Available at: <https://www.ucdmc.ucdavis.edu/publish/news/newsroom/2763>. Accessed May 22, 2018.

## **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.

## **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 (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, types of tobacco, ingredients in the cigarette and tobacco filler, number of puffs, and the mass transfer behavior of combustion products along the cigarette.<sup>5</sup>

However, the cumulative impacts from cigarette butts is declining because the use of cigarettes in the United States is declining.

## **7.8. 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 disposed of in the United States.

## **8. List of Preparers**

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

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<sup>5</sup> NIST Technical Report 8147 available at: <http://dx.doi.org/10.6028/NIST.IR.8147>. Accessed April 24, 2018.

**Preparer:**

William E. Brenner, B.S., Center for Tobacco Products

Education: B.S. in Biology

Experience: Five years in various scientific activities

Expertise: NEPA analysis, environmental risk assessment, air quality analysis, archaeological and archival preservation

**Reviewer:**

Hoshing W. Chang, Ph.D., Center for Tobacco Products

Education: M.S. in Environmental Science and Ph.D. in Biochemistry

Experience: Eleven years in FDA-related NEPA review

Expertise: NEPA analysis, environmental risk assessment, wastewater treatment

**9. A Listing of Agencies and Persons Consulted**

Not applicable.

**10. References**

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U.S. Department of Health and Human Services. 2006a. The Health Consequences of Involuntary Exposure to Tobacco Smoke: A Report of the Surgeon General. Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Coordinating Center for Health Promotion, Office on Smoking and Health. Atlanta, GA.

U.S. Department of Health and Human Services. 2006b. The Health Consequences of Involuntary Exposure to Tobacco Smoke: A Report of the Surgeon General—Secondhand Smoke: What It Means to You (Consumer Booklet). Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Coordinating Center for Health Promotion, Office on Smoking and Health. Atlanta, GA.

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**CONFIDENTIAL APPENDIX 1. Modifications: New Products as Compared with the Corresponding Original Products**

STN	Modification
EX0000736	
EX0000737	
EX0000738	Deletion of (b) (4)
EX0000739	[Redacted]
EX0000740	[Redacted]
EX0000741	
EX0000742	Addition of (b) (4)
EX0000743	[Redacted]
EX0000744	
EX0000745	



**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 of the new products were compared to the total forecasted use of cigarettes in the United States.<sup>6</sup> The projected use of the new products in the first and fifth years of marketing after marketing orders are issued account for about (b) (4) and (b) (4), respectively, of the forecasted cigarette use in the United States. The applicant stated that the new products will replace the corresponding original products.

STN	Projected Market Volume			
	First Year		Fifth Year	
	New Product (Cigarettes)	New Product as a Percent of Total Cigarettes Used <sup>7</sup>	New Product (Cigarettes)	New Product as a Percent of Total Cigarettes Used <sup>8</sup>
EX0000736	(b) (4)	(b) (4)	(b) (4)	(b) (4)
EX0000737	(b) (4)	(b) (4)	(b) (4)	(b) (4)
EX0000738	(b) (4)	(b) (4)	(b) (4)	(b) (4)
EX0000739	(b) (4)	(b) (4)	(b) (4)	(b) (4)
EX0000740	(b) (4)	(b) (4)	(b) (4)	(b) (4)
EX0000741	(b) (4)	(b) (4)	(b) (4)	(b) (4)
EX0000742	(b) (4)	(b) (4)	(b) (4)	(b) (4)
EX0000743	(b) (4)	(b) (4)	(b) (4)	(b) (4)
EX0000744	(b) (4)	(b) (4)	(b) (4)	(b) (4)
EX0000745	(b) (4)	(b) (4)	(b) (4)	(b) (4)
<b>Total</b>	(b) (4)	(b) (4)	(b) (4)	(b) (4)

<sup>6</sup> The Agency used historical data regarding total use of cigarettes from 2002 to 2018 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 228.657 billion cigarettes in the first year and 205.021 billion cigarettes in the fifth year of marketing the new products.

<sup>7</sup> Projected Market Occupation of the New Products 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>8</sup> Ibid.