Environmental Assessment for Marketing Order for a New Cigar Component by

Fronto King LLC

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

6/29/2022

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1. Applicant and Manufacturer Information

Applicant Name:	Fronto King LLC
Applicant Address:	22 Court Avenue, Brockton, Massachusetts 02301
Manufacturer Name:	(b)(4)
Product Manufacturing Location:	(b)(4)

2. Product Information

New Product (STN), New Product Name, and Predicate Product Name

New Product STN	New Product Name	Predicate Product Name
SE0023356	Fronto King Mini Leaf	Fronto King Original Whole Leaf

Product Identification

Product Type	Cigar
Product Subcategory	Cigar Component (wrapper)
Quantity per Retail Sale Unit	One cigar wrapper per pouch
Product Package	The packaging material consists of a foil pouch

3. The Need for the Proposed Action

The proposed action, requested by the applicant, is for FDA to issue a marketing order under the provisions of sections 910 and 905(j) of the Federal Food, Drug, and Cosmetic Act after finding the new product substantially equivalent to the predicate product. The applicant wishes to introduce the new product into interstate commerce for commercial distribution in the United States and submitted to the Agency one substantial equivalence (SE) Report to obtain the marketing order. The new product is intended to compete with and eventually replace similar tobacco products on the market. The Agency shall issue the marketing order if the new product is found substantially equivalent to the predicate product.

The new product and the predicate product differ in their target length and width (Appendix 1).

4. Alternative to the Proposed Action

The no-action alternative is FDA does not issue a marketing order for the new product in the United States.

5. Potential Environmental Impacts of the Proposed Actions and the Alternatives - Manufacturing the New Product

The new product is manufactured outside of the United States at the address listed in section 1 of this document. The applicant stated that manufacturing the new product would not (1) require an expansion of the manufacturing facility, (2) require additional environmental controls, or (3) lead to changes in air emission or wastewater discharges. The applicant also stated that the manufacturing facility complies with all applicable environmental regulations and is not located within or near a habitat, critical or otherwise, of a threatened or endangered species. Therefore, the Agency does not expect adverse environmental effects due to manufacturing the new product.

6. Potential Environmental Impacts of the Proposed Action and Alternatives – Use of the New Product

The Agency considered potential impacts to resources in the environment that could be affected by use of the new product and found no significant impact 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 product as proxy for use in the United States (Confidential Appendix 1).

6.1 Affected Environment

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

6.2 Air Quality

The impact from use of combusted tobacco products include exposure to secondhand smoke (SHS) produced from burned cigars, cigarettes, cigarillos and pipes. 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 a mixture in the environment alongside SHS. [1, 2]

There is no safe level of exposure to SHS. [3, 4] 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 20-30%. [5]
- 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. Such exposure can cause coughing, wheezing, phlegm, and breathlessness. [3, 4]
- SHS causes more than 40,000 deaths a year. [5]

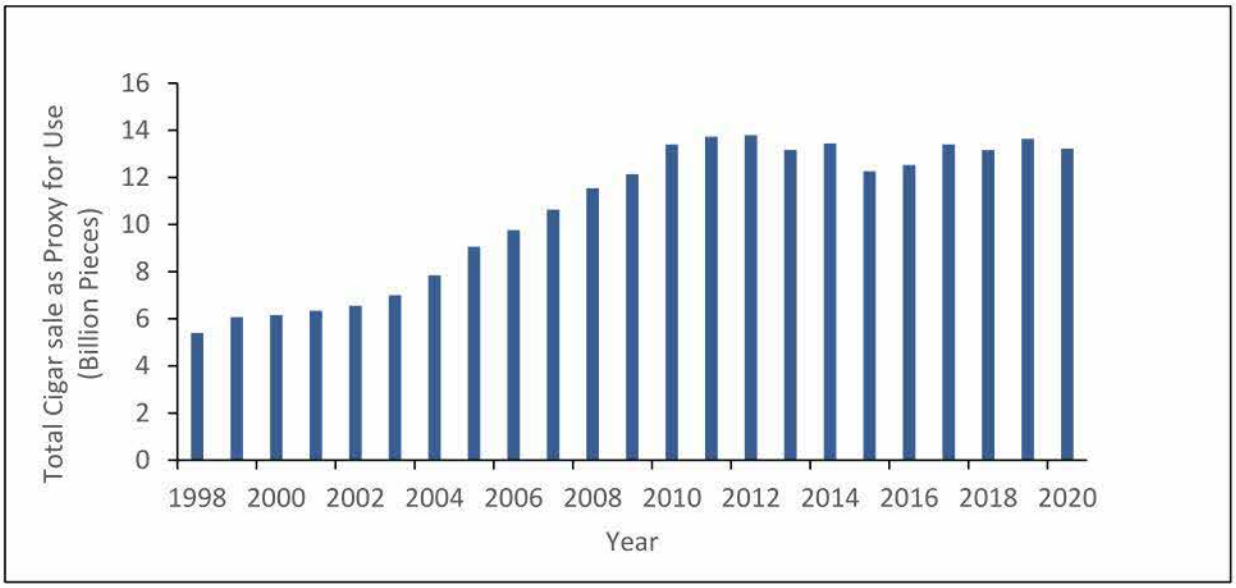
Cigar sale as proxy for consumption in the United States increased significantly from 1997 to 2011. Since 2011 through 2020, the trend of cigar use* has stabilized with a minor decrease overall, per the U.S.

*Cigar sale data reported in TTB tobacco statistical reports is used as proxy for use.

Alcohol and Tobacco Tax and Trade Bureau (TTB) Statistical Release reports (Figure 1). [6] In combination with declines in use of other tobacco products, a decline in SHS exposure was observed in several studies that evaluated the levels of SHS exposure in children and nonsmokers living in homes of smokers. [7, 8]

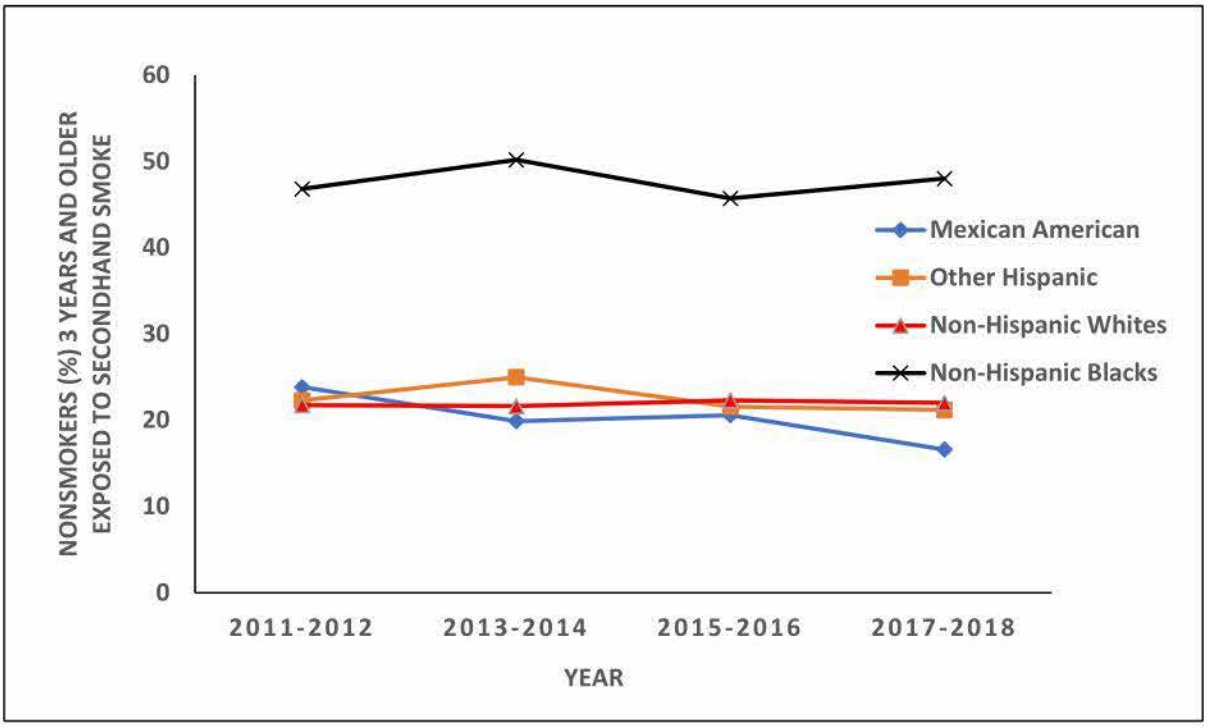
Despite the considerable ethnic and racial disparities in SHS exposure in vulnerable populations, data from the National Health and Nutrition Examination Survey showed a decline in SHS exposure from 87.5% in 1988-1991 to 25.1% in 2013-2014 with the highest prevalence of exposure among non-Hispanic black (50.3%), compared to Mexican Americans (20%) and non-Hispanic whites (21.4%) in 2013-2014. [9] However, no change in exposure occurred between 2011–2012 and 2013–2014. [9] There were also significant declines in SHS exposure prevalence noted in the 2000 and 2010 National Health Interview Survey Cancer Control Supplements. Exposure to SHS 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. [8]

Figure 1. Total Cigar Sale as Proxy for Use in the United States, 1997 – 2020. [6]



However, in recent years, a stagnation in reduction in rate of SHS exposure has been reported (Figure 2). [10]

Figure 2. Trends in the Exposure of Nonsmokers to Secondhand Smoke [10]



As of December 2020, 28 states and the District of Columbia had implemented comprehensive smoke-free laws. [11] Such laws are also expected to reduce the levels of non-users' 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 product, relative to chemicals released into the environment due to use of other cigars already on the market, because (1) the combustion products from the new product would be released in the same manner as the combustion products of other marketed cigars; (2) the new product is expected to compete and replace other currently marketed cigars; and (3) the ingredients in the new product are used in other currently marketed tobacco products.

6.3 Environmental Justice

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

6.4 Impacts of the No Action Alternative

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

7. Potential Environmental Impacts of the Proposed Actions and Alternatives – Disposal of the New Product

The Agency considered potential impacts to resources in the environment that may be affected by disposal of the new product. Based on TTB data, which shows relatively stable rates of cigar use in the

United States since 2010[1] and the applicant's submitted information, including market volume projections for the new product, the Agency found no significant impacts (Confidential Appendix 1).

7.1 Affected Environment

The affected environment includes human and natural environments in the United States because the marketing order would allow for the applicant to distribute and sell the new product to consumers in the United States.

7.2 Air Quality

The Agency does not anticipate disposal of the new product, 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 cigar butts of the new product. The chemicals in the cigar butts are commonly used in other currently marketed cigars. The new product is currently commercially marketed and will compete with and replace other cigars currently on the market. Because the market for cigars is not expected to materially increase (Figure 1), the butt waste generated from the new product would replace the same type of waste. Therefore, the fate and effects of any materials emitted into the air from disposal of the new product is anticipated to be the same as any materials from other cigars disposed of in the United States.

No changes in air quality from disposal of the packaging materials for the new product would be expected because; (1) the foil packages is more likely to be recycled or at least a portion of the packaging waste is likely to be recycled, (2) the foil packaging material is commonly used in the United States, and (3) the waste generated due to disposal of the foil packaging is a minuscule portion of the municipal solid waste per FDA's experience in evaluating the packaging waste generated from tobacco products. [12]

7.3 Water Resources

No new impacts on water resources are expected due to disposal of the unburned cigars and packaging from the new product because the chemicals in the new product would be the same or similar as in currently marketed cigars and the new product would compete with or replace other cigars currently on the market.

7.4 Biological Resources

The proposed action is 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. Endangered Species Act (ESA) because (1) the disposal of the new product would be similar to the disposal of cigar tobacco products that are currently marketed in the United States, and (2) there would be no anticipated increase in number of cigar tobacco products being disposed of as the new product is anticipated to compete and replace similar marketed tobacco products.

7.5 Solid Waste

The use of the new product may impact the environment similarly through littering of discarded non-combusted cigar butts. The environmental impacts from cigar litter are not well studied, and potentially poses similar environmental risk as cigarette butts, which can persist in the environment. [13]

The Agency does not foresee the introduction of the new product would notably affect the current and packaging waste generated from all cigars. The waste generated due to disposal of the new product would be handled in the same manner as any other waste generated from any other cigars disposed of in the United States. The number of cigars generated is equivalent to the market projections; 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 product. The waste generated due to disposal of the new product is expected to be handled in the same manner as the waste generated from other cigars in the United States. No new emissions are expected due to disposal of the new product and therefore, there would be no new disproportionate impacts on minority or low-income populations.

7.7 Impact of the No-Action Alternative

The no-action alternative would not change the existing condition of disposal of cigars and cigar packaging, as 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 environmental assessment:

Preparer:

Vyomesh Patel, Ph.D., Center for Tobacco Products

- Education: PhD in Head and Neck Cancer
- Experience: Twenty-four years in pharmaceutical toxicology and experimental carcinogenesis
- Expertise: Preclinical drug evaluation, regulatory toxicology, animal models of human cancers

Reviewer:

Shannon K. Hanna, Ph.D., Center for Tobacco Products

- Education: Ph.D. in Environmental Science and Management
- Experience: Six years in environmental science, three years in toxicology
- Expertise: Ecotoxicology of new substances and materials, bioaccumulation of chemicals including heavy metals, soil/sediment and water quality

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 ten years in NEPA practice
- Expertise: NEPA analysis, environmental risk assessment, evidence-based assessment of health technologies, NEPA Implementation

9. A Listing of Agencies and Persons Consulted

None

10. References

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Appendix 1. Changes in the New Product Compared to the Predicate Product

STN	Changes from Predicate Product
SE0023356	• The range of new product length decreased from (b)(4) mm in the predicate to (b)(4) mm • The range of new product width decreased from (b)(4) mm–(b)(4) mm in the predicate to (b)(4) mm

Confidential Appendix 1. Market Volumes for the New and Predicate Products

The new and predicate products are currently marketed in the United States. The new product is intended to compete with and eventually replace similar tobacco products already on the marketplace. The first- and fifth year market projections for the new product is compared to the total forecasted use of cigars in the United States. [**,†,‡] The projected use of the new product in the first- and fifth-year of marketing after marketing orders are issued would account for (b)(4), respectively, of the forecasted cigar use in the United States. Retail unit is one cigar wrapper per pack.

STN	Market Volume					
	New product (Number of Cigar Wrappers)			Predicate product (Number of Cigar Wrappers)		
	Current-Year	First-Year	Fifth-Year	Current-Year	First-Year	Fifth-Year
SE0023356	(b)(4)					

** Market volumes are used as proxy for use, assuming that all produced products will be consumed or used in the United States.

† The Agency used historical data regarding total sale of cigars as proxy for use from 1997 to 2020 to mathematically estimate the total number of cigars used in the United States. Using the best-fit trend line with an R^2 value of 0.926, the forecasted number of cigars that would be used in the United States is estimated at 13.42 billion cigars in the first year and 12.75 billion cigars in the fifth year of marketing the new product.

‡ Projected Market Occupation of the New Product in the United States (%) =

$$\frac{\text{Projected Market Volume of the New Product (cigar pieces)}}{\text{Projected Use of Cigars in United States (cigar pieces)}} x\ 100$$