

**Programmatic Environmental Assessment
for Marketing Orders for New Cigars
by Ashton Distributors Inc.**

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

December 20, 2021

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1. Applicant and Manufacturer Information

Applicant Name:	Ashton Distributors Inc.
Applicant Address:	12270 Townsend Rd, Philadelphia PA 19154
Manufacturer Name:	(b) (4)
Product Manufacturing Location:	(b) (4)

2. Product Information

Submission Tracking Numbers (STNs), New Products, and Predicate Products

New Product STN	New Product	Predicate Product
SE0018754	Ashton Senioritas Bx50	Ashton Senioritas (10-Cigar Box)
SE0018755	Ashton Connecticut Senioritas Bx50	Ashton Senioritas (10-Cigar Box)

Product Identification

Product Category	Cigars
Product Subcategory	Leaf-Wrapped Cigars
Product Number per Retail Unit	50
Product Package	Paper box

3. Need for the Proposed Actions

The proposed actions, requested by the applicant, are for the US Food and Drug Administration (FDA) to issue marketing orders under provisions of sections 910 and 905(j) of the Federal Food, Drug, and Cosmetic Act after finding the new products substantially equivalent to corresponding predicate products. The applicant wishes to introduce the new products into interstate commerce for commercial distribution in the United States and submitted to the Agency substantial equivalence (SE) reports to obtain marketing orders. The Agency shall issue the marketing orders if the new products are found substantially equivalent to corresponding predicate products. The applicant indicates that new products differ from corresponding predicate products only in package quantity (Confidential Appendix 1) and that new products will not replace corresponding predicate products (Confidential Appendix 2).

4. Alternative to the Proposed Actions

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

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

The new products are manufactured outside of the United States by (b) (4)

(b) (4)

The applicant indicates that the same materials

currently used in the manufacturing process would be used to manufacture the new products. Therefore, production of the new products will not result in new compounds emitted or increased amounts of compounds currently emitted by the manufacturing facility. The applicant also indicates that new or revised air emissions or wastewater discharge permits are not required, that no additional environmental controls are necessary, that manufacturing does not affect critical habitat, and that the manufacturing facility to their knowledge is not within or in close proximity to threatened or endangered species habitat.

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

The Agency evaluated potential impacts of new product use to resources in the environment and found no significant impacts based on Agency-gathered information and the applicant's submitted information. Included in the information that the Agency considered were projected first and fifth year market volumes and documented cigar use in the United States (Confidential Appendix 2 and Figure 1).

6.1 Affected Environment

The affected environment includes human and natural environments in the United States because marketing orders would allow the new 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 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 (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:

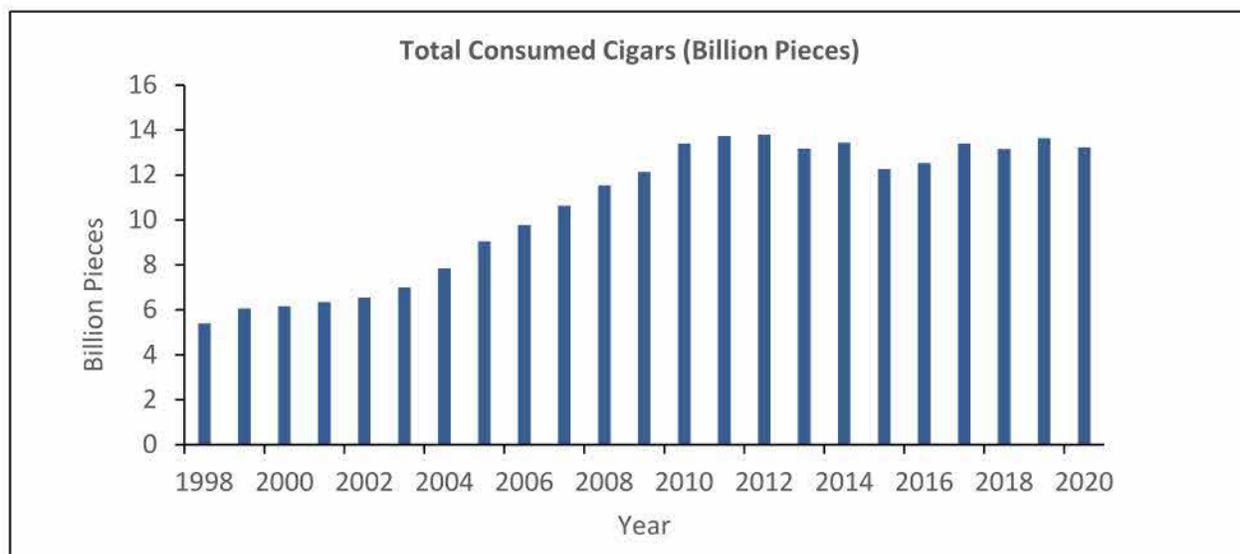
- The U.S. Surgeon General estimates that living with a smoker increases a nonsmoker's chances of developing lung cancer by 20 to 30% (U.S. Department of Health and Human Services, 2014).
- Exposure to SHS increases school children's risk for ear infections, lower respiratory illnesses, more frequent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

The consumption of cigars 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. Alcohol and Tobacco Tax and Trade Bureau (TTB) Statistical Release reports (Figure 1; U.S. Alcohol and Tobacco Tax and Trade Bureau, 2021). In combination with declines in use of other tobacco products, it is likely that this 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 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 (Yao et al., 2016).

Figure 1. Use of Cigars in the United States, 1997 – 2020



As of December 2020, 28 states and the District of Columbia had implemented comprehensive smoke-free laws (American Lung Association, 2020). Such laws are also expected to reduce the levels of non-users' exposure to SHS and THS.

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 cigars already on the market, because (1) combustion products from the new products would be released in the same manner as combustion products of other marketed cigars, (2) the new products are expected to compete with other currently marketed cigars, and (3) ingredients in the new products are used in other currently marketed tobacco products .

6.3 Environmental Justice

Because new products are not expected to increase overall cigar consumption, no new emissions are expected. Therefore, there would be no new disproportionate impacts on minority or low-income populations.

6.4 Cumulative Impacts

The Agency did not identify any actions that would lead to cumulative impacts from use of the new products under the proposed actions.

6.5 Impacts of the No-Action Alternative

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

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

The Agency considered potential impacts of new product disposal to resources in the environment. Based on TTB data, which shows relatively stable cigar use rates in the United States since 2011 (Figure 1; U.S. Alcohol and Tobacco Tax and Trade Bureau, 2021), and the applicant's submitted information, including market volume projections for the new products (Confidential Appendix 2), the Agency found no significant impacts.

7.1 Affected Environment

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

7.2 Air Quality

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

No changes in air quality are anticipated from disposal of unburned new products or butts. Chemicals in the new products and butt waste are commonly found in other currently marketed cigars. Because the new products are anticipated to compete with other currently marketed cigars, butt waste generated from new products would replace the same type of waste. Therefore, the fate and effects of materials emitted into the air from new product disposal are anticipated to be the same as for that of materials from disposal of other cigars in the United States.

No changes in air quality from disposal of new product packaging materials would be expected because: (1) at least a portion of packaging waste is likely to enter the recycling stream, (2) packaging materials are commonly used in the United States, and (3) waste generated from packaging disposal (U.S.

Environmental Protection Agency, 2020) is a minuscule portion of municipal solid waste per FDA's experience evaluating packaging waste generated from tobacco products.

7.3 Water Resources

No new impacts to water resources are expected from disposal of unburned cigars, packaging, or cigar butts because chemicals in the new products would be the same or similar to those in currently marketed cigars and new products would compete with other cigars currently on the market.

7.4 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. Endangered Species Act (ESA) because: (1) new product disposal would be similar to currently marketed similar products in the United States, and (2) there would be no anticipated increase in cigar disposal, because new products are anticipated to compete with similar products.

7.5 Solid Waste

Environmental impacts from cigar litter are not well studied, and potentially pose similar risks as cigarette butts, which can persist in the environment (Novotny and Zhao, 1999). Compounds in cigar butts can leach into water and like cigarettes, might threaten human health and the environment, especially in aquatic and marine ecosystems (Kadir and Sarani, 2015). Characteristics influencing air emissions might also resemble those from cigarettes, such as chemicals in the butts, brand, length, filter material, tobacco type, filler ingredients, number of puffs, mass transfer behavior of combustion products along the cigarette, and environmental conditions (Poppendieck et al., 2016).

The Agency does not foresee the introduction of the new products would notably affect current waste generated from all cigars. Waste generated from new product disposal would be handled in the same manner as waste generated from other cigars in the United States. The number of cigars would be equivalent to market projections (Confidential Appendix 2), and a portion of those would be littered.

7.6 Socioeconomics and Environmental Justice

The Agency does not anticipate changes in impacts to socioeconomic conditions or environmental justice from new product disposal. Wastes are expected to be handled in the same manner as wastes from other cigars in the United States. No new emissions are expected and therefore there would be no new disproportionate impacts on minority or low-income populations.

7.7 Cumulative Impacts

The Agency did not identify any actions that would lead to cumulative impacts from disposal of the new products under the proposed actions.

7.8 Impacts 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:

Christy Leppanen, Ph.D., Center for Tobacco Products

Education: Ph.D. in Biological Sciences

Experience: Twenty-two years in environmental management and compliance

Expertise: Environmental toxicology, risk assessment, population management, regulatory compliance

Reviewer:

Gregory Gagliano, M.S., Center for Tobacco Products

Education: M.S. in Environmental Science

Experience: Thirty-eight years in environmental compliance and analysis

Expertise: Environmental toxicology, risk assessment, NEPA analysis, regulatory compliance

9. A Listing of Agencies and Persons Consulted

Not applicable.

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Confidential Appendix 1: Comparison of New Products with Corresponding Predicate Products

STN	Target Diameter (mm)		Target Length (mm)		Package Type		Package Quantity (# cigars/box)	
	New Product	Predicate Product	New Product	Predicate Product	New Product	Predicate Product	New Product	Predicate Product
SE0018754	11.91	11.91	88.90	88.90	paper box	paper box	50	10
SE0018755	11.91	11.91	88.90	88.90	paper box	paper box	50	10

Confidential Appendix 2: Projected Market Volumes and Percent of United States Cigar Use Attributed to New and Predicate Products

First and fifth year market volume projections for the new and predicate products were compared to the total forecasted use of cigars in the United States.¹ The sum of the new product (SE0018754) and associated predicate product would account for about (b) (4) % and (b) (4) % of forecasted United States cigar use in the first and fifth years of marketing, respectively. Likewise, the new product (SE0018755) and its associated predicate product would account for (b) (4) % and (b) (4) %.

STN	Current Volumes		Projected Volumes					
	New Product (# cigars)	Predicate (# cigars)	First Year			Fifth Year		
			New Product (# cigars)	Predicate (# cigars)	% of Total Cigars Used ²	New Product (# cigars)	Predicate (# cigars)	% of Total Cigars Used ³
SE0018754	(b) (4)							
SE0018755								

¹ The Agency used historical data about total cigar use from 1997 to 2020 (U.S. Alcohol and Tobacco Tax and Trade Bureau, 2021) to mathematically estimate the total number of cigars used in the United States. Using the best-fit trend line with an R² value of 0.9287, the forecasted number of cigars 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.

² Projected Market Occupation of the New and Predicate Products in the United States (%) = $\frac{\text{Projected Market Volume of the New and Predicate Products (\# of cigars)}}{\text{Projected Use of Cigars in United States (\# of cigars)}} \times 100$

³ Ibid.