

**Environmental Assessment for a
Marketing Order for a New Cigar Component
by**

BBK Tobacco & Foods, LLP Company dba HBI International

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

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1. Applicant and Manufacturer Information

Applicant Name:	BBK Tobacco & Foods, LLP Company dba HBI International
Applicant Address:	3401 West Papago Street Phoenix, AZ 85009
Manufacturer Name:¹	(b) (4)
Product Manufacturing Location¹:	The manufacturing facilities are located outside the United States

2. Product Information

New Product Name, Submission Tracking Number (STN), and Predicate Product Name

Tobacco Product	New Product	Predicate Product (Previously Found SE)	Predicate (Grandfathered)
STN	SE0015386	Not applicable	Not available
Name	CYCLONESHONEY 2FER	Not applicable	CYCLONESHONEY
Eligibility status	Not applicable	Not applicable	Grandfathered
Relevant amendments	SE0015437 SE0015473 SE0016004 SE0021982		

Product Identification

Product Category	Cigar
Product Subcategory	Cigar component
Quantity per Retail Unit	Two-cigar cones per tube, twenty-four tubes per display box
Product Package	The packaging materials consist of a polypropylene individual cigar tube and a polypropylene tube cap. The tubes are packaged in paperboard packs, which are overwrapped with polypropylene tear tape, and packed in corrugated board shipping case.

¹ The new and predicate products are marketed by HBI International but manufactured at a foreign facility; the cigar cones are hand-rolled by (b) (4)

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 tobacco product substantially equivalent to the predicate product. The applicant wishes to introduce the new tobacco product into interstate commerce for commercial distribution in the United States and submitted to the Agency a substantial equivalence (SE) report to obtain the marketing order. The predicate product is no longer marketed in the United States. The Agency shall issue the marketing order if the new product is found substantially equivalent to the predicate product.

The new and predicate products are [REDACTED] (b) (4) to form a cone that is attached on the outside of a paper tip with adhesive at one end. The new product differs from the predicate product in quantity of cones per retail tube, cone length and cone weight (Appendix 1).

4. Alternative to the Proposed Action

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

5. Potential Environmental Impacts of the Proposed Action and the Alternative - Manufacturing the New Product

The Agency considered potential environmental impacts that may be caused by manufacturing the new product and found no significant impacts. Included in the information the Agency considered were the projected market volumes for the new product (Confidential Appendix 1).

The new products are currently manufactured outside of the United States at two separate locations as indicated in Section 1. The predicate product is no longer manufactured.

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

The Agency evaluated potential impacts to resources in the environment that may be affected by use of the new product 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 current year, first- and fifth-year of marketing of the new product and the documented use of cigars in the United States (Confidential Appendix 1 and Figure 1, respectively).

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 tobacco 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 (Burton, 2011; Matt et al., 2011).

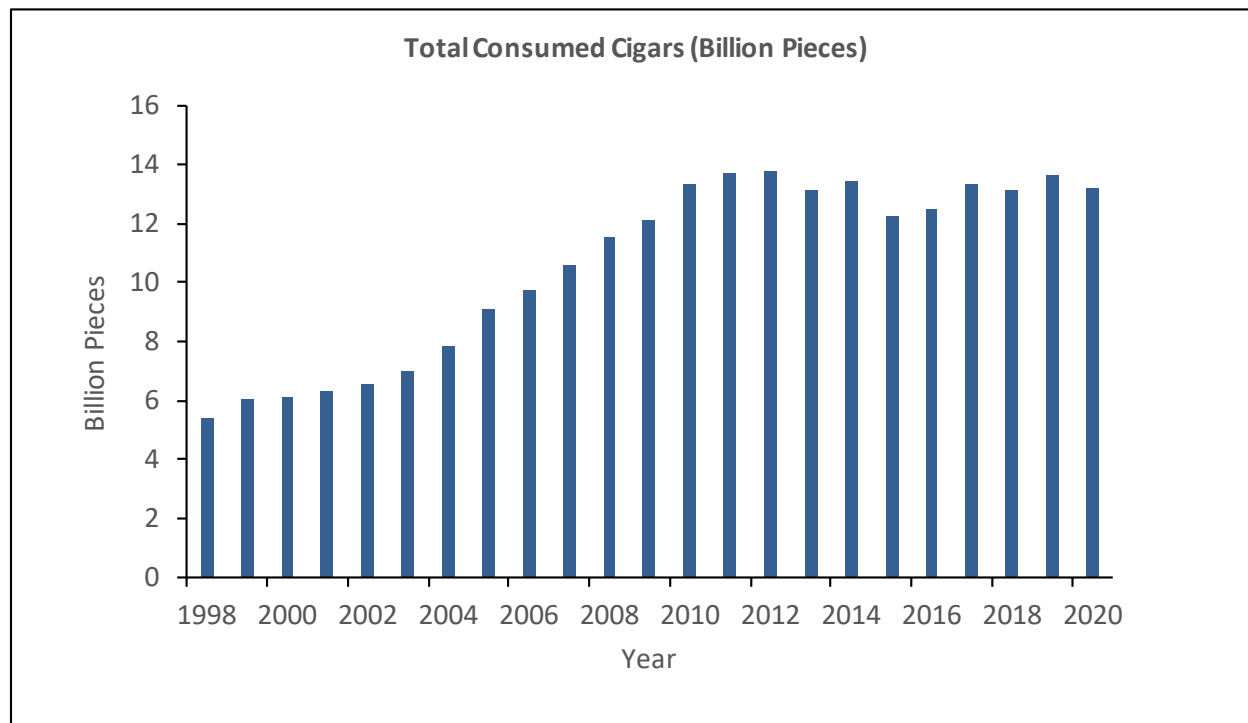
There is no safe level of exposure to SHS (U.S. Department of Health and Human Services, 2006a and 2006b). Even low levels of SHS can harm children and adults in many ways, including the following:

- 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 2019, the trend of cigar usage has stabilized with a minor decrease overall, per the U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) Statistical Release reports (Figure 1).² In combination with declines in use of other tobacco products, 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. 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).

²U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) statistical data available at: <https://www.ttb.gov/tobacco/tobacco-stats.shtml>. Accessed March 2021.

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 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 is 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 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 Alternative – 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 2010², 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 polypropylene cigar tubes, paperboard, polypropylene tear tape and corrugated board shipping cases of the new tobacco product. The chemicals in the packaging are commonly used in other currently marketed cigar products. Because the new product will compete with other cigar products on the market, the 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 are anticipated to be the same as any materials from other cigar products and their packaging 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) polypropylene cigar tubes, paperboard, polypropylene tear tape and corrugated board shipping case 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 tobacco products (U.S. Environmental Protection Agency, 2019).

7.3 Water Resources

No new impacts on water resources are expected due to disposal of the unburned paper tip of the cigar cone, polypropylene cigar tubes, paperboard, polypropylene tear tape and corrugated board shipping cases 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 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) 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 is not well studied, and potentially poses similar environmental risk as cigarette butts, which can persist in the environment (Novotny and Zhao, 1999).

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:

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: Five 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

9. A Listing of Agencies and Persons Consulted

Not applicable.

10. References

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Appendix 1. Comparison Between the New Product and the Predicate Product.

STN	Change in the New Product as Compared to the Predicate Product
SE0015386	<ul style="list-style-type: none">• Increase in quantity from one cone to two-stacked cones per retail plastic tube• Decrease in length of cone from 4-inch to 3-inch• Decrease in weight of cone• Inclusion of a small wooden stick inside retail tube used for packing cones with tobacco

Confidential Appendix 1. Current, First- and Fifth-Year Market Volume and Market Projections for the New Product.

The predicate product is no longer manufactured. Current, first- and fifth-year market volume and market projections for the new product are for the finished product that includes pre-rolled cone with paper tip.

STN	Market Volume Projections of the New Product (Number of Cones with Tips)		
	Current Year	First-Year	Fifth-Year
SE0015386			(b) (4)