

**Environmental Assessment for Marketing Order for
Roll-Your-Own Tobacco Product by
BBK Tobacco & Foods, LLP Company**

**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:	See Confidential Appendix 1
Address Where Product is Manufactured	See Confidential Appendix 1

2. Product Information

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

New Product Name	New Product STN	Predicate Product Name
Double Dutch Tips	SE0015150	Elementstips Original

Product Identification

Product Type	Roll-Your-Own
Product Subtype	Paper Tip
Product Package	100 paper tips per book; 24 booklets per display box. The packaging materials consist of cardstock, ink and glue. The display box is made from cardstock.

3. The Need for the Proposed Action

The proposed action, requested by the applicant, is for the Food and Drug Administration (FDA) to issue a marketing order under the provisions of sections 910 and 905(j) of the Federal Food, Drug, and Cosmetic Act.

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 a marketing order. The Agency shall issue a marketing order if the new product is found substantially equivalent to the predicate product. The predicate product is a grandfathered product commercially marketed in the United States as of February 15, 2007.

The new product differs from the predicate product in the package quantity and product design (Confidential Appendix 2).

4. Alternatives to the Proposed Action

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

5. Potential Environmental Impacts of the Proposed Action and Alternatives – Manufacturing the New Product

The Agency considered potential impacts on resources in the environment that may be affected by manufacturing the new product and found no significant impacts based on the Agency-gathered information and the submitted information by the applicant.

5.1 Affected Environment

The new product would be manufactured at the address listed in Confidential Appendix 1 of this document.

5.2 Analysis of Potential Environmental Impacts

The Agency evaluated the proposed action for potential environmental impacts due to manufacturing based on Agency-gathered information and the applicant’s submitted information, including projected market volume for the new product (Confidential Appendix 3).

Environmental Resource	Analysis of Potential Impacts
Air Quality	The applicant stated that manufacturing the new product is not expected to require any additional environmental controls. This is supported by the applicant noting that the materials used in manufacturing the new product are currently used in the facility.
Water Resources	The applicant stated that manufacturing the new product is not expected to require any additional environmental controls. This is supported by the applicant noting the materials used in manufacturing the new product are currently used in the facility.
Soil, Land Use, and Zoning	The Agency does not anticipate that manufacturing the new product would lead to changes in soil, land use, or zoning. The applicant stated that there would be no expected facility expansion due to manufacturing the new product. Therefore, there would be no zone change or land conversion of prime farmland, unique farmland, or farmland of statewide importance to non-agricultural use.
Biological Resources	No facility expansion is expected; therefore, the Agency does not anticipate manufacturing the new product would jeopardize the continued existence of any listed species or result in adverse effects on species or habitats addressed under the Convention on International Trade in Endangered Species of Wild Flora and Fauna (CITES).
Socioeconomics and Environmental Justice	The Agency does not anticipate any impacts on employment, revenue, or taxes because the new product is intended to compete with and eventually replace similar tobacco products currently manufactured at the facility. Therefore, no disproportionate impacts to minority populations near the manufacturing facility is expected.
Solid Waste and Hazardous Materials	The Agency does not foresee that the introduction of the new product would notably affect the current manufacturing waste generated from the production of all RYO tobacco products at this facility.

Floodplains, Wetlands, and Coastal Zones	There would be no facility expansion due to manufacturing the new product and the applicant did not propose any land disturbance; therefore, there would be no effects on floodplains, wetlands, or coastal zones.
Regulatory Compliance	The applicant stated that the manufacturing facility is in compliance with all applicable laws, regulations, and local ordinances.

5.3 Cumulative Impacts

No action was identified that, when considered with the proposed action, would lead to cumulative impacts.

5.4 Impacts of the No-Action Alternative

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

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 may be affected by use of the new product and found no significant impacts.

6.1. Affected Environment

The affected environment includes human and natural environments in the United States. The marketing order would allow for the distribution and sale of the new tobacco product to consumers in the United States. The new product is a RYO tobacco product that is intended to be filled with tobacco and smoked by users indoors or outside, as the law permits.

6.2. Analysis of Potential Environmental Impacts

The Agency evaluated the proposed action for potential environmental impacts from the new product use based on the applicant’s submitted information.

Environmental Resource	Analysis of Potential Impacts
Air quality	The Agency anticipates that no new compounds would be emitted from use of the new product because (1) the new product is expected to compete with, or replace, similar currently marketed tobacco products and (2) the ingredients in the new product are used in other currently marketed tobacco products.
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.

6.3. Cumulative Impacts

No action was identified that, when considered with the proposed action, would lead to cumulative impacts.

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 the RYO tipping papers, as many other similar tobacco products would continue to be marketed.

7. Potential Environmental Impacts of the Proposed Action 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 and its packaging and found no significant impacts.

7.1. Affected Environment

The affected environment includes human and natural environments in the United States. The market order would allow the applicant to distribute and sell the new tobacco product to consumers in the United States. Consumers would dispose of the used product and packaging via municipal solid waste landfills, recycling centers, or as litter.

7.2. Analysis of Potential Environmental Impacts

The proposed action was evaluated for potential environmental impacts from disposal.

Environmental Resource	Analysis of Potential Impacts
Air quality	The Agency does not anticipate disposal of the product or the packaging material would lead to the release of new or increased chemicals into the air because (1) introducing the new product into the U. S. market is not expected to increase the nationwide use and eventual disposal of RYO tobacco products; (2) the new product is anticipated to compete with or replace other currently marketed RYO tobacco products; and (3) the packaging materials are commonly used and disposed of in the United States.
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. ESA. Although improper handling of waste could occur in undeveloped areas and wildlife habitats, introducing the new product into the U. S. market is not expected to increase the nationwide use and eventually the disposal of RYO tobacco products. Therefore, it is not expected that the current amount of littering would change due to disposal of the new product.
Environmental justice	The Agency does not anticipate changes in impacts on socioeconomic conditions or environmental justice from disposal of the new product. No new emissions are expected due to disposal of the new product. Therefore, there

	would be no new disproportionate impacts on minority or low-income populations.
Water resources	Proper handling of waste generated due to disposal of the new product and packaging would not affect water resources. Although improper disposal could occur in or near surface water, there would be no expected changes of impacts on water quality due to disposal of the new product because (1) the chemicals in the new product are the same as in currently marketed RYO paper tips and (2) the new product would replace similar tobacco products currently on the market.

7.3. Cumulative Impacts

No action was identified that, when considered with the proposed action, would lead to cumulative impacts.

7.4. Impacts of the No-Action Alternative

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

8. List of Preparers

The following individuals were primarily responsible for preparing and reviewing this environmental assessment (EA):

Preparer:

Mehran Niazi, Ph.D., Center for Tobacco Products

Education: Ph.D. in Environmental Sciences

Experience: Twelve years in environmental fate and transport and environmental modeling

Expertise: Water quality modeling, environmental fate and transport modeling

Reviewer:

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

Education: M.S. in Environmental Science

Experience: Thirty-six years in environmental compliance and analysis

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

9. A Listing of Agencies and Persons Consulted

Not applicable.

Confidential Appendix 1

Location of the Manufacturing Facility

The applicant stated that the paper tips are manufactured in a facility located at the following address:

(b) (4) [REDACTED]

The books are assembled by (b) (4) [REDACTED].

Confidential Appendix 2:

Changes to the to the Predicate Product to Create the New Product

STN	Changes
SE0015150	Increase in quantity of the paper tip per book (100 tips/book compared to 50 tips/book) Decrease in quantity of books per case (24 books/case compared to 50 books/case) Increase in product dimensions (18.5 x 58.5 mm compared to 17.5 x 51.0 mm)

Confidential Appendix 3:

Current Year Market Volume and First- and Fifth-Year Market Volume Projections for the New and Predicate Products

The applicant intends to continue marketing the predicate product after receiving a marketing order for the new product. The applicant used the 2016 presentation by (b) (4) for paper and paper board production in China and stated that the combined production of the new and predicate products account for a minute fraction ((b) (4) percent) of total paper and paperboard production in China.¹

STN	Market Volume				
	Unit	First-Year Projection		Fifth-Year Projection	
		New Product	Predicate Product	New Product	Predicate Product
SE0015150	# of paper tip	(b) (4)			

¹ 2016 China Paper Industry Development Situation and Strategic Measures 2016; http://www.cepi.org/system/files/public/documents/publications/statistics/2017/KeyStatistics2016_Final.pdf. Accessed June 25, 2019.