

**Environmental Assessment for Marketing Order for  
New Roll-Your-Own Rolling Papers  
Manufactured by**

**BBK Tobacco & Foods, LLP Company dba HBI International**

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

**April 21, 2021**

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### 1. Applicant and Manufacturer Information

<b>Applicant Name:</b>	BBK Tobacco & Foods, LLP Company dba HBI International
<b>Applicant Address:</b>	3401 West Papago Street Phoenix, AZ 85009
<b>Manufacturer Name:</b>	BBK Tobacco & Foods, LLP Company dba HBI International
<b>Product Manufacturing Location:</b>	The manufacturing facilities are located outside the U.S. (Confidential Appendix 1).

### 2. Product Information

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

<b>Tobacco Product</b>	<b>New Product</b>	<b>Predicate Product (Previously Found SE)</b>	<b>Predicate (Grandfathered)</b>
STN	SE0015654	Not applicable	Not available
Name	Jays Rolls Single Wide	Not applicable	Elements Rolls Ultra Thin SW
Eligibility status	Not applicable	Not applicable	Grandfathered
Relevant amendments	SE0015679 SE0021132		

#### Product Identification

<b>Product Category</b>	Roll-Your-Own
<b>Product Subcategory</b>	Rolling Paper
<b>Product Quantity per Retail Unit</b>	Twenty-four paper rolls per display case
<b>Product Package</b>	Paper is rolled on a cardboard core. Each roll is packaged in a cardboard box. Twenty-four paper rolls are packaged in a display case and packaged cases are cellophane wrapped.

### 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 one 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 marketing order. The new product is currently marketed in the United States and will not replace the predicate product. The new product will compete with similar tobacco products currently on the market.

The new product differs from the predicate product in quantity and design features (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 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 2).

The applicant stated that the manufacturing facilities are located outside the United States (Confidential Appendix 1) and that the manufacturers are in full compliance with all environmental regulations in their respective national jurisdictions and the European Union.

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

The Agency evaluated potential environmental impacts that may be caused 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 because the marketing order would allow for the new tobacco product to be sold to consumers in the United States.

##### 6.2. Analysis of Potential Environmental Impacts

The proposed action was evaluated for potential environmental impacts from use of the new product based on Agency-gathered information and the applicant's submitted SE Report.

Environmental Resource	Analysis of Potential Impacts
Air Quality	The Agency does not anticipate that using the new product would lead to the release of new chemicals into the air, as compared to other currently marketed roll-your-own (RYO) tobacco products. The applicant stated the new product differs from the predicate product in quantity change and design features (Appendix 1).
Environmental Justice	No new emissions are expected due to the use of the new product. Therefore, there would be no new disproportionate impacts on minority or low-income populations.

##### 6.3. Impacts of the No-Action Alternative

The no-action alternative would not change the existing conditions of use of RYO tobacco products, as similar RYO tobacco products would continue to be used in the United States.

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

The Agency evaluated potential environmental impacts that may be caused by disposal of the new product and found no significant impacts.

### 7.1. Affected Environment

The affected environment includes human and natural environments in the United States because the marketing order would allow the new tobacco product to be sold to consumers nationwide who would dispose of the used product and packaging as municipal solid waste (MSW), recycled material, or litter.

### 7.2. Analysis of Potential Environmental Impacts

The Agency evaluated the proposed action for potential environmental impacts from disposal of the new product based on information in the SE Report, including market volume information for the new product (Confidential Appendix 2).

Environmental Resource	Analysis of Potential Impacts
Air Quality	Introducing the new product into the U.S. market is not expected to increase the nationwide use of RYO tobacco products; therefore, disposal of the used product and packaging would not significantly affect air quality.
Biological Resources	Proper disposal of the used new product and packaging materials in the MSW stream would not affect biological resources. Although the used product and packaging materials may be littered in undeveloped areas and wildlife habitat, littering levels are not expected to change from the current levels due to existing tobacco products. Introducing the new product into the U.S. market is not expected to increase the nationwide use of RYO tobacco products based on the projected market volumes reported by the applicant (Confidential Appendix 2).
Environmental Justice	No significant environmental impacts associated with the disposal of the used new product and packaging were identified, therefore no change in impacts to environmental justice populations are anticipated.
Water Resources	Proper disposal of the used new product and packaging materials in the MSW stream would not affect water resources. Improper disposal (littering) of used new product could result in hazardous substances leaching to water systems. However, no net increase in littering is expected; introducing the new product into the U.S. market is not expected to increase the nationwide use and disposal of RYO tobacco products, because the new products would compete for the same market share with other currently marketed RYO products.

### 7.3. Impacts of the No-Action Alternative

The environmental impacts of the no-action alternative would not change the existing condition of the disposal of RYO tobacco products and packaging materials, as many other RYO 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 (EA):

### **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: Four 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.

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

STN	Change in the New Product as Compared to the Predicate Product
SE0015654	<ul style="list-style-type: none"><li>• Increase in weight of paper roll from 3.63 g to 4.53 g</li><li>• Increase in number of rolls packaged per display box from 10 to 24</li><li>• Change in rolling paper holder from plastic to cardboard</li><li>• Increase in average air permeability from 9.5 CU to 12.6 CU</li></ul>

**Confidential Appendix 1. Manufacturing Location Information**

STN	Product Component	Manufacturer	Manufacturer's Address
SE0015654	Rolling Paper	(b) (4)	
	Watermark and assembly		

## Confidential Appendix 2. Current, First- and Fifth-Year Market Volume and Market Projections for the New Product

The applicant stated the new product is marketed simultaneously with the predicate product. The applicant also stated that the weight data for RYO paper production in (b) (4) was not available and instead the applicant provided internal sales data as unit sales, for the current year and first-and fifth-year market projections of the new and predicate products. Based on this information, cigarettes that could be potentially made from the current year and first-and fifth-year market projection unit sales was estimated.

STN	Unit	Current Year		First-Year		Fifth-Year	
		New	Predicate	New	Predicate	New	Predicate
SE0015654	Units <sup>1</sup>	(b) (4)					
	Cigarettes <sup>2</sup>	(b) (4)					

<sup>1</sup>Internal sales data for the current year and first-and fifth-year market projections of the new and predicate products.

<sup>2</sup>Each rolling paper is 7000 mm long and 70 mm length equates to 1 RYO cigarette; 1-rolling paper is ~ 100 cigarettes.