

**Programmatic Environmental Assessment for  
Marketing Orders for Roll-Your-Own Rolling Papers**

**by**

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

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

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### 1. Applicant and Manufacturer Information

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

### 2. Product Information

#### New Products (STNs), New Product Names, and Predicate Product Names

New Product STN	New Product Name	Predicate Product Name
SE0016741	RAW ORGANIC HEMP 1 1/4	ELEMENTS 1 ¼
SE0017682	RAW PRE-ROLLED CONE LEAN 20 PACK	TORPEDOES PRE ROLLED CONE PAPERS
SE0017689	RAW PRE-ROLLED CONE 98 SPECIAL 20 PACK	TORPEDOES PRE ROLLED CONE PAPERS
SE0017790	RAW SW DF (DOUBLE FEED)	ELEMENTS SW

#### Product Identification

<b>Product Category</b>	Roll-Your-Own	
<b>Product Subcategory</b>	SE0016741	Rolling Paper
	SE0017790	
	SE0017682	Non-Filtered Cigarette Tube/ Filtered Cigarette Tube
	SE0017689	Non-Filtered Cigarette Tube
<b>Quantity per Retail Sale Unit</b>	SE0016741	Fifty papers and tips per booklet
		Fifty papers and tips per booklet; per tray
	SE0017682 SE0017689	Twenty cigarette tubes per slider tray box
	SE0017790	Two stack of fifty rolling papers per booklet with a cardboard stabilizer
<b>Product Package</b>	The booklets, stabilizers, slider boxes, tray, and display cases are made of carboard.	

### 3. The Need for the Proposed Actions

The proposed actions, requested by the applicant, are for the Food and Drug Administration (FDA) to issue marketing orders under the provisions of sections 910 and 905(j) of the Federal Food, Drug, and Cosmetic Act. The applicant wishes to continue to market four new products into interstate commerce for commercial distribution in the United States and submitted to the Agency four substantial equivalence (SE) reports to obtain marketing orders. The new products are currently marketed in the United States. The new products will not replace the predicate products as the predicate products are not manufactured.

The new products differ from the corresponding predicate products in quantity and design features (Confidential Appendix 2).

#### **4. Alternative to the Proposed Actions**

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

#### **5. Potential Environmental Impacts of the Proposed Actions and Alternatives – Manufacturing the New Products**

The Agency considered potential environmental impacts that may be caused by manufacturing the new products and found no significant impacts. Included in the information the Agency considered were the projected market volumes for the new products (Confidential Appendix 3).

The applicant stated that the manufacturing facilities are located at several locations outside the United States (Confidential Appendix 1) and that the manufactures are in compliance with environmental laws and regulations in their respective countries.

#### **6. Potential Environmental Impacts of the Proposed Actions and Alternatives – Use of the New Products**

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

##### **6.1. Affected Environment**

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

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

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

##### **6.3. Air Quality**

The Agency does not anticipate that using the new products 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 products differ from the predicate products only in quantity change and design features

##### **6.4. Environmental Justice**

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



## **6.5. 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 Actions and Alternatives – Disposal of the New Products**

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

### **7.1. Affected Environment**

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

### **7.2. Analysis of Potential Environmental Impacts**

The Agency evaluated the proposed actions for potential environmental impacts from disposal of the new products based on information in the SE Report, including market volume information for the new products (Confidential Appendix 3).

### **7.3. Air Quality**

Introducing the new products into the United States market is not expected to increase the nationwide use of RYO tobacco products; therefore, disposal of the used products and packaging would not significantly affect air quality.

### **7.4. Biological Resources**

Proper disposal of the used new products and packaging materials in the MSW stream would not affect biological resources. Although the used products 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 products into the United States 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 3).

### **7.5. Environmental Justice**

No significant environmental impacts associated with the disposal of the used new products and packaging were identified, therefore no change in impacts to environmental justice populations are anticipated.

## 7.6. Water Resources

Proper disposal of the used new products and packaging materials in the MSW stream would not affect water resources. Improper disposal (littering) of used new products could result in hazardous substances leaching to water systems. However, no net increase in littering is expected; introducing the new products into the United States 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.

## 7.7. 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 programmatic environmental assessment (PEA):

### **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:**

Ronald L. Edwards Jr., MS, Center for Tobacco Products

Education: MS in Biology

Experience: Twenty-seven years in environmental regulation and laboratory toxicology

Expertise: NEPA analysis, heavy metal analysis, water quality, environmental remediation, FDA, EPA, and USDA investigator

## 9. A Listing of Agencies and Persons Consulted

Not applicable.

**Confidential Appendix 1. Manufacturing Location Information.**

STN	Product Component	Manufacturer	Manufacturer's Address
SE0017790	Rolling Paper	(b) (4)	
	Watermark and assembly		
SE0016741	Rolling Paper		
	Tips		
	Co-Pack and assembly		
SE0017682 SE0017689	Rolling paper		
	Watermark		
	Assembly		

**Confidential Appendix 2. Comparison Between the New Products and the Predicate Products.**

STN	Change in the New Product as Compared to the Predicate Product
SE0017790	<ul style="list-style-type: none"> <li>• Watermark changed from "HBI" to "RAW"</li> <li>• Increase in air permeability (target (b) to (b))</li> <li>• Paper grade changed from (b) to (b)</li> </ul>
SE0016741	<ul style="list-style-type: none"> <li>• Watermark changed from "HBI" to "RAW"</li> <li>• Increase in air permeability (target (b) to (b))</li> <li>• Paper grade changed from (b) to (b)</li> <li>• Small decrease in basis weight and increase in glue add on</li> </ul>
SE0017682	<ul style="list-style-type: none"> <li>• Increase in total length of cone and tip</li> <li>• Decrease in cone paper weight</li> <li>• Packaging changed from a plastic container to cardboard tray slider</li> <li>• Cones per box increased from 3 to 20</li> </ul>
SE0017689	<ul style="list-style-type: none"> <li>• Decrease in total length of cone and tip</li> <li>• Decrease in cone paper weight</li> <li>• Packaging changed from a plastic container to cardboard tray slider</li> <li>• Cones per box increased from 3 to 20</li> </ul>



**Confidential Appendix 3. Current, First- and Fifth-Year Market Volumes and Projections for the New Products.**

The new products are currently marketed and the predicate products are no longer manufactured.

STN	Unit	New Product		
		Current Year	First-Year	Fifth-Year
SE0016741	Paper Sheets	(b) (4)		
SE0017682	Tubes			
SE0017689	Tubes			
SE0017790	Paper Sheets			
<b>Total</b>	<b>NA</b>			