

**Environmental Assessment for a Marketing Order for  
ELEMENTS KING SIZE SLIM  
Manufactured by  
BBK Tobacco & Foods, LLP Company  
dba HBI International**

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

September 30, 2019

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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:<sup>1</sup></b>	(b) (4)
<b>Product Manufacturing Location:<sup>2</sup></b>	(b) (4)

**2. Product Information**

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

STN	New Product	Predicate Product
SE0015403	ELEMENTS KING SIZE SLIM	ELEMENTS KING SIZE SLIM

**Product Identification**

<b>Product Category</b>	Roll-Your-Own
<b>Product Subcategory</b>	Rolling Paper
<b>Product Quantity per Retail Unit</b>	32 leaves per booklet
<b>Product Package</b>	Cardboard booklet cover and display case

**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 quantity change, design features, and the inclusion of a starting paper (Confidential Appendix 2).

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<sup>1</sup> The booklets are assembled in (b) (4)

<sup>2</sup> See Confidential Appendix 1 for the location of the paper manufacturer.

#### 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.

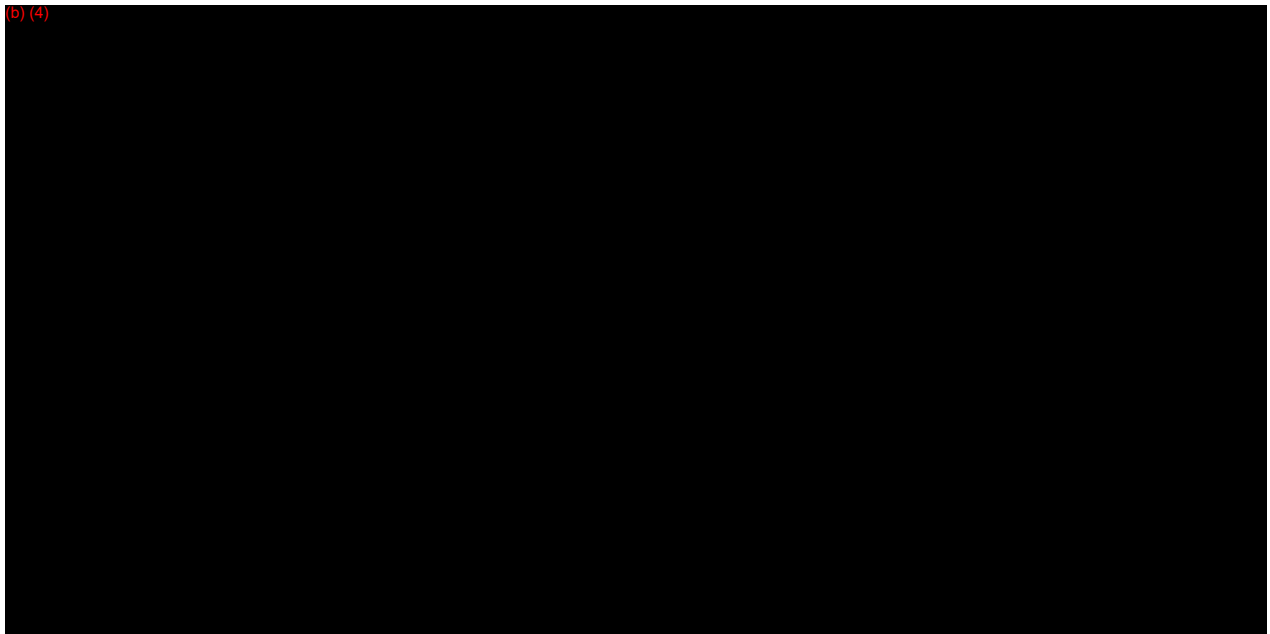
#### 5. Potential Environmental Impacts of the Proposed Action and Alternatives– Manufacturing the New Product

The Agency considered potential environmental impacts that may be caused by manufacturing the new product and found no significant impacts.

##### 5.1 Affected Environment

The affected environment includes human and natural environments surrounding the facility. The new product is manufactured at (b) (4) (Figure 1). The manufacturer is located in a mixed-used industrial and residential area surrounded by forests.

**Figure 1. Location of the Manufacturing Facility<sup>3</sup>**



##### 5.2 Analysis of Potential Environmental Impacts

The Agency considered potential impacts to resources in the environment that could be affected by manufacturing the new product 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 new product (Confidential Appendix 3).

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<sup>3</sup> Land use surrounding manufacturing facility via Google Map. Accessed August 26, 2019.

Environmental Resource	Analysis of Potential Impacts
Air Quality	The applicant stated that manufacturing the new product is not expected to result in changes to air emissions or require any additional environmental controls for air emissions because (1) the new product is expected to compete with and potentially replace other rolling papers currently manufactured at the facility; (2) the materials used in manufacturing the new product are currently used in the facility; and (3) any forecasted increase in the production of the new product rolling papers would add a fraction of a percent to the total paper and paperboard production in the country where the rolling papers are manufactured. (Confidential Appendix 3).
Water Resources	No impacts on water resources are expected because the liquid waste discharge is not anticipated to change at the manufacturing facility. The applicant stated that the new product is intended to replace similar tobacco products currently manufactured at the facility and that manufacturing the new product would not require any additional environmental controls for water discharges.
Land use and zoning	The applicant stated that there would be no facility expansion due to manufacturing the new product. Therefore, no changes in land use or zoning would occur as a direct impact from the proposed action.
Biological Resources	The applicant stated that the raw materials used in the new product are from sustainable 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). Furthermore, the applicant stated the manufacturing facilities comply with CITES, along with environmental regulations specific to their national jurisdictions.
Socioeconomic Conditions	No impacts would be expected on employment, state or municipal revenue and taxes, or on police force and fire department resources because there would be no facility expansion anticipated.
Solid waste and hazardous materials	The applicant stated that no additional manufacturing environmental controls would be required from manufacturing the new product. Furthermore, the applicant stated the new product would potentially replace current products being manufactured at the facility. Additionally, proper disposal of any waste related to manufacturing the new product would be handled in compliance with applicable laws and regulations.
Floodplains, wetlands, and coastal zones	There would be no expected facility expansion due to manufacturing the new product. Therefore, no effects on floodplains, wetlands, or coastal zones are anticipated.
Regulatory Compliance	The applicant stated that the manufacturing facility is in compliance with all applicable national environmental regulations.

**5.3 Cumulative Impacts**

No actions were 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 RYO rolling papers, as many similar tobacco products would continue to be manufactured at the same manufacturing facility.

**6. Potential Environmental Impacts of the Proposed Action and Alternatives – 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 RYO tobacco products. The applicant stated the new product differs from the predicate product only in quantity change, design features, and possessing a starting paper .
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. Cumulative Impacts**

No actions were identified that would lead to cumulative impacts when considered with use of the new product under the proposed action.

**6.4. 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 Alternatives – 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 3).

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 3).
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 product would compete for the same market share with other currently marketed RYO products.

**7.3. Cumulative Impacts**

No actions were identified that would lead to cumulative impacts when considered with the new product disposal under the proposed action.

#### **7.4. 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:**

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

Education: MS in Biology

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

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

**Reviewer:**

Gregory Gagliano, MS, Center for Tobacco Products

Education: MS in Environmental Science

Experience: Thirty-seven 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 papers are manufactured by (b) (4) [REDACTED]. In addition, the applicant stated both manufacturing facilities are in full compliance with all environmental regulations in their respective national jurisdictions and the (b) (4) [REDACTED]. Furthermore, the applicant states that both manufacturing facilities have ratified CITES, and as such they do not anticipate any impact on endangered species in any form due to the production of the new product.

**Confidential Appendix 2:**

**Comparison Between the New Product and the Predicate Product**

STN	Component	Change in the New Product as Compared to the Predicate Product
SE0015403	Rolling paper	Addition of a starting paper
		Change in watermark design to "ELEMENTS"
		Decrease of one rolling paper per booklet

**CONFIDENTIAL APPENDIX 3**

**First- and Fifth-Year Market Volume Projections for the New Product**

The applicant stated the predicate product is not currently being marketed.

STN	Market Volume		
	Unit	First-Year Projection	Fifth-Year Projection
		New Product	New Product
SE0015403	Leaves	(b) (4)	(b) (4)
	Metric Tons <sup>4</sup>	(b) (4)	(b) (4)

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<sup>4</sup> Metric tons = ( individual leaf weight 71.30 mg) \*(market projection in leaves) \*(1 X 10<sup>-9</sup>)