

**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

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

2. Product Information

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

STN	New Product	Predicate Product
SE0016734	WIZ KHALIFA TIPS	ELEMENTS TIPS REGULAR
SE0016735	RAW ORGANIC HEMP CONNOISSEUR 11/4 (with tips)	RAW TIPSORIGINAL
SE0016736	RAW ORGANIC HEMP ARTESANO 11/4 WITH TRAY+ PAPERS+ TIPS	RAW TIPSORIGINAL

Product Identification

Product Category	Roll-Your-Own	
Product Subcategory	SE0016734	Paper tips
	SE0016735 SE0016736	Rolling paper and paper tips
	SE0016734	SO-Rolling paper tips per book with SO-books per display box
Product Quantity per Retail Unit	SE0016735 SE0016736	SO-Rolling paper per booklet and SO-tips as co-pack
	The booklets, slider boxes, and display cases are made of cardboard and SE0016736 is bound by an external rubber band.	

3. The Need for the Proposed Actions

The proposed actions, requested by the applicant, are for FDA to issue marketing orders under the provisions of sections 910 and 9050) of the Federal Food, Drug, and Cosmetic Act after finding the new products substantially equivalent to the predicate products. The applicant wishes to introduce the new products into interstate commerce for commercial distribution in the United States and submitted to the Agency three substantial equivalence (SE) Reports to obtain the marketing orders. The new and corresponding predicate products are currently marketed in the United States. The Agency shall issue the marketing orders if the new products are found substantially equivalent to the corresponding predicate products.

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 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 tobacco 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 Reports.

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 corresponding predicate products only in quantity 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:

Shannon K. Hanna, Ph.D., Center for Tobacco Products

Education: Ph.D. in Environmental Science and Management

Experience: Six 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.

Confidential Appendix 1. Manufacturing Location Information.

STN	Product Component	Manufacturer	Manufacturer's Address
SE0016734	Paper Tips	(b)	(4)
SE0016735 SE0016736	Rolling Paper		
	Paper Tips		
	Co-Pack and 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
SE0016734	<ul style="list-style-type: none"> • Decrease in basis weight • Marginal change in (b) (4) and (b) (4) composition • Marginal changes to the ink composition
SE0016735 SE0016736	<ul style="list-style-type: none"> • Watermark changed from "HBI" to "RAW" • Air permeability marginally increased (target: (b) (4), range (b) (4) in predicate compared to target (b) (4) range: (b) (4) in New product) • Paper grade changed from (b) (4) to (b) (4) • Small decrease in basis weight and increase in glue add on • Tips width increased and length decreased. SE0016736 tips have perforations.

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

The new and corresponding predicate products are currently manufactured and marketed.

STN	Unit	Current Year		First-Year		Fifth-Year	
		New	Predicate	New	Predicate	New	Predicate
SE0016734	Paper Tips	<div style="display: flex; justify-content: space-around; font-size: 48px; color: red; font-weight: bold;"> (b) (4) </div>					
SE0016735*	Paper Sheets And Paper Tips						
SE0016736*	Paper Sheets And Paper Tips						

*New and predicate products for the current year volumes and, first-year and fifth-year market projections, were combined.