

**Environmental Assessment for a Marketing Order for New
Roll-Your-Own Rolling Paper by BBK Tobacco & Foods, LLP
dba HBI International**

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

December 27, 2019

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1. Applicant and Manufacturer Information

Applicant Name:	BBK Tobacco & Foods, LLP dba HBI International
Applicant Address:	3401 West Papago Street Phoenix, AZ 85009
Manufacturer Name¹:	(b) (4)
Product Manufacturing Address²:	(b) (4)

2. Product Information

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

STN	New Product Name	Predicate Product Name
SE0015423	Rawblack King Size Slim	Elements King Size Slim

Product Identification

Product Category	Roll-Your-Own
Product Sub-Category	Rolling Paper
Number of Products per Retail Unit	32 papers per booklet; 50 booklets per display box
Product Package	The packaging materials consist of cardboard booklet cover with starter and warning paper between the cover and the booklet papers, and cardboard display box

3. The Need for the Proposed Action

The proposed action, requested by the applicant, is for U.S. 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 after finding the new tobacco product substantially equivalent to the predicate product. The applicant wishes to introduce the new tobacco product into interstate commerce for commercial distribution in the United States.

The applicant submitted to the Agency a substantial equivalence (SE) report to obtain a marketing order for the new 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 design features and product quantity. (Confidential Appendix 2).

¹ The booklets are assembled in (b) (4)

² See Confidential Appendix 1 for the location of the paper manufacturer

4. Alternatives 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.

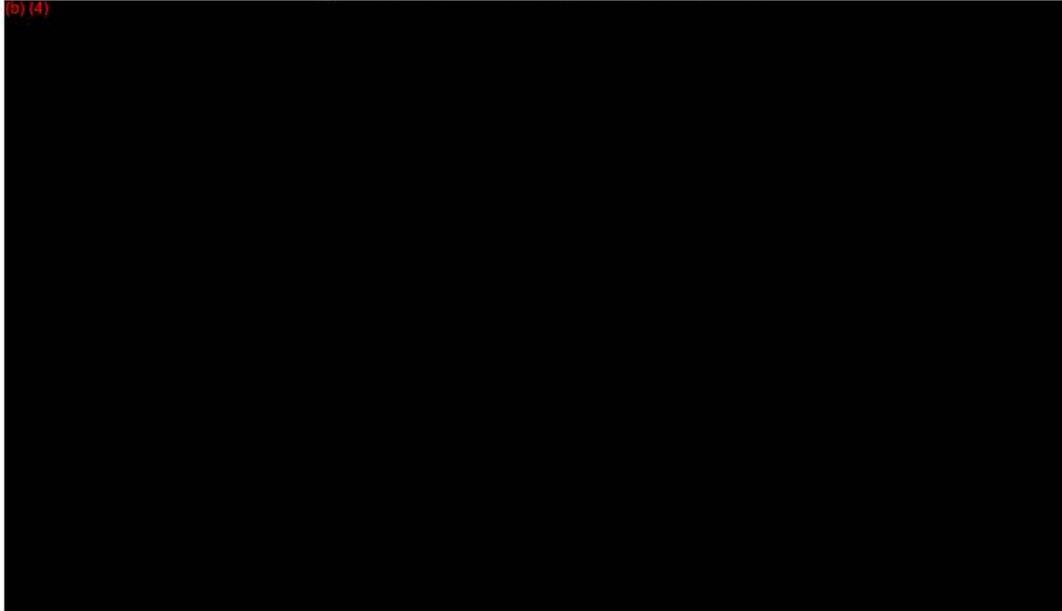
5. Potential Environmental Impacts of the Proposed Action and Alternative – Manufacturing the New Product

The Agency considered potential impacts to resources in the environment that may be affected 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 would be manufactured at the address listed in section 1 of this document (Figure 1).

Figure 1. Location of the Manufacturer



5.2 Analysis of Potential Environmental Impacts

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

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. According to the applicant, overall manufacturing

	at the facility is not expected to increase as result of manufacturing the new product.
Water resources	The Agency does not anticipate that manufacturing the new product would cause any new chemicals to be discharged into the water. 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 wastewater discharges.
Soil, Land Use, and Zoning	The applicant stated that there would be no 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	The applicant stated that there would be no facility expansion. Therefore, the Agency does not anticipate that 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).
Socioeconomic conditions	There would be no expected impacts on employment, revenue, taxes, or community resources because the new product is intended to compete with and eventually replace similar tobacco products currently manufactured at the facility.
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 papers at this facility. The waste generated due to manufacturing the new product would be released to the environment and disposed of in landfills in the same manner as the waste generated from any other products manufactured in the same facility. The manufacturer's compliance with applicable environmental regulations is assumed to indicate no significant impacts would occur.
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 environmental regulations, including CITES.

5.3 Cumulative Impacts

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

5.4 Impacts of the No-Action Alternative

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

6. Potential Environmental Impact of the Proposed Action and Alternative – 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 because the marketing order would allow for the new tobacco product to be sold to consumers in the United States. The new product is a RYO 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 use of the new product based on the applicant’s submitted information.

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 the predicate product or other currently marketed RYO tobacco products.
Environmental justice	The new product is expected to be used by the same consumers that use the predicate product. Therefore, no changes in impact to environmental justice populations are anticipated.

6.3. Cumulative Impacts

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

6.4. Impacts of the No-Action Alternative

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

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 found no significant impacts.

7.1. Affected Environment

The affected environment is the entire United States because the marketing order would allow for the new tobacco product to be sold to consumers nationwide. The disposal would be via municipal solid waste (MSW) landfills, recycling centers, or as litter.

7.2. Analysis of Potential Environmental Impacts

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

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 currently marketed RYO products; (3) the paper components of the packages are more likely to be recycled, or at least a portion of the packaging waste is likely to be recycled; and (4) the packaging materials are commonly used and disposed of in the United States.
Biological resources	Proper disposal of the used new product and packaging materials in the MSW stream would not affect biological resources. 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 disposal of RYO tobacco products, based on the projected market volumes reported by the applicant (Confidential Appendix 3). Therefore, littering levels are not expected to change from the current levels.
Environmental justice	No significant environmental impacts associated with the disposal of the used new product and packaging were identified. 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. Improper disposal could result in hazardous substances leaching to water systems. However, no net increase in littering would be expected because the new product would replace similar tobacco products currently on the market.

7.3. Cumulative Impacts

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

7.4. Impacts of the No-Action Alternative

The no-action alternative would not change the existing condition of disposal of RYO tobacco products and packaging in the United States, as many similar tobacco products would continue to be disposed of.

8. List of Preparers

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

Preparer:

Susana Addo Ntim, Ph.D., Center for Tobacco Products

Education: Ph.D. in Environmental Science

Experience: Seven years in various scientific activities

Expertise: NEPA Analysis; fate, transport and ecotoxicology of new and emerging contaminants; applications and environmental implications of nanotechnology

Reviewer:

Hoshing W. Chang, Ph.D., Center for Tobacco Products

Education: M.S. in Environmental Science and Ph.D. in Biochemistry

Experience: Ten years in FDA-related NEPA review

Expertise: NEPA analysis, environmental risk assessment, wastewater treatment

9. List 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]
[REDACTED]

The booklets are assembled by (b) (4) [REDACTED]

CONFIDENTIAL APPENDIX 2. Comparison of the New Product to the Predicate Product

STN	Component	Change from Predicate Product
SE0015423	Cigarette paper	Decreased paper basis weight and (b) (4) content
		Addition of starter paper
		Reduction in number of leaves per booklet by one

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 2017 statistical data of paper and paperboard production in Europe to conclude that the combined production of the new and predicate products rolling papers accounts for a minute fraction of total paper and paperboard production in (b) (4) ■

STN	Unit	Market Volume					
		Current Year		First-Year Projection		Fifth-Year Projection	
		New Product	Predicate Product	New Product	Predicate Product	New Product	Predicate Product
SE0015423	Number of Leaves	(b) (4) ■					
	Metric Tons ⁴						

■ Key Statistics 2017;
http://www.cepi.org/system/files/public/documents/publications/statistics/2018/210X140_CEP1_Brochure_KeyStatistics2017_WEB.pdf. Accessed September 26, 2019.

⁴ Converted from weight in kilograms