

**Programmatic Environmental Assessment for Marketing  
Orders for New Roll-Your-Own Rolling Papers by BBK Tobacco  
& Foods, LLP d/b/a HBI International**

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

**April 21, 2022**

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**1. Applicant and Manufacturer Information**

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

**2. Product Information**

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

STN	New Product Name	Original Product Name
EX0001834-PD1	RAW BLACK ORGANIC HEMP 1¼	RAWBLACK 1 ¼
EX0001835-PD1	RAW BLACK ORGANIC HEMP King Size Slim	RAWBLACK King Size Slim

**Product Identification**

<b>Product Category</b>	Roll-Your-Own
<b>Product Subcategory</b>	Rolling Papers
<b>Product Number per Retail Unit</b>	EX0001834-PD1 – 50 rolling papers per booklet, 50 booklets per display case EX0001835-PD1 – 32 rolling papers per booklet, 50 booklets per display case
<b>Product Package</b>	EX0001834-PD1 – The packaging materials consist of a cardboard booklet, stabilizer, and display case with a plastic film overwrap. EX0001835-PD1- The packaging material consist of a cardboard booklet, stabilizer, and display case with a plastic film overwrap.

**3. The Need for the Proposed Actions**

The proposed action, requested by the applicant, is for the Food and Drug Administration (FDA) to issue exemptions from substantial equivalence (SE) reporting for a marketing orders under section 905(j)(3) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for two roll-your-own (RYO) rolling papers, which are used for making RYO cigarettes. A tobacco product that is modified by adding or deleting a tobacco additive, or increasing or decreasing the quantity of an existing tobacco additive, may be considered for exemption from demonstrating substantial equivalence if (1) the product is a modification of another tobacco product and the modification is minor, (2) the modifications are to a tobacco product that may be legally marketed under the FD&C Act, (3) an SE Report is not necessary to ensure that permitting the tobacco product to be marketed would be appropriate for the protection of public health, (4) the modified tobacco product is marketed by the same organization as the original product, and (5) an exemption is otherwise appropriate.

The applicant wishes to introduce the new products into interstate commerce for commercial distribution in the United States. The applicant must obtain a written notification that FDA has granted the products exemptions from demonstrating substantial equivalence under section 905(j)(3) before submitting an abbreviated report. Ninety days after FDA receipt of the abbreviated report, the applicant may introduce or deliver for introduction into interstate commerce for commercial distribution the new products for which the applicant has obtained exemptions from demonstrating substantial equivalence.

The new products differ from the corresponding original products due to a change in the paper basis weight and the quantity of the gum adhesive (Confidential Appendix 2).

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

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

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

The applicant stated that the manufacturing facility is in compliance with all applicable environmental regulations. However, because the new products are manufactured outside of the United States, the environmental impacts associated with manufacturing the new products will not be discussed.

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

The Agency evaluated potential impacts of the new products' use to resources in the environment and found no significant impacts based on Agency-gathered information and the applicant's submitted information. Included in the information that the Agency considered were projected first- and fifth-year market volumes (Confidential Appendix 3).

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

The affected environment includes human and natural environments in the United States because the marketing orders will allow for the new products to be sold to consumers in the United States. The new RYO rolling paper products are intended to be rolled and filled with tobacco by users who may smoke them indoors or outdoors, as the law permits.

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

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

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

The Agency does not anticipate new chemicals will be released into the environment as a result of use of the new products, relative to chemicals released into the environment due to use of other RYO rolling paper products already on the market.

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

The new products are anticipated to compete with, or replace, similar marketed RYO tobacco products. No new emissions are expected due to use of the new products. Therefore, there will be no new disproportionate impacts on minority or low-income populations.

#### **6.5. Impacts of the No-Action Alternative**

The environmental impacts of the no-action alternative will not change the existing condition of use of RYO tobacco products, as many similar tobacco products will 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 considered potential impacts of the new products' disposal to resources in the environment. Based on the applicant's submitted information, including market volume projections for the new products (Confidential Appendix 3), the Agency found no significant impacts.

#### **7.1. Affected Environment**

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

#### **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 EX Reports, including market volume information for the new products (Confidential Appendix 3).

#### **7.3. Air Quality**

No changes in air quality from disposal of the new products' package materials will be expected because the paper and plastic 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 the waste generated due to disposal of the new products' packaging is a minuscule portion of the municipal solid waste in the United States<sup>1</sup> per FDA's experience in evaluating the packaging waste generated from cigars.

#### **7.4. Biological Resources**

The proposed actions are not expected to change the continued existence of any endangered species or result in the destruction or adverse modification of the habitat of any such species, as prohibited under the U.S. Endangered Species Act (ESA) because (1) disposal of new products will be similar to currently marketed similar products in the United States, and (2) there will be no anticipated increase in RYO

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<sup>1</sup> U.S. Environmental Protection Agency. Advancing Sustainable Materials Management: 2017 Fact Sheet. November 2019. [https://www.epa.gov/sites/default/files/2019-11/documents/2017\\_facts\\_and\\_figures\\_fact\\_sheet\\_final.pdf](https://www.epa.gov/sites/default/files/2019-11/documents/2017_facts_and_figures_fact_sheet_final.pdf). Accessed February 15, 2022.

tobacco product disposal because the new products are anticipated to replace and compete with similar products.

#### **7.5. Environmental Justice**

The Agency does not anticipate changes in impacts on socioeconomic conditions or environmental justice from disposal of the new products. The waste generated due to disposal of the new products will be handled in the same manner as the waste generated from disposal of other RYO tobacco products in the United States. No new emissions are expected due to disposal of the new products. Therefore, there will be no disproportionate impacts on minority or low-income populations.

#### **7.6. Water Resources**

The Agency does not anticipate any new impacts on water resources due to disposal of the RYO rolling papers and packaging from the new products because the chemicals in the new products are used in currently marketed RYO tobacco products. Furthermore, the new products will compete with similar products currently on the market.

#### **7.7. Impacts of the No-Action Alternative**

The environmental impacts of the no-action alternative will not change the existing condition of disposal of RYO tobacco products and packaging as many similar tobacco products will 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:**

Chad Baisden, MS, Center for Tobacco Products

Education: MS in Natural Resources

Experience: Five years in various scientific activities

Expertise: Environmental risk assessment, regulatory compliance

#### **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.

## **10. References**

References located in the footnotes.

**Confidential Appendix 1: Location of the New Product's Paper Manufacturing and Packaging Facilities<sup>2</sup>**

The cigarette papers and packaging papers are milled in (b) (4)

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(b) (4)



(b) (4)

**Confidential Appendix 2: Comparison Between the New and Corresponding Original Products**

STN	Component	Modification in the New Product as Compared to the Original Product
EX0001834	Rolling Paper	<ul style="list-style-type: none"><li>• Decrease in the paper basis weight</li><li>• Decrease in the quantity of the (b) (4) [REDACTED]</li></ul>
EX0001835	Rolling Paper	<ul style="list-style-type: none"><li>• Decrease in the paper basis weight</li><li>• Decrease in the quantity of the (b) (4) [REDACTED]</li></ul>

**Confidential Appendix 3: Current Year Market Volume and First- and Fifth-Year Market Volume Projections for the New and Original Products**

The applicant states the new products are not currently marketed. Additionally, (b) (4) [redacted] The applicant used the 2019 statistical data of paper and paperboard production in (b) (4) to conclude that the combined production of the new and original products' rolling papers accounts for a small fraction of total paper and paperboard production in (b) (4)

STN	Units	Current Market Volume	Market Volume Projections	
			First-Year	Fifth-Year
EX0001834/PD1	Number of Leaves	(b) (4)	(b) (4)	(b) (4)
Original to EX0001834/PD1 (SE0015544)	Number of Leaves			
EX0001835/PD1	Number of Leaves			
Original to EX0001835/PD1 (SE0015423)	Number of Leaves			

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<sup>4</sup> (b) (4) [redacted]