

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

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

December 9, 2019

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1. Applicant and Manufacturer Information

Applicant Name:	BBK Tobacco & Foods, LLP Company d/b/a HBI International
Applicant Address:	3401 West Papago Street Phoenix, AZ 85009
Manufacturer Name:	BBK Tobacco & Foods, LLP Company d/b/a HBI International
Address Where Product is Manufactured	(b) (4)

2. Product Information

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

New Product Name	STN	Original Product Name
RAW AUTO BOX 79MM	EX0000832	ZEN AUTOMATIC ROLL BOX 70MM

Product Identification

Product Category	Roll-Your-Own
Product Subcategory	Other
Product Quantity per Retail Unit	One rolling box per cardboard box.
Product Package	The rolling box is packaged in a cardboard box.

3. The Need for the Proposed Action

The proposed action, requested by the applicant, is for the Food and Drug Administration (FDA) to issue an exemption from substantial equivalence (SE) reporting for a marketing order under the provisions of section 905(j)(3) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for the introduction of a roll-your-own (RYO) rolling box, which is 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 tobacco product into interstate commerce for commercial distribution in the United States. The applicant must obtain a written notification that FDA has granted the product an exemption 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 product for which the applicant has obtained an exemption from demonstrating substantial equivalence.

The new product is made by modifying the original product, which is a grandfathered product commercially marketed in the United States as of February 15, 2007. The new product differs from the original product in the addition of paint to the rolling box frame and increase in the amount of red dye in the apron (Confidential Appendix 1).

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.

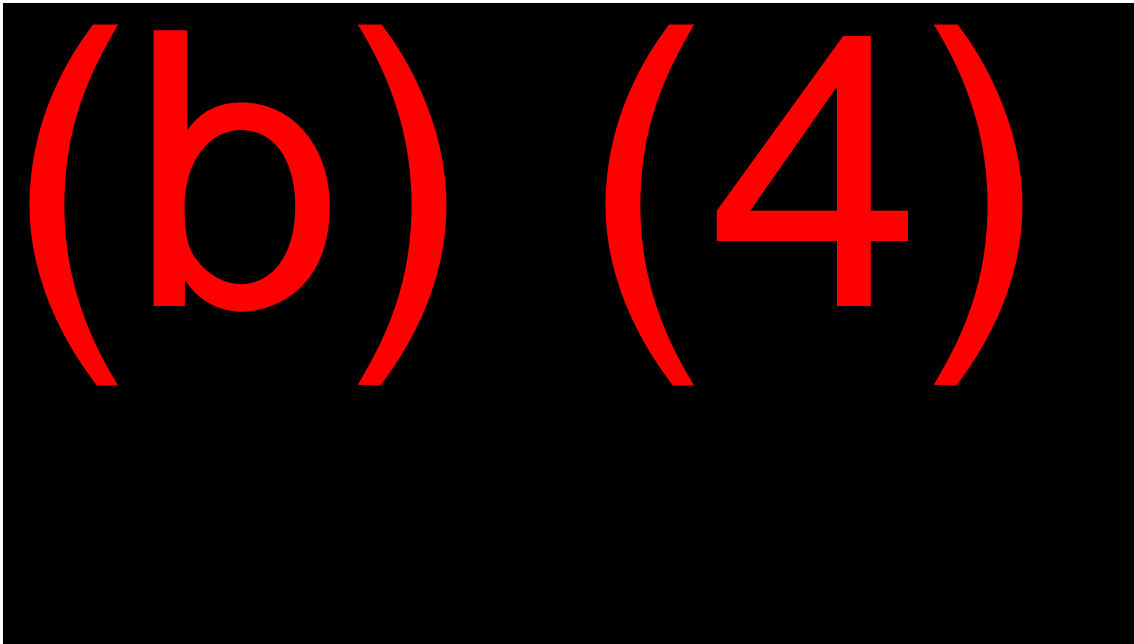
5. Potential Environmental Impacts of the Proposed Action and the Alternative – Manufacturing the New Product

The Agency considered potential impacts on resources in the environment that may be affected by manufacturing the new product and found no significant impacts based on the Agency-gathered information and the information submitted by the applicant.

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). The manufacturing facility is located inside a shopping mall in the (b) (4).

Figure 1. Location of the Manufacturer¹



(b) (4)

5.2 Analysis of Potential Environmental Impacts

The Agency evaluated the proposed action for potential environmental impacts due to manufacturing the new product based on Agency-gathered information and the applicant's submitted information, including projected market volumes for the new and original products (Confidential Appendix 2).

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 manufacturing the new product is not expected to result in changes to wastewater discharges or require any additional environmental controls.
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 products 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 boxes at the listed facility, as other similar products would continue to be manufactured.

6. Potential Environmental Impacts of the Proposed Action and the 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 for rolling tobacco-filled RYO paper.

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
Environmental Justice	No new emissions are expected due to use of the new product, a RYO rolling box. Therefore, there would be no new disproportionate impacts on the minority or low-income populations.

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 products in the United States, as many other similar tobacco products would continue to be used.

7. Potential Environmental Impacts of the Proposed Action and the 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 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 nationwide. Consumers would dispose of the used product and packaging via municipal solid waste landfills, recycling centers, or as litter.

7.2. Analysis of Potential Environmental Impacts

The proposed action was evaluated for potential environmental impacts from disposal.

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 intended for repeat use; (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, the new product 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 2). Additionally, the new product is intended for repeat use and littering levels are expected to be low.
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 increase in littering would be expected because the new product is intended for repeat use.

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:

Thomas Creaven, Ph.D., Center for Tobacco Products

Education: Ph.D. in Biology/Neuroscience

Experience: Ten years in science education and three years in NEPA document review

Expertise: NEPA document review and science education

Reviewer:

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

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

Experience: Eleven years in FDA-related NEPA review

Expertise: NEPA analysis, environmental risk assessment, wastewater treatment

9. A Listing of Agencies and Persons Consulted

Not applicable.

Confidential Appendix 1. Modification in the New Product as Compared to the Original Product

STN	Component	Modification in the New Product as Compared to the Original Product
EX0000832	Rolling Box	<ul style="list-style-type: none">• The new product is painted black with red and beige inscriptions.• Decrease in the amount of (b) (4) in the top and bottom lids of the new product• Increase in the amount of (b) (4) of the new product

Confidential Appendix 2. Current Year Market Volume and First- and Fifth-Year Market Volume Projections for the New and Original Products

The applicant intends to continue marketing the original product after receiving a marketing order for the new product. The applicant used statistical data for steel production in China to conclude that the combined production of the new and original products accounts for a minute fraction of total steel production in China.²

STN	Market Volume						
	Unit	Current Year		First-Year Projection		Fifth-Year Projection	
		Original Product	New Product	New Product	Original Product	New Product	Original Product
EX0000832	Number of Boxes	(b) (4)					
	Metric Tons ³						

² China is producing more steel than ever; <https://www.bloomberg.com/news/articles/2019-04-17/china-s-steel-machine-revs-up-to-record-to-feed-infrastructure>. Accessed October 24, 2019.

³ Converted from weight in kilograms