FDA U.S. FOOD & DRUG ADMINISTRATION

Technical Project Lead (TPL) Review: Exemption Requests EX0000470 – EX0000475

EX0000470: Barton Blue 100s Soft Pack	
Length	99 mm
Diameter	7.88 mm
Ventilation	<1%
Characterizing Flavor	None
Product Modifications	Addition/Deletion of tobacco additives: • Deletion of non-FSC[1] cigarette paper (b) (4) (b) (4) • Addition of FSC cigarette paper (b) (4)
EX0000471: Barton Blue Kings Soft Pack	
Length	83.5 mm
Diameter	7.88 mm
Ventilation	<1%
Characterizing Flavor	None
Product Modifications	Addition/Deletion of tobacco additives: • Deletion of non-FSC cigarette paper (b) (4) (b) (4) • Addition of FSC cigarette paper (b) (4) (b) (4)
EX0000472: Barton Full Flavor Kings Soft Pack	
Length	83.5 mm
Diameter	7.88 mm
Ventilation	<1%
Characterizing Flavor	None
Product Modifications	Addition/Deletion of tobacco additives: • Deletion of non-FSC cigarette paper (b) (4) (b) (4) • Addition of FSC cigarette paper (b) (4) (b) (4)
EX0000473: Barton Menthol Full Flavor 100s Soft Pack	
Length	99 mm
Diameter	7.88 mm
Ventilation	<1%
Characterizing Flavor	Menthol
Product Modifications	Addition/Deletion of tobacco additives: • Deletion of non-FSC cigarette paper (b) (4) (b) (4) • Addition of FSC cigarette paper (b) (4) (b) (4)

[1] Fire Standards Compliant

EX0000474: Barton Menthol Full Flavor Kings Soft Pack	
Length	83.5 mm
Diameter	7.88 mm
Ventilation	<1%
Characterizing Flavor	Menthol
Product Modifications	Addition/Deletion of tobacco additives: • Deletion of non-FSC cigarette paper (b) (4) (b) (4) • Addition of FSC cigarette paper (b) (4) (b) (4)
EX0000475: Bueno Full Flavor Kings Soft Pack	
Length	83.5 mm
Diameter	7.88 mm
Ventilation	<1%
Characterizing Flavor	None
Product Modifications	Addition/Deletion of tobacco additives: • Deletion of non-FSC cigarette paper (b) (4) (b) (4) • Addition of FSC cigarette paper (b) (4) (b) (4)
Attributes of Exemption Requests	
Applicant	Westgate Distribution, LLC
Product Category	Cigarette
Product Sub-Category	Combusted Filtered
Package Quantity	20 cigarettes
Package Type	Soft Pack
Recommendation	
Issue Exempt order letters.	

Technical Project Lead (TPL):

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Date: 2019.04.16 09:34:22 -04'00'

Matthew J. Walters, Ph.D., MPH
CDR, U.S. Public Health Service
Deputy Director
Division of Product Science

Signatory Decision:

☒ Concur with TPL recommendation and basis of recommendation

☐ Concur with TPL recommendation with additional comments (see separate memo)

☐ Do not concur with TPL recommendation (see separate memo)

Digitally signed by Matthew R. Holman -S
Date: 2019.04.16 09:43:40 -04'00'

Matthew R. Holman, Ph.D.
Director
Office of Science

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1. BACKGROUND

1.1. ORIGINAL TOBACCO PRODUCTS

The applicant submitted the following original tobacco products:

Table 1. Original Tobacco Products

EX0000470: Barton Blue 100s Soft Pack	
Product Name	Barton Lights 100's
Package Quantity	20 cigarettes
Package Type	Soft Pack
Length	99 mm
Diameter	7.88 mm
Ventilation	<1%
Characterizing Flavor	None
EX0000471: Barton Blue Kings Soft Pack	
Product Name	Barton Lights
Package Quantity	20 cigarettes
Package Type	Soft Pack
Length	83.5 mm
Diameter	7.88 mm
Ventilation	<1%
Characterizing Flavor	None
EX0000472: Barton Full Flavor Kings Soft Pack	
Product Name	Barton Full Flavor
Package Quantity	20 cigarettes
Package Type	Soft Pack
Length	83.5 mm
Diameter	7.88 mm
Ventilation	<1%
Characterizing Flavor	None
EX0000473: Barton Menthol Full Flavor 100s Soft Pack	
Product Name	Barton Menthol 100's
Package Quantity	20 cigarettes
Package Type	Soft Pack
Length	99 mm
Diameter	7.88 mm
Ventilation	<1%
Characterizing Flavor	Menthol

EX0000474: Barton Menthol Full Flavor Kings Soft Pack	
Product Name	Barton Menthol
Package Quantity	20 cigarettes
Package Type	Soft Pack
Length	83.5 mm
Diameter	7.88 mm
Ventilation	<1%
Characterizing Flavor	Menthol
EX0000475: Bueno Full Flavor Kings Soft Pack	
Product Name	Barton Full Flavor
Package Quantity	20 cigarettes
Package Type	Soft Pack
Length	83.5 mm
Diameter	7.88 mm
Ventilation	<1%
Characterizing Flavor	None

The applicant manufactures the original tobacco products and claims that they are grandfathered.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On February 28, 2019, FDA received Exemption Requests EX0000470 – EX0000475 from Westgate Distribution, LLC. On March 13, 2019, FDA issued Acknowledgement letters to the applicant. On March 11, 2019 FDA received amendments in response to our March 6, 2019 and March 7, 2019 information requests (EX0000483 – EX0000488). On March 18, 2019, FDA received an amendment to OCE's March 14, 2019 information request (EX0000499).

1.3. SCOPE OF REVIEW

This review captures all regulatory, compliance, and scientific reviews completed for these Exemption Requests.

1.4. TOBACCO ADDITIVE MODIFICATION

The new tobacco products contain the following modifications compared to the original tobacco products:

- Deletion of non-FSC cigarette paper (b) (4)
  (b) (4)
- Addition of FSC cigarette paper (b) (4)

2. REGULATORY REVIEW

Regulatory reviews were completed by Rodney Hammond on March 13, 2019. These reviews conclude that the Exemption Requests are administratively complete.

3. COMPLIANCE REVIEW

The Office of Compliance and Enforcement (OCE) completed reviews to determine whether the applicant established that the original tobacco products are legally marketed. The OCE reviews, dated April 2, 2019, conclude that the original tobacco products are grandfathered products (i.e., were commercially marketed in the United States other than exclusively in test markets as of February 15, 2007). Therefore, the original products are eligible for modification under the Exemption Request pathway.[2]

4. SCIENTIFIC REVIEW

A scientific review was completed by Salome Bhagan on April 2, 2019.

The review states that the new tobacco products have been modified by adding or deleting tobacco additives. Cigarette paper is used in the manufacturing of the original tobacco products, and is an additive because its intended use may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of the tobacco products. The review concludes that the modifications are minor modifications of a tobacco product in accordance with section 905(j)(3)(A)(i) of the FD&C Act. The review concludes that the deletion of non-FSC cigarette paper and addition of FSC cigarette paper in the new products is a minor modification. The change from non-FSC to FSC cigarette paper may result in increased HPHC yields; however, the reduction in household fires is anticipated to outweigh any potential increased health risks from the small increases in HPHC exposures that may occur from the use of the FSC cigarette paper, as outlined in the July 17, 2017, toxicology memo.

[2] Any tobacco product that can be sold under the FD&C Act (e.g., legally marketed in the United States) is eligible for modification under the Exemption Request pathway.

5. ENVIRONMENTAL DECISION

An environmental review was completed by Shannon Hanna on March 26, 2019.[3]

The final environmental review found that the applicant did not provide individual environmental assessments (EAs) for each new tobacco product, detailed information about how the new products will be packaged, address of the manufacturing facilities for the new products, information on the environmental effects of manufacturing the new products, information on the first- and fifth-year projected market volumes of the new products, information on the environmental effects of disposal of the new products, and information of compliance with the Endangered Species Act (ESA) and the Convention on International Trade in Endangered Species of Wild Flora and Fauna (CITES). Therefore, additional information is needed to determine whether to prepare an Environmental Impact Statement (EIS) or Finding of No Significant Impact (FONSI).

6. CONCLUSION AND RECOMMENDATION

The new tobacco products contain the following modifications compared to the corresponding original tobacco products:

- Deletion of non-FSC cigarette paper (b) (4) (b) (4))
- Addition of FSC cigarette paper (b) (4)

I concur with the conclusion of the scientific review that these modifications are minor modifications of a tobacco product in accordance with section 905(j)(3)(A)(i) of the FD&C Act. Section 900(1) of the FD&C Act defines 'additive' as "any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristic of any tobacco product (including any substances intended for use as a flavoring or coloring or in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding), . . ." I concur with the scientific review that the modifications are the deletion of non-FSC cigarette paper and the addition of FSC cigarette paper. In addition, it is my conclusion that, consistent with section 905(j)(3)(A)(ii) of the FD&C Act, an SE Report is not necessary to ensure that permitting the new tobacco products to be marketed would be appropriate for protection of the public health. At this time, based on the information available and CTP's scientific understanding and experience with non-FSC to FSC cigarette paper modifications that are limited to changes in tobacco additives and do not result in other changes to the product (e.g., no changes to blend, filter, design parameters such as ventilation, etc.), the benefit of using FSC paper in cigarettes to reduce household fires is anticipated to outweigh any potential increased health risks from the small increases in HPHC exposures that may occur from the use of FSC paper. Lastly, FDA finds, based on the information contained in the Exemption Requests and CTP's scientific understanding, that exemptions for these modifications are otherwise appropriate as required by section 905(j)(3)(a)(iii) of the FD&C Act. Therefore, the new tobacco products should be found

[3] An amendment (EX0000499) was received by the FDA in which the applicant updated the names of the original products. The names of the original products were incorrect in the environmental review as this review was finalized before receipt of this amendment. The original product names reflected in this TPL review are accurate based on the amendment received by the applicant.

exempt from the requirements of substantial equivalence under section 910(a)(3)(A) of the FD&C Act.

The original tobacco products are eligible for modifications through the exemption request pathway because they are legally marketed in the United States. The original products are grandfathered products (i.e., were commercially marketed in the United States, other than exclusively in test markets, as of February 15, 2007).

FDA has examined the environmental effects of finding these new tobacco products exempt from substantial equivalence and found additional information is necessary to determine the impact of the action. Without this information, FDA is precluded from issuing EX orders.

An Advice/Information Request letter should be issued requesting the following information:

1. All of your EX Requests lack individual environmental assessments (EAs); that is, one EA for each EX Request. FDA's regulations implementing the National Environmental Policy Act (NEPA) of 1969 (21 CFR 25.15(a)), requires that "[a]ll applications or petitions requesting agency action require the submission of an [environmental assessment] or a claim of categorical exclusion." Each EA should describe the product information, including certain characterizing information, manufacturing, and projected sales. These items may be different across each product. For FDA to fulfill obligations under NEPA, each product needs an accompanying EA for each proposed action.

2. All of your EX Requests lack detailed information about how the new products will be packaged, such as the packaging material used. Packaging materials include such things as booklets; display boxes containing multiple booklets; any liners, inserts, or overwrap in booklets or display boxes; twine or string used on booklets; larger packaging for product distribution such as cartons holding multiple boxes; and any other packaging materials. This information allows for an accurate assessment of the solid waste generated from end use of the products. Provide the following to address packaging details:
    a. How are the retail units of the new products packaged? Provide details as to how each retail unit is packaged. For example, the 20-cigarette soft pack contains a liner, outer film, and tear tape. Ten cigarette packs are packaged in a carton.
    b. What are the material types of each packaging component of the new products? For example, the soft pack consists of paper, the inner liner is paper lined foil, the outer film is propylene, the tear tape is propylene, the carton is paperboard.

3. All of your EX Requests lack the address of the manufacturing facilities for the new products. This information is used to evaluate the environmental effects of manufacturing the new and original products. Provide the manufacturing facility address for the new products.

4. All of your EX Requests lack information on the environmental effects of manufacturing the new products. This information is used to assess the environmental impact of marketing of the new products. To address the potential effects of manufacturing, address the following:
    a. Will there be increased manufacturing due to the new products? If so, will that require additional resources for manufacturing waste disposal, such as onsite solid

or hazardous waste accumulation capacity, new or expanded landfills, recycling centers, or other waste disposal or handling capacity? If these additional resources would be required, describe the environmental effects.

b. Will manufacturing the new products result in an expansion of the manufacturing facility? If so, identify and evaluate any potential environmental impacts due to the expansion.
c. Will there be new compounds emitted or increased amounts of compounds currently emitted from manufacturing the new products? If so, list the compounds and describe the environmental effects of those new compounds being emitted.
d. Will manufacturing the new products lead to changes in air emissions or wastewater discharges from increased manufacturing? Will a revised or new air emissions or wastewater discharge permit be required?
e. Will manufacturing the new products require any additional environmental controls? If yes, what are these controls and describe the environmental effects of these controls?

5. All of your EX Requests lack information on the first- and fifth-year projected market volumes of the new products. Marketing information is used to quantitatively assess the environmental impacts of manufacturing, use, and disposal of the new products. In Table 1, provide the projected market volumes of the new products. Note any information you deem confidential so that it can be placed in a confidential appendix to the public EA document.

Table 1			
STN	Measure	First-Year Market Volume	Fifth-Year Market Volume
EX0000470	Cigarettes		
	Metric Tons		
EX0000471	Cigarettes		
	Metric Tons		
EX0000472	Cigarettes		
	Metric Tons		
EX0000473	Cigarettes		
	Metric Tons		
EX0000474	Cigarettes		
	Metric Tons		
EX0000475	Cigarettes		
	Metric Tons		

6. All of your EX Requests lack environmental effects of disposal of the new products. This information is used to assess the environmental impact of marketing the new products. To address the potential effects of disposal, provide answers to the following questions:

a. Will disposal of the new products require additional resources (e.g., new landfills, recycling centers) for waste disposal? If so, describe the environmental effects of these increased resources.
b. Will there be new or increased compounds emitted from the disposal of the new products? If so, list the compounds and describe the environmental effects of those new compounds being emitted.

7. All of your EX Requests lack evidence that you are in compliance with the Endangered Species Act (ESA) and the Convention on International Trade in Endangered Species of Wild Flora and Fauna (CITES). All federal actions are required to comply with ESA and CITES therefore FDA evaluates the potential for violations of ESA and CITES due to its proposed product authorization actions. To assess if any adverse effects are anticipated from the proposed actions, address the following:
    a. Is any critical habitat affected from materials or ingredients used to manufacture the new products?
    b. Discuss any adverse effects, if applicable, on any endangered species or the critical habitat of the species identified under ESA and CITES due to (i) the materials used to manufacture the new products, (ii) the manufacturing process itself, (and iii) the disposal of the new products.

If the applicant adequately responds to the request and an EIS or FONSI is completed, EX order letters should be issued for the new tobacco products in EX0000470 – EX0000475, as identified on the cover page of this review.