FDA U.S. FOOD & DRUG ADMINISTRATION

# Technical Project Lead (TPL) Review: Exemption Requests EX0000717 – EX0000720

| | |
|---|---|
| **EX0000717: Aura Robust Red** | |
| **Length** | 84 mm |
| **Diameter** | 7.90 mm |
| **Ventilation** | 0% |
| **Characterizing Flavor** | None |
| **Modifications** | Addition/Deletion of tobacco additives:<br>• Deletion of non-FSC[1] cigarette paper (b) (4) [redacted]<br>• Addition of FSC paper (b) (4) [redacted] |
| **EX0000718: Aura Radiant Gold** | |
| **Length** | 84 mm |
| **Diameter** | 7.90 mm |
| **Ventilation** | 30% |
| **Characterizing Flavor** | None |
| **Package Type** | Addition/Deletion of tobacco additives:<br>• Deletion of non-FSC paper (b) (4) [redacted]<br>• Addition of FSC paper (b) (4) [redacted] |
| **EX0000719: Aura Sky Blue** | |
| **Length** | 84 mm |
| **Diameter** | 7.90 mm |
| **Ventilation** | 33% |
| **Characterizing Flavor** | None |
| **Modifications** | Addition/Deletion of tobacco additives:<br>• Deletion of non-FSC paper (b) (4) [redacted]<br>• Addition of FSC paper (b) (4) [redacted] |
| **EX0000720: Aura Menthol Glen** | |
| **Length** | 84 mm |
| **Diameter** | 7.90 mm |
| **Ventilation** | 30% |
| **Characterizing Flavor** | Menthol |
| **Modifications** | Addition/Deletion of tobacco additives:<br>• Deletion of non-FSC paper (b) (4) [redacted]<br>• Addition of FSC paper (b) (4) [redacted] |

[1] FSC: Fire Standards Compliant

| Common Attributes of Exemption Requests | |
|---|---|
| Applicant | Cheyenne International, LLC |
| Product Category | Cigarettes |
| Product Sub-Category | Combusted, Filtered |
| Package Quantity | 20 Cigarettes |
| Package Type | Box |
| **Recommendation** | |
| Issue an Exempt order letter. | |

**Technical Project Lead (TPL):**

Digitally signed by Matthew J. Walters -S
Date: 2019.09.12 14:23:02 -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: 2019.09.12 14:38:15 -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 Product**

| | |
|---|---|
| **EX0000717: Aura Robust Red** | |
| **Product Name** | Cayman Full Flavor |
| **Package Quantity** | 20 Cigarettes |
| **Package Type** | Box |
| **Length** | 84 mm |
| **Diameter** | 7.90 mm |
| **Ventilation** | 0% |
| **Characterizing Flavor** | None |
| **EX0000718: Aura Radiant Gold** | |
| **Product Name** | Cayman Light |
| **Package Quantity** | 20 Cigarettes |
| **Package Type** | Box |
| **Length** | 84 mm |
| **Diameter** | 7.90 mm |
| **Ventilation** | 30% |
| **Characterizing Flavor** | None |
| **EX0000719: Aura Sky Blue** | |
| **Product Name** | Cayman Ultra Light |
| **Package Quantity** | 20 Cigarettes |
| **Package Type** | Box |
| **Length** | 84 mm |
| **Diameter** | 7.90 mm |
| **Ventilation** | 33% |
| **Characterizing Flavor** | None |
| **EX0000720: Aura Menthol Glen** | |
| **Product Name** | Cayman Menthol Light |
| **Package Quantity** | 20 Cigarettes |
| **Package Type** | Box |
| **Length** | 84 mm |
| **Diameter** | 7.90 mm |
| **Ventilation** | 30% |
| **Characterizing Flavor** | Menthol |

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

### 1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On July 31, 2019, FDA received Exemption Requests (EX REQs) (EX0000717 – EX0000720) from Cheyenne International, LLC. On August 12, 2019, FDA issued acknowledgment letters to the applicant. On August 13, 2019, FDA requested clarification on the unique identification of the tobacco products and the description of the modification. On August 14, 2019, FDA requested additional information on the original tobacco products. In response to the August 13, 2019 and August 14, 2019 information requests, the applicant submitted amendments which were received by FDA on August 19, 2019 (EX0000751), August 21, 2019 (EX0000752) and August 29, 2019 (EX0000767).

### 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 modification compared to the corresponding original tobacco products:

- Deletion of non-FSC cigarette paper
- Addition of FSC cigarette paper

## 2. REGULATORY REVIEW

Regulatory reviews were completed by Kristopher Van Amburg on August 8, 2019. The reviews conclude that these EX REQs are administratively complete.

## 3. COMPLIANCE REVIEW

The Office of Compliance and Enforcement (OCE) completed a review to determine whether the applicant established 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). The OCE reviews dated September 9, 2019 for EX0000717 and September 10, 2019 for EX0000718-EX0000720, concludes that the original tobacco products are grandfathered products. Therefore, the original products are eligible for modification under the Exemption Request pathway.[2]

[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.

## 4. SCIENTIFIC REVIEW

A scientific review was completed by Melis Coraggio on September 12, 2019.

The review states that the new tobacco products have been modified by adding and deleting a tobacco additive. Cigarette paper is used in the manufacturing of the original tobacco products and 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 modification is a minor modification 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 tobacco 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 14, 2017, toxicology memo.

## 5. ENVIRONMENTAL DECISION

An environmental review was completed by Shannon Hannon on August 23, 2019.

The final environmental review found that the applicant did not provide an environmental assessment specific to each Exemption Request under review in this submission, did not identify the specific manufacturer or manufacturing location(s) for the new and original products, did not fully address the environmental effects of manufacturing the new products, did not state if the manufacturing facility is in compliance with relevant federal, state, and local environmental regulations, did not provide the first- and fifth-year projected market volumes of the new products, did not fully address the environmental impacts associated with disposal of the new products, and did not provide information or supporting evidence that the applicant is in 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 modification compared to the corresponding original tobacco products:

- Deletion of non-FSC cigarette paper
- Addition of FSC cigarette paper

I concur with the conclusion of the scientific review that this modification is a minor modification 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 deletion of non-FSC

cigarette paper and the addition of FSC cigarette paper is an addition/deletion of a tobacco additive. 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 cigarette 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 cigarette paper. Lastly, FDA finds, based on the information contained in the Exemption Requests and CTP's scientific understanding, that an exemption for this modification is otherwise appropriate as required by section 905(j)(3)(a)(iii) of the FD&C Act. Therefore, the new tobacco products should be found 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 modification through the Exemption Request pathway because they can be legally marketed in the United States. 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).

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 Exempt order letters.

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

1. All of your EX REQs lack individual EAs; that is, one EA for each EX REQ. FDA's regulations implementing the National Environmental Policy Act (NEPA) of 1969 (21 CFR 25.15(a)), require 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. Therefore, each product needs an accompanying EA to evaluate each proposed action's environmental impacts.

2. All of your EX REQs do not identify the manufacturing facility or its location. List the facility for manufacturing the new and original tobacco products and its location. This information is used to address the environmental effects of manufacturing the new tobacco products.

3. All of your EX REQs lack information on the environmental effects of manufacturing the new tobacco products. This information is used to assess the environmental impact of marketing of the new tobacco products. To address the potential effects of manufacturing, provide answers to the following:
    a. Will there be increased manufacturing due to the new tobacco products? If so, will that require additional resources for manufacturing waste disposal, such as on-site 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 tobacco 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 tobacco products? If so, list the compounds and describe the environmental effects of those new compounds being emitted.
d. Will manufacturing the new tobacco 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 tobacco products require any additional environmental controls? If yes, what are these controls and describe the environmental effects of these controls?

4. All of your EX REQs lack evidence that the manufacturing facility is in compliance with relevant federal, state, and local environmental regulations. The significance of environmental impacts (and thus the justification for a finding of no significant impact) is in part indicated by whether the action may violate federal, state, or local law or requirements imposed for the protection of the environment (40 CFR 1508.27(b)(10)). If applicable, provide a statement that you comply with relevant federal, state, and local environmental regulations. Otherwise, discuss potential violations of any federal, state, and local environmental regulations and your mitigation to comply with the regulations.

5. All of your EX REQs lack information on the first- and fifth-year projected market volumes of the new tobacco products. Marketing information is used to quantitatively assess the environmental impacts of manufacturing, use, and disposal of the new tobacco products. In Table 1, provide the projected market volumes of the new tobacco 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 |
|---|---|---|---|
| EX0000717 | Cigarettes | | |
| EX0000718 | Cigarettes | | |
| EX0000719 | Cigarettes | | |
| EX0000720 | Cigarettes | | |

6. All of your EX REQs lack information about the environmental effects of disposal of the new tobacco products. This information is used to assess the environmental impact of marketing the new tobacco products. Will disposal of the new tobacco products require additional resources (e.g., new landfills, recycling centers) for waste disposal? If so, describe the environmental effects of these increased resources.

7. All of your EX REQs 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, provide a discussion of 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 or ingredients used to manufacture the new tobacco products, (ii) the manufacturing process itself, and (iii) the disposal of the new tobacco products.

If the applicant adequately responds to the request and an EIS or FONSI is completed, Exempt order letters should be issued for the new tobacco products in EX0000717 – EX0000720, as identified on the cover page of this review.