

**Technical Project Lead (TPL) Review:
Exemption Request EX0000155, EX0000156,
EX0000159, EX0000161 – EX0000165**

EX0000155: Camel Gold	
Length	83 mm
Diameter	7.79 mm
Ventilation	29%
Characterizing Flavor	None
Product Modifications	Removal of tobacco additives: deletion of monogram ink on the barrel of the cigarette (monogram ink on the barrel of the cigarette)
EX0000156: Camel Royal	
Length	83 mm
Diameter	7.79 mm
Ventilation	24%
Characterizing Flavor	None
Product Modifications	Removal of tobacco additives: deletion of monogram ink on the barrel of the cigarette (monogram ink on the barrel of the cigarette)
EX0000159: Camel Silver	
Length	83 mm
Diameter	7.79 mm
Ventilation	32%
Characterizing Flavor	None
Product Modifications	Removal of tobacco additives: deletion of a tobacco additive (monogram ink on the barrel of the cigarette)
EX0000161: Camel Gold 100s	
Length	98 mm
Diameter	7.79 mm
Ventilation	38%
Characterizing Flavor	None
Product Modifications	Removal of tobacco additives: deletion of a tobacco additive (monogram ink on the barrel of the cigarette)
EX0000162: Camel Jade	
Length	83 mm
Diameter	7.79 mm
Ventilation	0%
Characterizing Flavor	Menthol
Product Modifications	Removal of tobacco additives: deletion of a tobacco additive (monogram ink on the barrel of the cigarette)

EX0000163: Camel Jade 100s	
Length	98 mm
Diameter	7.79 mm
Ventilation	15%
Characterizing Flavor	Menthol
Product Modifications	Removal of tobacco additives: deletion of a tobacco additive (monogram ink on the barrel of the cigarette)
EX0000164: Camel Jade Silver	
Length	83 mm
Diameter	7.79 mm
Ventilation	38%
Characterizing Flavor	Menthol
Product Modifications	Removal of tobacco additives: deletion of a tobacco additive (monogram ink on the barrel of the cigarette)
EX0000165: Camel Jade Silver 100s	
Length	98 mm
Diameter	7.79 mm
Ventilation	40%
Characterizing Flavor	Menthol
Product Modifications	Removal of tobacco additives: deletion of a tobacco additive (monogram ink on the barrel of the cigarette)
Common Attributes of Exemption Requests	
Applicant	R.J. Reynolds Tobacco Company
Product Category	Cigarette
Product Sub-Category	Combusted Filtered
Package Quantity	20 cigarettes
Package Type	Hard Pack
Recommendation	
Issue Exempt order letters.	

Technical Project Lead (TPL):

Digitally signed by Colleen K. Rogers -S
Date: 2017.08.31 10:13:38 -04'00'

For 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: 2017.08.31 10:38:34 -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

EX0000155	
Product Name	Camel Gold
Package Quantity	20 cigarettes
Package Type	Hard Pack
Length	83 mm
Diameter	7.79 mm
Ventilation	29%
Characterizing Flavor	None
EX0000156	
Product Name	Camel Royal
Package Quantity	20 cigarettes
Package Type	Hard Pack
Length	83 mm
Diameter	7.79 mm
Ventilation	24%
Characterizing Flavor	None
EX0000159	
Product Name	Camel Silver
Package Quantity	20 cigarettes
Package Type	Hard Pack
Length	83 mm
Diameter	7.79 mm
Ventilation	32%
Characterizing Flavor	None
EX0000161	
Product Name	Camel Gold 100s
Package Quantity	20 cigarettes
Package Type	Hard Pack
Length	98 mm
Diameter	7.79 mm
Ventilation	38%
Characterizing Flavor	None

EX0000162	
Product Name	Camel Jade
Package Quantity	20 cigarettes
Package Type	Hard Pack
Length	83 mm
Diameter	7.79 mm
Ventilation	0%
Characterizing Flavor	Menthol
EX0000163	
Product Name	Camel Jade 100s
Package Quantity	20 cigarettes
Package Type	Hard Pack
Length	98 mm
Diameter	7.79 mm
Ventilation	15%
Characterizing Flavor	Menthol
EX0000164	
Product Name	Camel Jade Silver
Package Quantity	20 cigarettes
Package Type	Hard Pack
Length	83 mm
Diameter	7.79 mm
Ventilation	38%
Characterizing Flavor	Menthol
EX0000165	
Product Name	Camel Jade Silver 100s
Package Quantity	20 cigarettes
Package Type	Hard Pack
Length	98 mm
Diameter	7.79 mm
Ventilation	40%
Characterizing Flavor	Menthol

The applicant manufactures the original tobacco products and claims that they were previously found substantially equivalent.

1.2. REGULATORY ACTIVITY RELATED TO THIS MEMO

The applicant submitted the original Exemption Requests EX0000155, EX0000156, EX0000159, and EX0000161 – EX0000165 on February 16, 2017. FDA issued the applicant Acknowledgement letters for the Exemption Requests on March 6, 2017. The applicant submitted an unsolicited amendment (EX0000166) to EX0000161. FDA sent the applicant an Advice and Information Request (A/I) letter for these Exemption Requests on June 29, 2017. In

response, the applicant submitted an amendment (EX0000187) to these Exemption Requests.

1.3. SCOPE OF MEMO

This memo captures all administrative, 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 tobacco product:

- Deletion of a tobacco additive (monogram ink on the barrel of the cigarette)

2. ADMINISTRATIVE REVIEW

An acceptance review was completed by Jennifer Schmitz on March 6, 2017. The review concludes that the Exemption Requests are administratively complete.

3. COMPLIANCE REVIEW

The original tobacco products are eligible original tobacco products, as they were previously found in compliance with the requirements of the FD&C Act and substantially equivalent to a tobacco product that was commercially marketed in the United States as of February 15, 2007 (i.e., SE0013007, SE0013008, SE0013010, SE0013012, SE0013013, SE0013014, SE0013015, SE0013016).¹

4. SCIENTIFIC REVIEW

A scientific review was completed by Caroline Agarabi on August 28, 2017. The review concludes that the modification is a minor modification of tobacco additives in accordance with section 905(j)(3)(A)(i) of the FD&C Act. The review concludes the removal of monogram ink is a minor modification. Furthermore, the removal of the monogram is not expected to materially affect any other characteristic (materials, ingredients, design, composition, heating source, or other features) of the product and may potentially decrease HPHC yields.

¹ Any tobacco product that can be sold under the FD&C Act (i.e., legally marketed in the United States) is eligible for modification under the Exemption Request pathway.

5. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on August 30, 2017. The FONSI was supported by an environmental assessment prepared by FDA on August 22, 2017.

6. CONCLUSION AND RECOMMENDATION

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

- Deletion of a tobacco additive (monogram ink on the barrel of the cigarette)

I concur with the conclusion of the chemistry review that these modifications are minor modifications involving tobacco additives in accordance with section 905(j)(3)(A)(i) of the FD&C Act. Monogram ink is an additive because it is a substance that is a component of a tobacco product. In addition, it is my conclusion and consistent with section 905(j)(3)(A)(ii) of the FD&C Act, SE Reports are not necessary to ensure that permitting the new tobacco products to be marketed would be appropriate for protection of the public health. The removal of the monogram ink is not expected have any toxicological or other concerns. 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 product 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 meet statutory requirements because they were previously found in compliance with the requirements of the FD&C Act and substantially equivalent to a tobacco product that was commercially marketed in the United States as of February 15, 2007.

FDA has examined the environmental effects of finding the new tobacco products exempt and made a finding of no significant impact.

Exempt order letters should be issued for the new tobacco products in EX0000155, EX0000156, EX0000159, and EX0000161 – EX0000165 as identified on the cover page of this review.