



Technical Project Lead (TPL) Review: Exemption Request EX0000167, EX0000168, EX0000170 – EX0000173

EX0000167: Monarch Red 100's Soft Pack	
Length	99 mm
Diameter	7.89 mm
Ventilation	0%
Characterizing Flavor	None
Product Modifications	Substitution of tobacco additive: deletion of (b) (4) and replacement with (b) (4)
EX0000168: Monarch Gold 100's Soft Pack	
Length	99 mm
Diameter	7.89 mm
Ventilation	34%
Characterizing Flavor	None
Product Modifications	Substitution of tobacco additive: deletion of (b) (4) and replacement with (b) (4)
EX0000170: Monarch Blue 100's Soft Pack	
Length	99 mm
Diameter	7.89 mm
Ventilation	54%
Characterizing Flavor	None
Product Modifications	Substitution of tobacco additive: deletion of (b) (4) and replacement with (b) (4)
EX0000171: Monarch Red Box	
Length	83 mm
Diameter	7.79 mm
Ventilation	0%
Characterizing Flavor	None
Product Modifications	Substitution of tobacco additive: deletion of (b) (4) and replacement with (b) (4)
EX0000172: Monarch Gold Box	
Length	83 mm
Diameter	7.79 mm
Ventilation	15%
Characterizing Flavor	None
Product Modifications	Substitution of tobacco additive: deletion of (b) (4) and replacement with (b) (4)

EX0000173: GPC Non-Filter Soft Pack	
Length	83 mm
Diameter	7.89 mm
Ventilation	Not Applicable
Characterizing Flavor	None
Product Modifications	Substitution of tobacco additive: deletion of (b) (4) and replacement with (b) (4)
Common Attributes of Exemption Requests	
Applicant	R.J. Reynolds Tobacco Company
Product Category	Cigarette
Product Sub-Category	Combusted Filtered: EX0000167, EX0000168, EX0000170, EX0000171, EX0000172
	Combusted Non-Filtered: EX0000173
Package Quantity	20 cigarettes
Package Type	Hard Pack: EX0000171, EX0000172
	Soft Pack: EX0000167, EX0000168, EX0000170, EX0000173
Recommendation	
Issue Exempt order letters.	

Technical Project Lead (TPL):

Digitally signed by Colleen K. Rogers -S
Date: 2017.08.31 10:35:02 -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 13:02:22 -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

EX0000167	
Product Name	Monarch Full Flavor 100s Soft Pack
Package Quantity	20 cigarettes
Package Type	Soft Pack
Length	99 mm
Diameter	7.89 mm
Ventilation	0%
Characterizing Flavor	None
EX0000168	
Product Name	Monarch Light 100s Soft Pack
Package Quantity	20 cigarettes
Package Type	Soft Pack
Length	99 mm
Diameter	7.89 mm
Ventilation	34%
Characterizing Flavor	None
EX0000170	
Product Name	Monarch Ultra Light 100s Soft Pack
Package Quantity	20 cigarettes
Package Type	Soft Pack
Length	99 mm
Diameter	7.89 mm
Ventilation	54%
Characterizing Flavor	None
EX0000171	
Product Name	Monarch Full Flavor Box
Package Quantity	20 cigarettes
Package Type	Hard Pack
Length	83 mm
Diameter	7.79 mm
Ventilation	0%
Characterizing Flavor	None

EX0000172	
Product Name	Monarch Light Box
Package Quantity	20 cigarettes
Package Type	Hard Pack
Length	83 mm
Diameter	7.79 mm
Ventilation	15%
Characterizing Flavor	None
EX0000173	
Product Name	GPC Non-Filter King Soft Pack
Package Quantity	20 cigarettes
Package Type	Soft Pack
Length	83 mm
Diameter	7.89 mm
Ventilation	Not Applicable
Characterizing Flavor	None

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

1.2. REGULATORY ACTIVITY RELATED TO THIS MEMO

The applicant submitted the original Exemption Requests EX0000167, EX0000168, and EX0000170 – EX0000172 on March 17, 2017 and on March 20, 2017 for EX0000173. FDA issued the applicant Acknowledgement letters for the Exemption Requests on March 31, 2017 (EX0000167, EX0000168, and EX0000170 – EX0000172) and on April 5, 2017 (EX0000173) and Advice and Information Request (A/I) letters 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:

- Substitution of tobacco additive: deletion of (b) (4) and replacement with (b) (4)

2. ADMINISTRATIVE REVIEW

An acceptance review was completed by Jennifer Schmitz on March 31, 2017 (EX0000167, EX0000168, and EX0000170 – EX0000172) and on April 5, 2017 (EX0000173). The review concludes 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 grandfathered products (i.e., were commercially marketed as of February 15, 2007). The OCE reviews dated April 21, 2017 (EX0000173) and April 25, 2017 (EX0000167, EX0000168, and EX0000170 – EX0000172), conclude that the original tobacco products are grandfathered products. Therefore the original tobacco products are eligible for modification under the Exemption Request pathway.¹

4. SCIENTIFIC REVIEW

A scientific review was completed by Salome Bhagan on August 25, 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 that the removal of the complex ingredient (b) (4) and addition of (b) (4) is a minor modification. Furthermore, the removal of (b) (4) with an equal increase in (b) (4) is not expected, to materially affect any other characteristic (materials, ingredients, design, composition, heating source, or other features) of the product.

5. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on August 29, 2017. The FONSI was supported by an environmental assessment prepared by FDA on August 29, 2017.

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.

6. CONCLUSION AND RECOMMENDATION

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

- Substitution of tobacco additive: deletion of (b) (4) and replacement with (b) (4)

I concur with the conclusion of the chemistry review that this modification is a minor modification involving tobacco additives in accordance with section 905(j)(3)(A)(i) of the FD&C Act. 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 complex ingredient - (b) (4) - and replacement with (b) (4) 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 are legally marketed in the United States. The original products are grandfathered products (i.e., were 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 EX0000167, EX0000168, EX0000159, and EX0000170 – EX0000173 as identified on the cover page of this review.