FDA U.S. FOOD & DRUG ADMINISTRATION

Technical Project Lead (TPL) Review of Exemption Requests: EX0000916 – EX0000917

Common Attributes of EX Requests		
Applicant	R.J. Reynolds Tobacco Company	
Product category	Cigarettes	
Product subcategory	Combusted, Filtered	
EX Requests Included in this Review		
Tobacco Product	**New**	**Original**
Submission tracking number	EX0000916	EX0000763
Product name	GPC Classic Silver Box	Doral Classic Silver
Eligibility status	Not applicable	Previously found EX
Marketing order date	Not applicable	October 18, 2019
Abbreviated report date	Not applicable	December 10, 2019
Package type	Box	Box
Package quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	None	None
Length	83 mm	83 mm
Diameter	7.8 mm	7.8 mm
Ventilation	59%	59%
Product modifications	Addition/Deletion of tobacco additives: • Deletion of white tipping paper (b) (4) ; target: [redacted] mg/cigarette) • Addition of white tipping paper (b) (4) target: [redacted] mg/cigarette)	
Tobacco Product	**New**	**Original**
Submission tracking number	EX0000917	EX0000766
Product name	GPC Classic Silver 100 Box	Doral Classic Silver 100
Eligibility status	Not applicable	Previously found EX
Marketing order date	Not applicable	October 18, 2019
Abbreviated report date	Not applicable	December 10, 2019
Package Type	Box	Box
Package Quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	None	None
Length	83 mm	83 mm
Diameter	7.8 mm	7.8 mm
Ventilation	59%	59%
Product modifications	Addition/Deletion of tobacco additives: • Deletion of white tipping paper (b) (4) target: [redacted] mg/cigarette) • Addition of white tipping paper (b) (4) target: [redacted] mg/cigarette)	

Recommendation
Issue Exempt (EX) order.

Technical Project Lead (TPL):

Digitally signed by Matthew J. Walters -S
Date: 2020.02.11 16:03:52 -05'00'

Matthew J. Walters, Ph.D., MPH
CDR, US 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: 2020.02.11 16:12:36 -05'00'

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

TABLE OF CONTENTS

1. BACKGROUND

1.1. ORIGINAL TOBACCO PRODUCTS

The original tobacco products are combusted, filtered cigarettes manufactured by the applicant as indicated on the cover page of this review.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On December 20, 2019, FDA received Exemption Requests EX0000916 - EX0000917 from RAI Services Company on behalf of R.J. Reynolds Tobacco Company. FDA issued an Acceptance letter on December 27, 2019.

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:

- deleting an additive (white tipping paper) in both of the EX Requests
- adding an additive (white tipping paper) in both of the EX Requests

2. REGULATORY REVIEW

Regulatory reviews were completed by Crystal Caesar on December 27, 2019. The reviews conclude that the Exemption Requests are administratively complete.

3. COMPLIANCE REVIEW

The original tobacco products in EX0000916 – EX0000917 were determined to be exempt from the requirements of section 905(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) relating to the demonstration of substantial equivalence under EX0000763 and EX0000766, respectively, by FDA. Reports under section 905(j)(1)(A)(ii) (Abbreviated Reports) were received on December 10, 2019. Therefore, the original tobacco products are eligible for modification under the Exemption Request pathway[1] on March 9, 2020, the date when 90 days will elapse since FDA receipt of the Abbreviated Reports.

[1] 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 chemistry review was completed by Sandra Salido on January 16, 2020.

The review states that the new tobacco products have been modified by adding or deleting tobacco additives. White tipping paper is used in the manufacturing of the original tobacco products, and is an additive because their intended use may reasonably be expected to result, directly or indirectly, in their 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 applicant proposed the deletion of white tipping paper and the addition of white tipping paper, which is not expected to have any significant effects on product chemistry or consumer perception as outlined in the May 16, 2017 social science memo. The scientific review has found this modification to be minor.

5. ENVIRONMENTAL DECISION

An environmental review was completed by Dilip Venugopal on January 14, 2020.

The final environmental review found that the applicant did not provide the overall market volumes from concurrent marketing of the new and original tobacco products. 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:

- deleting an additive (white tipping paper) in both of the EX Requests
- adding an additive (white tipping paper) in both of the EX Requests

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 white tipping paper is an addition/deletion of tobacco additives. 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 the protection of the public health. The addition of white tipping paper and the deletion of white tipping paper is not expected to have any significant effects on product chemistry or consumer perception. 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 previously found Exempt by FDA under EX0000763 and EX0000766, a report under section 905(j)(1)(A)(ii) (Abbreviated Reports) were received on Decemer 10, 2019. Therefore, the original tobacco products are eligible for modification under the Exemption Request pathway on March 9, 2020, the date when 90 days will elapse since FDA receipt of the Abbreviated Reports.

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

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

1. Both of your EX Requests indicate that the original tobacco products will continue to be manufactured and marketed after receiving marketing orders for the new tobacco products. The current market volumes of the original tobacco products, and the projected market volumes in the first and fifth years for the new tobacco products are included in your EX Requests. However, the overall market volumes from concurrent marketing of the new tobacco products and the original tobacco products is unclear as there is conflicting information provided. Your EX Requests include statements indicating that "if the EX REQ for the new product is granted, the new product will replace current market volume" and "will replace some portion of the current in-market volume of the product." Marketing information is used to assess the cumulative environmental impacts of concurrent manufacturing, use, and disposal of the new and original tobacco products. For the original tobacco products, provide the projected market volumes in the first and fifth years of marketing the new tobacco products. You may provide the information in Table 1.

Table 1
Original Tobacco Product Market Volumes

Original Tobacco Product	Unit	First-Year Market Volume	Fifth-Year Market Volume
Doral Classic Silver (EX0000763)			
Doral Classic Silver 100 (EX0000766)			

If the applicant adequately responds to the request and an EIS or FONSI is completed, an EX order should be issued for the new tobacco products in EX0000916 – EX0000917, as identified on the cover page of this review.