FDA U.S. FOOD & DRUG ADMINISTRATION

Technical Project Lead (TPL) Review of Exemption Requests: EX0000997 – EX0001003

Common Attributes of EX Requests		
Applicant	ITG Brands, LLC	
Product category	Cigarettes	
Product subcategory	Combusted, Filtered	
EX Requests Included in this Review		
Tobacco Product	**New**	**Original**
Submission tracking number	EX0000997	GF1601939
Product name	Maverick Box	Maverick Box
Eligibility status	Not applicable	Grandfathered
Marketing order date	Not applicable	Not applicable
Abbreviated report date	Not applicable	Not applicable
Package type	Box	Box
Package quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	None	None
Length	80 mm	80 mm
Diameter	7.89 mm	7.89 mm
Ventilation	0%	0%
Product modifications	Addition/Deletion of tobacco additives: • Deletion of non-porous tipping paper (b) (4)); (b) (4) target: (b) (4) mg/cigarette) • Addition of non-porous tipping paper (b) (4) target: (b) (4) mg/cigarette) • Deletion of (b) (4) from the tipping paper ink • Addition of (b) (4) in the tipping paper ink Increasing/Decreasing the quantity of existing tobacco additives: • Increasing the quantity of (b) (4) in the tipping paper ink	

Tobacco Product	**New**	**Original**
Submission tracking number	EX0000998	GF1601943
Product name	Maverick Box 100s	Maverick Box 100s
Eligibility status	Not applicable	Grandfathered
Marketing order date	Not applicable	Not applicable
Abbreviated report date	Not applicable	Not applicable
Package Type	Box	Box
Package Quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	None	None
Length	99 mm	99 mm
Diameter	7.89 mm	7.89 mm
Ventilation	8%	8%
Product modifications	Addition/Deletion of tobacco additives: • Deletion of non-porous tipping paper (b) (4) (b) (4) target: (b) (4) mg/cigarette) • Addition of non-porous tipping paper ((b) (4)]; target: (b) (4) mg/cigarette) • Deletion of (b) (4) from the tipping paper ink • Addition of (b) (4) in the tipping paper ink	
Tobacco Product	**New**	**Original**
Submission tracking number	EX0000999	EX0000481
Product name	Maverick Gold Box	Maverick Gold Box
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	80 mm	80 mm
Diameter	7.89 mm	7.89 mm
Ventilation	30%	30%
Product modifications	Addition/Deletion of tobacco additives: • Deletion of non-porous tipping paper (b) (4)); (b) (4) target: (b) (4) mg/cigarette) • Addition of non-porous tipping paper (b) (4)]; target: (b) (4) mg/cigarette)	

Tobacco Product	**New**	**Original**
Submission tracking number	EX0001000	GF1601941
Product name	Maverick Gold Box 100s	Maverick Lights Box 100s
Eligibility status	Not applicable	Grandfathered
Marketing order date	Not applicable	Not applicable
Abbreviated report date	Not applicable	Not applicable
Package type	Box	Box
Package quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	None	None
Length	99 mm	99 mm
Diameter	7.89 mm	7.89 mm
Ventilation	34%	34%
Product modifications	Addition/Deletion of tobacco additives: • Deletion of non-porous tipping paper ((b) (4) (b) (4) target: (b)(4) mg/cigarette) • Addition of non-porous tipping paper (b) (4) target: (b) (4) mg/cigarette)	
Tobacco Product	**New**	**Original**
Submission tracking number	EX0001001	GF1601940
Product name	Maverick Menthol Box 100s	Maverick Menthol Box 100s
Eligibility status	Not applicable	Grandfathered
Marketing order date	Not applicable	Not applicable
Abbreviated report date	Not applicable	Not applicable
Package type	Box	Box
Package quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	Menthol	Menthol
Length	99 mm	99 mm
Diameter	7.89 mm	7.89 mm
Ventilation	0%	0%
Product modifications	Addition/Deletion of tobacco additives: • Deletion of non-porous tipping paper (b) (4)); (b) (4) target: (b) (4) mg/cigarette) • Addition of non-porous tipping paper (b) (4)]; target: (b) (4) mg/cigarette) • Deletion of (b) (4) from the tipping paper ink • Addition of (b) (4) in the tipping paper ink	

Tobacco Product	**New**	**Original**
Submission tracking number	EX0001002	GF1601942
Product name	Maverick Menthol Box	Maverick Menthol Box
Eligibility status	Not applicable	Grandfathered
Marketing order date	Not applicable	Not applicable
Abbreviated report date	Not applicable	Not applicable
Package type	Box	Box
Package quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	Menthol	Menthol
Length	80 mm	80 mm
Diameter	7.89 mm	7.89 mm
Ventilation	0%	0%
Product modifications	Addition/Deletion of tobacco additives: • Deletion of non-porous tipping paper (b) (4) ; (b) (4) ; target: (b) (4) mg/cigarette) • Addition of non-porous tipping paper (b) (4)]; target: (b) (4) mg/cigarette) • Deletion of (b) (4) from the tipping paper ink • Addition of (b) (4) in the tipping paper ink	
Tobacco Product	**New**	**Original**
Submission tracking number	EX0001003	GF1601944
Product name	Maverick Menthol Gold Box 100s	Maverick Menthol Lights Box 100s
Eligibility status	Not applicable	Grandfathered
Marketing order date	Not applicable	Not applicable
Abbreviated report date	Not applicable	Not applicable
Package type	Box	Box
Package quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	Menthol	Menthol
Length	99 mm	99 mm
Diameter	7.89 mm	7.89 mm
Ventilation	35%	35%
Product modifications	Addition/Deletion of tobacco additives: • Deletion of non-porous tipping paper (b) (4)); (b) (4) target: (b) (4) mg/cigarette) • Addition of non-porous tipping paper (b) (4)]; target: (b) (4) mg/cigarette) • Deletion of (b) (4) from the tipping paper ink • Addition of (b) (4) in the tipping paper ink	
Recommendation		
Issue Exempt (EX) order.		

Technical Project Lead (TPL):

Digitally signed by Matthew J. Walters -S
Date: 2020.04.16 13:07:15 -04'00'

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: 2020.04.16 13:47:27 -04'00'

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

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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 February 27, 2020, FDA received seven Exemption Requests (EX0000997-EX0001003) from ITG Brands, LLC. On March 4, 2020, FDA issued an acceptance letter to the applicant. On March 24, 2020, FDA sent an email with clarification questions for EX0000999, EX0001000, and EX0001003 to the applicant. ITG Brands, LLC submitted an amendment in response to these clarification questions (EX0001031) on March 31, 2020.

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 (non-porous tipping paper) in all the EX Requests
- adding an additive (non-porous tipping paper) in all the EX Requests
- deleting an additive ((b) (4) in the tipping paper ink) in EX0000997, EX0000998, and EX0001001 – EX0001003
- adding an additive (b) (4) in the tipping paper ink) in EX0000997, EX0000998, and EX0001001 – EX0001003
- increasing the quantity of an existing additive ((b) (4) in the tipping paper ink) in EX0000997

2. REGULATORY REVIEW

Regulatory reviews were completed by Elizabeth Eydelman on March 4, 2020. The reviews conclude that the Exemption Requests are administratively complete.

3. COMPLIANCE REVIEW

For EX0000997, EX0000998, and EX0001000 – EX0001003, 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 review dated April 1, 2020 concludes that the original tobacco products are grandfathered products. For EX0000999, the original tobacco product was 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 by FDA. A report under section 905(j)(1)(A)(ii) (Abbreviated Report) was submitted, and at least 90 days have elapsed since receipt of the Abbreviated Report by FDA. Therefore, the original tobacco products are eligible for modification under the Exemption Request pathway.[1]

4. SCIENTIFIC REVIEW

A scientific review was completed by Jiu Ali on April 9, 2020.

The review states that the new tobacco products have been modified by adding or deleting tobacco additives and increasing the quantity of an existing additive. Tipping paper and tipping paper ink[2] are used in the manufacturing of the original tobacco products, and are additives 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 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-porous tipping paper and the addition of an alternate non-porous tipping paper is a minor modification. The tipping paper between the new and original products contain minimal differences in the additives that compose the tipping papers. In addition, there was no change in the perforation during manufacturing. For EX0000997, EX0000998, and EX0001001 – EX0001003, the review concludes that the deletion of (b) (4) in the tipping paper ink of the original tobacco products and the addition of (b) (4) in the tipping paper ink of the new tobacco products is a minor modification. This modification resulted in a change in composition of the tipping paper ink but did not alter the overall total amount of tipping paper ink as these two additives were changed at equal amounts. Finally, for EX0000997 only, the existing additive of (b) (4) in the tipping paper ink was increased by (b) (4) mg/cigarette. Overall, these modifications are not expected to materially affect any other characteristic (materials, ingredients, design, composition, heating source, or other features) of the tobacco products.

5. ENVIRONMENTAL DECISION

An environmental review was completed by Bria Martin on March 20, 2020.

For EX0000997, EX0000998, and EX0001000 – EX0001003, a finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on April 15, 2020. The FONSI was supported by an environmental assessment prepared by FDA on April 15, 2020.

For EX0000999, the 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).

[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.
[2] EX0000997, EX0000998, and EX0001001 – EX0001003 only

6. CONCLUSION AND RECOMMENDATION

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

- deleting an additive (non-porous tipping paper) in all the EX Requests
- adding an additive (non-porous tipping paper) in all the EX Requests
- deleting an additive ((b) (4) in the tipping paper ink) in EX0000997, EX0000998, and EX0001001 – EX0001003
- adding an additive ((b) (4) in the tipping paper ink) in EX0000997, EX0000998, and EX0001001 – EX0001003
- increasing the quantity of an existing additive ((b) (4) in the tipping paper ink) in EX0000997

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 tipping paper is an addition/deletion of tobacco additives for all EX Requests, and an addition/deletion was made to an additive of the composition of the tipping paper ink for EX0000997, EX0000998, and EX0001001 – EX0001003. 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 deletion of non-porous tipping paper and the addition of an alternate non-porous tipping paper is a minor modification. The tipping paper between the new and original products contain minimal differences in the additives that compose the tipping papers. In addition, there was no change in the perforation during manufacturing. For EX0000997, EX0000998, and EX0001001 – EX0001003, the deletion of (b) (4) in the tipping paper ink of the original tobacco products and the addition of (b) (4) in the tipping paper ink of the new tobacco products is a minor modification. This modification resulted in a change in composition of the tipping paper ink but did not alter the overall total amount of tipping paper ink as these two additives were changed at equal amounts. Also, for EX0000997 only, the existing additive of (b) (4) in the tipping paper ink was increased by (b) (4) mg/cigarette. Overall, these modifications are not expected to materially affect any other characteristic (materials, ingredients, design, composition, heating source, or other features) of the tobacco products. Lastly, FDA finds, based on the information contained in the Exemption Requests and CTP's scientific understanding, that an exemption for these modifications 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. For EX0000997, EX0000998, and EX0001000 – EX0001003, the original tobacco products are grandfathered products (i.e., were commercially marketed in the United States other than exclusively test markets as of February 15, 2007). For EX0000999, the original tobacco product is previously found Exempt by

FDA, a report under section 905(j)(1)(A)(ii) (an Abbreviated Report) was submitted, and 90 days have elapsed since FDA receipt of the Abbreviated Report.

For EX0000997, EX0000998, and EX0001000 – EX0001003, FDA has examined the environmental effects of finding the new tobacco products exempt and made a finding of no significant impact.

An Exempt order should be issued for the new tobacco products in EX0000997, EX0000998, and EX0001000 – EX0001003, as identified on the cover page of this review.

For EX0000999, FDA has examined the environmental effects of finding this new tobacco product 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 Exempt order.

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

1. EX0000999 indicates that the original tobacco product will not continue to be marketed upon receiving a marketing order for the new tobacco product. However, your EX Request includes conflicting statements regarding current marketing status for the original tobacco product. On page 16 of the EX Request, you state that the original tobacco product "is currently on the market but will be replaced in the marketplace by the new product." On page 20 of the EX Request, you state that the "new product will replace the already discontinued [original] product." Clarify if the original tobacco product is currently marketed. If so, provide current market volume for the original tobacco product. Marketing information is used to assess the cumulative environmental impacts of concurrent manufacturing, use, and disposal of the new and original tobacco products. Table 1 can be used to present this information.

Original Tobacco Product	Current Market Volume (Number of Cigarettes)
Maverick Gold Box	

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 product in EX0000999, as identified on the cover page of this review.