FDA U.S. FOOD & DRUG ADMINISTRATION

# Technical Project Lead (TPL) Review: Exemption Request EX0000481

| EX0000481: Maverick Gold Box | |
|---|---|
| **Length** | 80 mm |
| **Diameter** | 7.89 mm |
| **Ventilation** | 30% |
| **Characterizing Flavor** | None |
| **Product Modifications** | Addition/Deletion of tobacco additives:<br>• Deletion of non-FSC[1] cigarette paper ((b) (4) [redacted])<br>• Addition of FSC cigarette paper ((b) (4) [redacted]) |
| **Attribute of Exemption Request** | |
| **Applicant** | ITG Brands, LLC |
| **Product Category** | Cigarette |
| **Product Sub-Category** | Combusted Filtered |
| **Package Quantity** | 20 cigarettes |
| **Package Type** | Box |
| **Recommendation** | |
| Issue an Exempt order letter. | |

[1] Fire Standards Compliant

**Technical Project Lead (TPL):**

Digitally signed by Matthew J. Walters -S
Date: 2019.04.22 08:24:25 -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 Deirdre L. Kittner -S
Date: 2019.04.22 09:46:27 -04'00'

For 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 product:

**Table 1. Original Tobacco Product**

| EX0000481: Maverick Gold Box | |
|---|---|
| Product Name | Maverick Lights Box |
| Package Quantity | 20 cigarettes |
| Package Type | Box |
| Length | 80 mm |
| Diameter | 7.89 mm |
| Ventilation | 30% |
| Characterizing Flavor | None |

The applicant manufactures the original tobacco product and claims that it is grandfathered.

## 1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On March 5, 2019, FDA received an Exemption Request (EX0000481) from ITG Brands, LLC. On March 8, 2019, FDA issued an Acknowledgement letter to the applicant.

## 1.3. SCOPE OF REVIEW

This review captures all regulatory, compliance, and scientific reviews completed for this Exemption Request.

## 1.4. TOBACCO ADDITIVE MODIFICATION

The new tobacco product contains the following modifications compared to the original tobacco product:

- Deletion of non-FSC cigarette paper ([redacted])
- Addition of FSC cigarette paper ([redacted])

# 2. REGULATORY REVIEW

A regulatory review was completed by Donna Cheung on March 7, 2019. The review concludes that the Exemption Request is 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 product is legally marketed. The OCE review, dated April 2, 2019, concludes that the original tobacco product is a grandfathered product (i.e., was

commercially marketed in the United States other than exclusively in test markets as of February 15, 2007). Therefore, the original product is eligible for modification under the Exemption Request pathway.[2]

## 4. SCIENTIFIC REVIEW

A scientific review was completed by Samantha Reilly on April 12, 2019.

The review states that the new tobacco product has been modified by adding or deleting tobacco additives. Cigarette paper is used in the manufacturing of the original tobacco product, and is 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 product. 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-FSC cigarette paper and addition of FSC cigarette paper in the new product 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 17, 2017, toxicology memo.

## 5. ENVIRONMENTAL DECISION

An environmental review was completed by William Brenner on April 2, 2019.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on April 19, 2019. The FONSI was supported by an environmental assessment prepared by FDA on April 19, 2019.

## 6. CONCLUSION AND RECOMMENDATION

The new tobacco product contains the following modifications compared to the corresponding original tobacco product:

- Deletion of non-FSC cigarette paper ([redacted])
- Addition of FSC cigarette paper ([redacted])

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

[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.

modifications are the deletion of non-FSC cigarette paper and the addition of FSC cigarette paper. 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 product 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 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 paper. Lastly, FDA finds, based on the information contained in the Exemption Request and CTP's scientific understanding, that exemptions for these modifications are 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 product is eligible for modifications through the exemption request pathway because it is legally marketed in the United States. The original product is a grandfathered product (i.e., was 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 the new tobacco product exempt and made a finding of no significant impact.

An Exempt order letter should be issued for the new tobacco product in EX0000481 as identified on the cover page of this review.