FDA U.S. FOOD & DRUG ADMINISTRATION

Technical Project Lead (TPL) Review of Exemption Request

New Product Subject of this Review[1]	
STN	EX0002340.PD1
Common Attributes	
Submission date	September 10, 2021
Receipt date	September 10, 2021
Applicant	Fumari Inc.
Product manufacturer	Fumari Inc.
Product category	Waterpipe Tobacco Products
Product subcategory	Waterpipe Tobacco Filler
Cross-Referenced Submissions	
EX0002340.PD1	(b) (4) [redacted]
Supporting FDA Memoranda Relied Upon in this Review	
EX0002340.PD1	None
Recommendation	
Issue an Exempt (EX) order for the new tobacco product subject of this review.	

Technical Project Lead (TPL):

Digitally signed by Delshanee Kotandeniya -S
Date: 2022.10.24 13:55:59 -04'00'

Delshanee Kotandeniya, Ph.D.
Chemistry Team Supervisor
Office of Science/ Division of Product Science

Signatory Decision: Concur with TPL recommendation and basis of recommendation

Todd L. Cecil -S Digitally signed by Todd L. Cecil -S
Date: 2022.10.24 14:52:38 -04'00'

Todd L. Cecil, Ph.D.
Acting Director
Office of Science

[1] Product details, amendments, and dates provided in the Appendix. EX means exemption (request) from substantial equivalence. STN means submission tracking number.

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Background

1.1. NEW AND ORIGINAL PRODUCTS

The applicant submitted information for the new and original product listed in detail in the Appendix.

1.2. REGULATORY ACTIVITY

See appendices for products.

1.3. SCOPE OF REVIEW

This review captures all compliance, regulatory, and scientific reviews completed for the new product that is the subject of this review.

Table 1. Disciplines reviewed

	Cycle 1	
Discipline	**Reviewer(s)**	**Review Date**
Regulatory	Rodney Hammond	9/17/2021
Chemistry	Zeus De los Santos	8/2/2022
Environmental science	Carla Figueroa	7/26/2022

Table 2. Consultations

Discipline	Reviewer(s)	Review Date
Toxicology	Mamata De	8/2/2022

1. COMPLIANCE REVIEW

The Office of Compliance and Enforcement (OCE) completed a review to determine whether the applicant established that the original product is a pre-existing tobacco product (i.e., was commercially marketed in the United States as of February 15, 2007).[2] The OCE review dated August 11, 2022, concludes that the evidence submitted by the applicant is adequate to demonstrate the original product is a pre-existing tobacco product.

Therefore, the original product is eligible for modification under the Exemption Request pathway.[3]

[2] On August 19, 2022, CTP updated the term “grandfathered tobacco product” to “pre-existing tobacco product” on all the Center’s websites and systems. In this review, "grandfathered product" is substituted with "pre-existing product" to reflect this change.

[3] Any 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. TOBACCO ADDITIVE MODIFICATION

The applicant claims that the modifications of the original product compared to the corresponding new product are the result of:

- adding an additive (b) (4) in EX0002340.PD1
- decreasing the quantity of an existing additive (b) (4) in EX0002340.PD1

3. SCIENTIFIC REVIEW

The review finds these modified ingredients (see Section 3) 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 product. The review concludes that the modifications are minor modifications of a product in accordance with section 905(j)(3)(A)(i) of the FD&C Act.

4. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Luis Valerio, Ph.D. on July 29, 2022. The FONSI was supported by an environmental assessment prepared by FDA on July 27, 2022.

5. CONCLUSION AND RECOMMENDATION

I concur with the conclusion of the scientific reviews that these modifications (see Section 3) to EX0002340.PD1 are minor modifications of a product in accordance with section 905(j)(3)(A)(i) of the FD&C Act. I concur that the modified ingredients are "additives" as defined in section 900(1) of the FD&C Act. 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 product to be marketed would be appropriate for the protection of the public health.

The applicant proposed to decrease the amount of flavor additive (b) (4) (b) (4)) and add flavor additive (b) (4) (b) (4)) for EX0002340.PD1. The applicant states that the purpose of the product modification is to add a new complex formulated flavor additive and to decrease the amount of an already existing complex formulated flavor additive. The applicant provided a signed certification certifying that the original and new tobacco products are identical except for the addition of one complex tobacco additive (flavor) and decrease in quantity of an existing complex tobacco additive.

The applicant referenced two Tobacco Product Master Files (TPMF), (b) (4) and (b) (4) , regarding the single ingredient compositions of the complex flavors ("(b) (4) " in (b) (4) and "(b) (4) " in (b) (4)) that are being modified in the tobacco blends of the new product in EX0002340.PD1. The applicant provided a letter of authorization on behalf of the TPMF owner, (b) (4) for (b) (4) and (b) (4) , for (b) (4) . After reviewing the TPMFs, the scientific reviewers

have determined that the information provided is sufficient to evaluate the public health impact of the new and original tobacco products of EX0002340.PD1. Specifically, a (b) mg/g increase in the complex flavor additive "(b) (4)" in the new tobacco product constitutes a 2% increase compared to the total tobacco mass and is small in quantity. The new product indicates a 25% decrease in the complex flavor additive "(b) (4)" compared to the original tobacco product leading to a 6% overall decrease in this complex flavor in total tobacco mass. Furthermore, the individual ingredient changes in these complex flavors are less than 5% of total tobacco product mass, and any modification on such a scale is not anticipated to have a measurable change in the waterpipe tobacco smoke yields. All other ingredients added to the tobacco in the new and original tobacco product such as (b) (4), (b) (4), (b) (4), (b) (4), (b) (4), (b) (4), (b) (4), and (b) (4) are identical in quantity between the new and original product (quantities varied from (b) (4) mg/g; this information was provided in the EX Request) and will not affect waterpipe smoke chemistry. Overall, the addition of the complex flavor additive ("(b) (4)") and decrease in the complex flavor additive ("(b) (4)") is not expected to materially affect any other characteristic (materials, ingredients, design, composition, heating source, or other features) of the tobacco product. Lastly, I find 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 product in EX0002340.PD1 should be found exempt from the requirements of substantial equivalence under section 910(a)(3)(A) of the FD&C Act.

The original product is eligible for modification through the Exemption Request pathway because it can be legally marketed in the United States. The original product is a pre-existing tobacco product, i.e., was commercially marketed in the United States as of February 15, 2007.

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

An exempt order should be issued for the new product, as identified on the cover page of this review.

6. APPENDICES

Appendix A.[4, 5] New and original products

Common Attributes		
Submission date	September 10, 2021	
Receipt date	September 10, 2021	
Applicant	Fumari Inc.	
Product manufacturer	Fumari Inc.	
Product category	Waterpipe Tobacco Products	
Product subcategory	Waterpipe Tobacco Filler	
Attributes	**New Product**	**Original Product**
STN	**EX0002340.PD1**	**GF1702437**
Product name	Fumari Watermelon with Mint Hookah Tobacco – 1 Kilo	Fumari Watermelon Hookah Tobacco – 1 Kilo
Eligibility status	Not applicable	Pre-existing
Package type	Pouch	Pouch
Package quantity	1 Kilogram	1 Kilogram
Characterizing flavor	Watermelon and Mint	Watermelon
Tobacco Cut Size	(b) (4)	(b) (4)
Tobacco Moisture	12.50%	12.50%
Product modifications	Addition/Deletion of tobacco additives: • Addition of complex flavor ingredient "(b) (4) " (b) (4) Target: (b mg/1 g) Increasing/Decreasing the quantity of existing tobacco additives: • Decrease in the quantity of complex flavor ingredient "(b) (4) (b) (4) Target: (b mg/1 g).	

[4] Properties to uniquely identify the new tobacco products were provided by the applicant as of the date of this review, and not confirmed by FDA.
[5] Brand/sub-brand or other commercial name used in commercial distribution.