

**Programmatic Environmental Assessment for Marketing
Orders for Two New Waterpipe Tobacco Products
By Fumari Inc.**

**Prepared by Center for Tobacco Products
U.S. Food and Drug Administration**

September 19, 2022

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1. Applicant and Manufacturer Information

Applicant Name:	Fumari Inc.
Applicant Address:	675 Gateway Center Drive, Suite A San Diego, CA 92102
Manufacturer Name:	Fumari Inc.
Product Manufacturing Location:	675 Gateway Center Drive, Suite A San Diego, CA 92102

2. Product Information

New Product (STN), New Product's Name, and Original Product's Name

New Product STN	New Product Name	Original Product Name
EX0002442.PD1	Fumari Watermelon and Mint Hookah Tobacco – 50 grams	Fumari Watermelon Hookah Tobacco – 50 grams
EX0002443.PD1	Fumari Watermelon and Mint Hookah Tobacco – 100 grams	Fumari Watermelon Hookah Tobacco – 100 grams

Product Identification

Product Category:	Waterpipe Tobacco
Product Subcategory:	Waterpipe Tobacco Filler
Product Quantity per Retail Unit:	50 grams (EX0002442.PD1) and 100 grams (EX0002443.PD1) per Pouch, 10 pouches per box
Product Package:	The packaging material consist of a polyethylene terephthalate and polyethylene pouch with an outer cardboard box

3. The Need for the Proposed Actions

The proposed actions, requested by the applicant, is for the Food and Drug Administration (FDA) to issue an exemption from substantial equivalence (SE) reporting for a marketing order under section 905(j)(3) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for two waterpipe tobacco filler products. A tobacco product that is modified by adding or deleting a tobacco additive, or increasing or decreasing the quantity of an existing tobacco additive, may be considered for exemption from demonstrating substantial equivalence if (1) the product is a modification of another tobacco product and the modification is minor, (2) the modifications are to a tobacco product that may be legally marketed under the FD&C Act, (3) an SE Report is not necessary to ensure that permitting the tobacco product to be marketed would be appropriate for the protection of public health, (4) the modified tobacco product is marketed by the same organization as the original product, and (5) an exemption is otherwise appropriate.

The applicant wishes to introduce the new products into interstate commerce for commercial distribution in the United States. The applicant must obtain written notification that FDA has granted the products an exemption from demonstrating substantial equivalence under section 905(j)(3) before submitting an abbreviated report.

The new products are made by modifying the corresponding original products. These modifications are to the added ingredients (Confidential Appendix 1).

4. Alternatives to the Proposed Actions

The no-action alternative is FDA does not issue a marketing order for the new products in the United States.

5. Potential Environmental Impacts of the Proposed Actions and Alternatives – Manufacturing the New Products

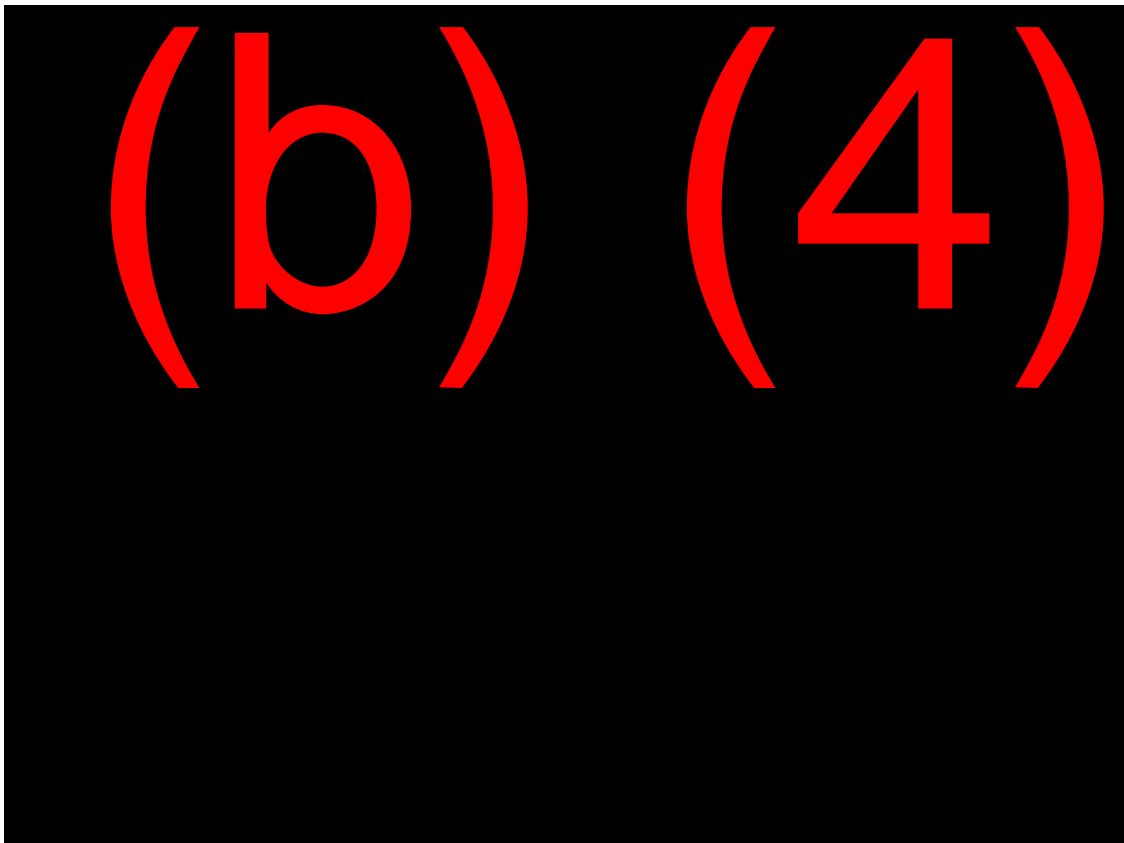
The Agency considered potential impacts to resources in the environment that may be affected by manufacturing the new products and found no significant impacts based on the Agency-gathered information and the following applicant-submitted information:

- No facility expansion is expected due to manufacturing the new products.
- No new or additional environmental controls are needed due to manufacturing the new products.
- The new products will compete with similar waterpipe products already on the market.

5.1 Affected Environment

The affected environment includes human and natural environments surrounding the facility. The new products will be manufactured at the address listed in section 1 of this document (Figure 1).

Figure 1. Location of the Manufacturing Facility ¹



The manufacturing facility is located in a mixed-use residential, industrial, and commercial area just south of the SR 20, east of the San Diego Bay, and north of National City, CA. Fumari, Inc. is located in the [REDACTED] (b) (4)).²

5.2 Air Quality

The Agency does not anticipate that any new chemicals will be released into the environment due to manufacturing the new products. A search in EPA's Toxic Release Inventory (TRI) database showed that the manufacturing facility is not listed, indicating that it does not release TRI listed chemicals in quantities above threshold levels in a given year.³ The applicant stated that manufacturing the new products are not expected to result in changes in the type of air emissions and, therefore, additional environmental controls for air emissions or a new air permit will not be required.

5.3 Water Resources

The Agency does not anticipate that manufacturing the new products will cause the discharge of any new chemicals into water after a TRI search indicating that it does not release TRI listed chemicals into the wastewater.³ The applicant stated that manufacturing the new products are not expected to result in changes in wastewater discharges. Therefore, no additional environmental controls or a new water discharge permit will be needed.

5.4 Soil, Land Use, and Zoning

The Agency does not anticipate that manufacturing the new products will lead to changes in soil, land use, or zoning. The applicant stated that there will be no expected facility expansion due to manufacturing the new products. Therefore, there will be no zone change or land conversion of prime farmland, unique farmland, or farmland of statewide importance to non-agricultural use.

5.5 Biological Resources

The Agency does not anticipate that manufacturing the new products would jeopardize the continued existence of any listed species or result in the destruction or adverse modification of the habitat of any such species identified under the Endangered Species Act (ESA). The Agency's search of the U.S. Fish and Wildlife Service's (U.S. FWS) critical habitat and endangered species maps shows 16 threatened species and 39 endangered species are listed in San Diego, California.^{4 5} However, because the proposed actions do not require expansion of the manufacturing facility, and the applicant stated that the listed species are not found in the immediate vicinity of the facility, there will be no impacts to the protected species or their potential habitat.

5.6 Regulatory Compliance

The applicant stated that the manufacturing facility complies with all applicable environmental regulations. The applicant also stated that the facility complies with the Endangered Species Act (ESA). The Agency's search of EPA's Enforcement and Compliance History Online (ECHO) did not reveal any violations of the federal environmental laws and regulations.⁶

5.7 Socioeconomics and Environmental Justice

No changes on socioeconomics or environmental justice are anticipated due to manufacturing the new products. The Agency does not anticipate any impacts on employment, revenue, or taxes because the

applicant stated that manufacturing the new products will lead to only an incremental increase in production at the manufacturing facility.

No changes in impacts on environmental justice are anticipated. The applicant stated that no new or increased compounds will be emitted, and no facility expansion will occur due to manufacturing the new products. Thus, no disproportionate impacts to environmental justice populations will occur as a result of manufacturing the new products.

5.8 Solid Waste and Hazardous Materials

The Agency does not foresee that the introduction of the new products will notably affect the current manufacturing waste generated from the facility production of all waterpipe tobacco. The Agency anticipates that the waste generated due to manufacturing the new products will be released to the environment and disposed of in landfills in the same manner as any other waste generated from any other products manufactured in the same facility. The applicant stated that manufacturing the new products would not require any additional environmental controls for waste disposal. Therefore, no new or revised waste permit or an expansion of a waste management facility is expected.

5.9 Floodplains, Wetlands, and Coastal Zones

There would be no facility expansion due to manufacturing the new products and the applicant did not propose any land disturbance; therefore, there will be no effects on floodplains, wetlands, or coastal zones.

5.10 Impacts of the No-Action Alternative

The environmental impacts of the no-action alternative will not change the existing condition of manufacturing waterpipe tobacco at the listed facility, as many similar tobacco products will continue to be manufactured.

6. Potential Environmental Impacts of the Proposed Actions and Alternatives – Use of the New Products

The Agency considered potential impacts to resources in the environment that could be affected by use of the new products and found no significant impacts based on Agency-gathered information and the applicant's submitted information. Included in the information the Agency considered were the current and projected market volumes for the new products as proxy for use in the United States (Confidential Appendix 2).

6.1. Affected Environment

The affected environment includes human and natural environments in the United States because the marketing orders will allow for the new products to be sold to consumers in the United States.

6.2. Air Quality

The impacts from use of waterpipe tobacco products include exposure to secondhand smoke (SHS) produced from smoking at homes, hookah bars, lounges, or anywhere else they are used. Particles emitted by smoking may remain on surfaces, be re-emitted back into the gas phase, or react with oxidants and other compounds in the environment to yield secondary pollutants, thirdhand smoke

(THS). These pollutants coexist in mixtures in the environment alongside SHS.^{7, 8} While these studies focus on SHS from cigarette smoking, research suggests that SHS from waterpipe smoking may be worse due to higher concentrations of carcinogens, carbon monoxide, and other chemicals.^{9, 10, 11} Carbon monoxide poisoning has been reported for users of waterpipe tobacco products as well as non-users in environments where waterpipe tobacco was being consumed,¹¹ raising concerns for employees and non-smoking patrons of establishments where waterpipe tobacco is consumed.

There is no safe level of exposure to SHS.^{12, 13} Even low levels of SHS can harm children and adults in many ways, including the following:

- The U.S. Surgeon General estimates that living with a smoker increases a nonsmoker's chances of developing lung cancer by 20 to 30%.¹⁴
- Exposure to SHS increases school children's risk for ear infections, lower respiratory illnesses, more frequent and more severe asthma attacks, and slowed lung growth. It can cause coughing, wheezing, phlegm, and breathlessness.^{12, 13}
- SHS causes more than 40,000 deaths a year.¹⁴

Use of waterpipe tobacco by youth and young adults is increasing¹⁵ and researchers believe this increase is due to the false belief that waterpipe tobacco smoking is less addictive and harmful than cigarette smoking.¹⁶ Waterpipe tobacco smoking exposes users to nicotine, carbon monoxide, polycyclic aromatic hydrocarbons, volatile aldehydes, phenols, heavy metals and other constituents.¹⁷ Comparisons between cigarette smoking and waterpipe tobacco smoking suggests that users of waterpipe inhale as much as 120 times the tobacco smoke than cigarette users in a single session with increased concentrations of many components found in cigarette smoke. Waterpipe tobacco smoking is associated with various respiratory diseases, cancer, low birthweight, cardiovascular disease, and other health related issues.¹⁸ This is especially concerning considering the prevalence of youth use.¹⁷ However, because marketing these products are not expected to increase overall consumption of waterpipe tobacco and waterpipe tobacco imports do not appear to be increasing, no cumulative environmental impacts from use are expected.

As of December 2020, 28 states and the District of Columbia have implemented comprehensive smoke-free laws.¹⁹ Such laws are expected to reduce the levels of non-user exposure to SHS and THS.

The Agency does not anticipate that new chemicals will be released into the environment as a result of use of the new products, relative to chemicals released into the environment due to use of other waterpipe tobacco products already on the market because (1) the emissions from the new products will be released in the same manner as the emissions of the original products and other marketed waterpipe tobacco products; (2) the new products are expected to compete with, or replace, other currently marketed waterpipe tobacco; and (3) the ingredients in the new products are used in other currently marketed tobacco products.

6.3. Socioeconomics and Environmental Justice

The Agency does not anticipate changes in impacts on socioeconomic conditions or environmental justice from manufacturing the new products. No new emissions are expected due to use of the new products. Therefore, there will be no disproportionate impacts on minority or low-income populations.

6.4. Impacts of the No-Action Alternative

The environmental impacts of the no-action alternative will not change the existing condition of use of waterpipe tobacco, as many similar tobacco products will continue to be used in the United States.

7. Potential Environmental Impacts of the Proposed Actions and Alternatives – Disposal of the New Products

The Agency considered potential impacts to resources in the environment that may be affected by disposal of the new products. Based on the applicant's submitted information, including market volume projections for the new products, the Agency found no significant impacts.

7.1. Affected Environment

The affected environment includes human and natural environments in the United States because the marketing orders will allow for the new products to be sold to consumers in the United States.

7.2. Air Quality

The Agency does not anticipate the disposal of the new products, or the packaging material will lead to the release of new or increased chemicals into the air.

The chemicals in the new products are commonly used in other currently marketed waterpipe tobacco. Because the new products are anticipated to compete with or replace other currently marketed waterpipe tobacco, the waste generated from the new products will replace the same type of waste. Therefore, the fate and effects of any materials emitted into the air from disposal of the new products are anticipated to be the same as any materials from other waterpipe tobacco disposed of in the United States.

No changes in air quality from disposal of the new products' packaging materials will be expected because (1) the packaging materials are commonly used in the United States, and (2) the waste generated due to disposal of the new products' packaging is a minuscule portion of the municipal solid waste in the United States²⁰ per FDA's experience in evaluating the packaging waste generated from tobacco products.

7.3. Biological Resources

The proposed actions are not expected to change the continued existence of any endangered species or result in the destruction or adverse modification of the habitat of any such species, as prohibited under the U.S. ESA. The new products are not expected to change disposal conditions as (1) the disposal of the new products will be the same as the disposal of other waterpipe tobacco products that are currently marketed in the United States, and (2) there will be no anticipated increase in amount of waterpipe tobacco being disposed of as the new products are anticipated to replace similar marketed waterpipe tobacco.

7.4. Water Resources

No changes in any impacts on water resources are expected due to disposal of the waterpipe tobacco and packaging from the new products because the chemicals in the new products are used in other

currently marketed waterpipe tobacco products. Furthermore, the new products will compete with or replace other waterpipe tobacco currently on the market.

Information on environmental impacts of disposal of water from waterpipe smoking is scarce. However, users who smoke waterpipe tobacco at home discard the water waste in various places including down the drain, backyard soil, and in storm drains.²¹ This is concerning considering the various compounds that may leach out of the discarded water after disposal including remaining heavy metals.^{22, 23}

Waterpipe tobacco contains ingredients similar to those used in cigarettes. While waterpipe products are mainly heated but not combusted during use as the case of cigarette smoking, similar types of toxic chemicals in the discarded waterpipe water may be introduced into the aquatic environment, potentially threatening human health and the environment, especially marine ecosystems.²³ Individually, however, marketing these products are not expected to increase the overall consumption of waterpipe tobacco (Confidential Appendix 2).

7.5. Solid Waste

Information on the environmental toxicity of discarded waterpipe tobacco is scarce. As discussed in section 7.4 of this document, users of waterpipe at home discard charcoal, used waterpipe tobacco, and bowl water waste in various places including trashcans, down the drain, in potted plants, in their yard, and in storm drains.²¹ The chemicals in discarded tobacco can be the original chemicals in the unsmoked tobacco or the pyrolysis and distillation products produced during waterpipe tobacco use. Airborne emissions from the discarded tobacco depend on the environmental conditions and the chemicals in the used tobacco. These emissions can be influenced by several factors, such as the brand, flavorings and other ingredients in the tobacco filler, types of tobacco, and extent of use. Emissions from disposal of the charcoal are unlikely to be of concern since the majority of charcoal will be used up in the smoking process.

However, the Agency does not foresee the introduction of the new products will notably affect the current waterpipe tobacco and packaging waste generated from all waterpipe tobacco products. The waste generated due to disposal of the new products will be disposed of in the same manner as any other waste generated from any other waterpipe tobacco products marketed in the United States. The amount of waterpipe tobacco waste generated will be equivalent to the market projections (Confidential Appendix 2) and a portion of that will be littered.

7.6. Socioeconomics and Environmental Justice

The Agency does not anticipate changes in impacts on socioeconomic conditions or environmental justice from disposal of the new products. The waste generated due to disposal of the new products will be handled in the same manner as the waste generated from disposal of other waterpipe tobacco products in the United States. No new emissions are expected due to disposal of the new products; therefore, there will be no disproportionate impacts on minority or low-income populations.

7.7. Impacts of the No-Action Alternative

The environmental impacts of the no-action alternative will not change the existing condition of disposal of waterpipe tobacco and packaging, as many other similar tobacco products will continue to be disposed of in the United States.

8. List of Preparers

The following individuals were primarily responsible for preparing and reviewing this environmental assessment:

Preparer:

William E. Brenner, B.S., Center for Tobacco Products

Education: B.S. in Biology

Experience: Eight years in various scientific activities

Expertise: NEPA analysis, environmental risk assessment, air quality analysis, archaeological and archival preservation

Reviewer:

Rudaina Alrefai-Kirkpatrick, Ph.D., Center for Tobacco Products

Education: Ph.D. in Plant Molecular Biology and Virology

Experience: Forty-three years in various scientific activities including nine years in NEPA practice

Expertise: NEPA analysis, environmental risk assessment, evidence-based assessment of health technologies, NEPA Implementation

9. A Listing of Agencies and Persons Consulted

None.

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Confidential Appendix 1. Modifications in the New Products as Compared with the Corresponding Original Products

STN	Modifications
EX0002442.PD1	<ul style="list-style-type: none"> • Decrease in quantity of (b) (4) (b) (4) • Addition of (b) (4)
EX0002443.PD1	<ul style="list-style-type: none"> • Decrease in quantity of (b) (4) • Addition of (b) (4)

Confidential Appendix 2. Market Volumes for the Original and New Products

STN	Market Volume					
	Units	Current	Projected			
			First-Year		Fifth-Year	
		Original Product	New Product	Original Product	New Product	Original Product
EX0002442.PD1	Pouches	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(4)
	Metric Tons					
EX0002443.PD1	Pouches					
	Metric Tons					

The original product for EX0002442.PD1 is not currently on the market. However, the applicant stated that the new products are expected to compete with, or replace, other currently marketed waterpipe tobacco.