



PMTA Coversheet: Environmental Science

SUBMISSION INFORMATION			
Applicant	22nd Century Group, Inc.		
Product Manufacturer	NASCO Products, LLC		
Submission Date	December 4, 2018	FDA Receipt Date	December 4, 2018
Cross-referenced Submission¹	Cross-referenced STN	Primary STN(s)	
	(b)(4)	Applies to all STNs	
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	PM0000493	Applies to all STNs	December 11, 2018
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	PM0000511	Applies to all STNs	April 3, 2019
	PM0000514	Applies to all STNs	June 27, 2019
	PM0000519	Applies to all STNs	July 18, 2019
	PM0000524	Applies to all STNs	August 7, 2019
	PM0000544	Applies to all STNs	September 13, 2019
PM0000549	Applies to all STNs	October 2, 2019	

NEW TOBACCO PRODUCTS	
PM0000491: Moonlight^{®2}	
Product Category	Cigarettes
Product Sub-Category	Combusted, Filtered
Package Type	Hard pack
Package Quantity	20 per pack
Characterizing Flavor	None
Length	83 mm
Diameter	7.9 mm
Ventilation	13%

¹ The application contains a valid and active cross-reference, which contains appropriate authorization for the applicant to reference the entire file or certain sections thereof.

² On December 4, 2018, FDA received original PMTAs for VLN™ King and VLN™ Menthol. On October 2, 2019, the applicant submitted a proposed name change for the products to Moonlight and Moonlight Menthol, respectively. The scientific reviews reflect the proposed names (VLN™ and VLN™ Menthol) in the original PMTA submissions.

STN PM0000491-PM0000492

PM0000492: Moonlight® Menthol²	
Product Category	Cigarettes
Product Sub-Category	Combusted, Filtered
Package Type	Hard pack
Package Quantity	20 per pack
Characterizing Flavor	Menthol
Length	83 mm
Diameter	7.9 mm
Ventilation	13%

**Programmatic Environmental Assessment:
Marketing Orders
for
VLN™ King and VLN™ Menthol King
by
22nd Century Group, Inc.**

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

October 29, 2019

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1. Introduction

1.1 Background

On December 4, 2018, 22nd Century Group, Inc. (22nd Century) submitted premarket tobacco product applications (PMTAs) for two very low nicotine cigarettes, VLN™ King and VLN™ Menthol King Cigarettes (collectively “VLN™ Cigarettes”). In the PMTAs, 22nd Century requests the U.S. Food & Drug Administration (FDA) issue marketing orders under section 910 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (Public Law 111-31).

This document reviews the potential environmental impacts from marketing VLN™ Cigarettes in the United States, and from the no-action alternative of the Agency not issuing marketing orders for the products. The Agency did not identify any significant environmental impacts from the proposed actions.

1.2 Applicant and Manufacturer Information

Applicant Name:	22 nd Century Group, Inc.
Applicant Address:	8560 Main Street, Suite 4 Williamsville, NY 14221
Manufacturer Name:	NASCO Products, LLC
Product Manufacturing Location:	321 Farmington Road Mocksville, NC 27028

1.3 Product Information

New Product Names and Submission Tracking Numbers (STNs)

New Product Name	STN New Product
VLN™ King	PM0000491
VLN™ Menthol King	PM0000492

Product Identification

Product Category	Cigarette
Product Subcategory	Combusted filtered
Product Number per Retail Unit	Twenty cigarettes per pack with ten packs per paperboard carton
Product Package	Foil inner liner, inner frame paper, paperboard box, polypropylene outer wrap, polypropylene tear tape, paperboard carton, and cardboard shipping case.

2. Purpose of and Need for Actions

Purpose: The proposed actions, requested by the applicant, are for FDA to issue marketing orders under the provisions of section 910 of the FD&C Act after finding the new tobacco products would be appropriate for the protection of public health. The applicant wishes to introduce the new tobacco

products into interstate commerce for commercial distribution in the United States and submitted to the Agency two premarket tobacco applications (PMTA) to obtain marketing orders. Upon receipt of a PMTA, FDA considers the submission, using criteria detailed in section 910(c) of the FD&C Act, to make a finding as to whether marketing orders for the new products would be appropriate for the protection of public health.

Need: FDA's responsibility to review a PMTA, make a finding as described in the previous paragraph, and subsequently determine whether or not to issue a marketing order for the new product is a statutory requirement under section 910(c) of the FD&C Act.

3. Proposed Actions and Alternatives

FDA proposes to issue marketing orders authorizing introduction or delivery for introduction of the two new tobacco products into interstate commerce in the United States. The applicant's PMTAs seek FDA's marketing orders under section 910(c)(A)(i) of the FD&C Act for two VLN™ Cigarettes.

The no-action alternative is FDA does not issue marketing orders for the new tobacco products. The new products would not be marketed in the United States and, for the purposes of the analysis in this programmatic environmental assessment, it is assumed that there would be no changes to the current combusted cigarette market; no changes to the current or future use of combusted cigarettes.

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

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

- Ingredients used in the new products are commonly used in other products manufactured at the facility.
- Similar cigarettes are currently manufactured at the listed facility.
- No facility expansion or new construction is expected due to manufacturing the new products.

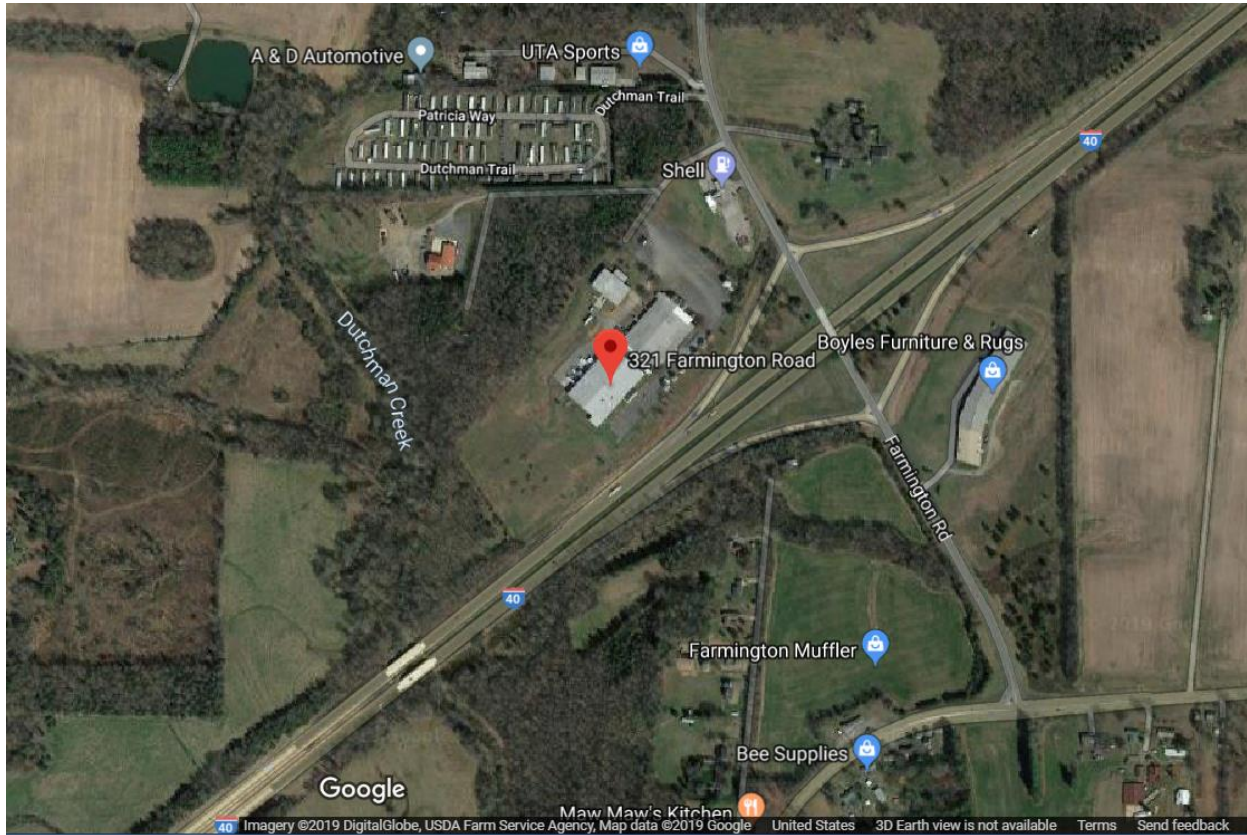
4.1 Affected Environment

The affected environment includes human and natural environments surrounding the manufacturing facility. The new products are manufactured at NASCO Products' (NASCO) facility at 321 Farmington Road, Mocksville, North Carolina (Figure 1). The facility is in an industrial area with U.S. Highway 40 to its southwest and northeast and woodland to the west. The facility is in the Yadkin watershed in Davie County.^{3, 4} The applicant stated that the facility's designated boundaries do not include any recognized or controlled fisheries or wetlands.

³ A watershed is an area of land where all bodies of water drain to a common outlet such as the outflow of a reservoir, mouth of a bay, or any point along a stream channel. Such bodies of water include the following: surface water from lakes, streams, reservoirs and wetlands; the underlying ground water; and rainfall. See <https://water.usgs.gov/edu/watershed.html>.

⁴ USGS. National Water Information System: Mapper. Available at: <https://water.usgs.gov/wsc/cat/03040101.html>. Accessed April 18, 2019.

Figure 1. Location of the Manufacturing Facility



4.2 Air Quality

The Agency does not anticipate that manufacturing the new products would cause the release of any new chemicals into the environment because (1) the facility is currently manufacturing similar cigarettes under the trade name SPECTRUM® and (2) the applicant stated that manufacturing the new products would not result in changes in air emissions. Accordingly, the applicant concluded that manufacturing the new products would not require any additional environmental controls for air emissions.

4.3 Water Resources

The Agency does not anticipate that manufacturing the new products would cause the discharge of any new chemicals into water. According to the North Carolina Department of Environmental Quality, water quality in the Yadkin River's Headwaters watershed where the facility is located is relatively good compared to other sub basins in the greater Yadkin-Pee Dee River basin.⁵ The applicant stated that manufacturing the new products would not require any additional environmental controls for water discharges.

⁵ North Carolina Department of Environmental Quality. Yadkin River Headwaters. Available at: https://files.nc.gov/ncdeq/Water%20Quality/Planning/BPU/BPU/Yadkin/Yadkin%20Plans/2010%20Plan/2_03040101%20Yadkin%20River%20Headwaters-2010.pdf. Accessed April 18, 2019.

4.4 Soil, Land Use, and Zoning

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

4.5 Biological Resources

The Agency does not anticipate 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 applicant reviewed the U.S. Fish and Wildlife Service's (U.S. FWS) critical habitat and endangered species maps^{6, 7} and stated that the manufacturing facility is not in a critical habitat area and its boundaries do not include any recognized or controlled fisheries or wetlands. The applicant stated there would be no anticipated changes in air emission or waste generation; accordingly, the applicant concluded that manufacturing the new products would not be expected to threaten any endangered species or critical habitat. Additionally, the applicant provided a certificate of compliance of the manufacturing and packaging materials suppliers with the convention on International Trade in Endangered Species of Wild Fauna and Flora and ESA.

4.6 Regulatory Compliance

The applicant stated that the manufacturing facility complies with all federal, state, and tribal environmental regulations and with the ESA.

4.7 Socioeconomics and Environmental Justice

No changes in socioeconomics, employment revenue, taxes, or impacts on minority populations would be expected due to manufacturing the new products because (1) the facility is located in an industrial zone with no residential housing or retail operations within its boundaries and (2) the facility is currently manufacturing similar cigarettes under the trade name SPECTRUM®.

4.8 Solid Waste and Hazardous Materials

The Agency does not foresee the introduction of the new products would notably affect the current manufacturing waste generated from the facility production of all combusted cigarettes. The Agency anticipates the waste generated due to manufacturing the new products would 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 materials, ingredients, and tobacco used in the new products are being used in other cigarettes currently manufactured at the facility. Therefore, there would be no expected change in pattern, amount, or type of waste generated due to manufacturing the new products.

⁶ U.S. Fish and Wildlife Services (U.S. FWS), available at: <https://www.fws.gov/endangered/>. Accessed April 16, 2019.

⁷ Critical habitat maps available at: <https://databasin.org/datasets/d579d87eb54f4374a77ea53e7ef66449>. Accessed April 16, 2019.

4.9 Floodplains, Wetlands, and Coastal Zones

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

4.10 Cumulative Impacts

The Agency does not anticipate that the proposed actions will incrementally increase or change the chemicals released to the environment from the tobacco manufacturing facility. The applicant stated that manufacturing the new products would not require additional environmental controls for air emission, water discharge or solid waste disposal. Therefore, no cumulative impacts were identified.

4.11 Impacts from the No-Action Alternative

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

5. 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 projected market volumes for the new products and the documented decline in cigarette use in the United States.

5.1. Affected Environment

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

5.2. Air Quality

The Agency does not anticipate new chemicals would 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 cigarettes already on the market because (1) the combustion products from the new products would be released in the same manner as the combustion products from the any other marketed cigarettes; (2) the new products are expected to be used by consumers of other cigarettes, hence replace other currently marketed cigarettes; and (3) the ingredients in the new products are used in other currently marketed tobacco products.

5.3. Environmental Justice

No new emissions are expected due to use of the new products. Therefore, there would be no disproportionate impacts on minority or low-income populations.

5.4. Cumulative Impacts

The impacts from use of combusted tobacco products include exposure to secondhand smoke (SHS) produced from burned cigarettes. 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 (Burton, 2011; Matt et al., 2011).

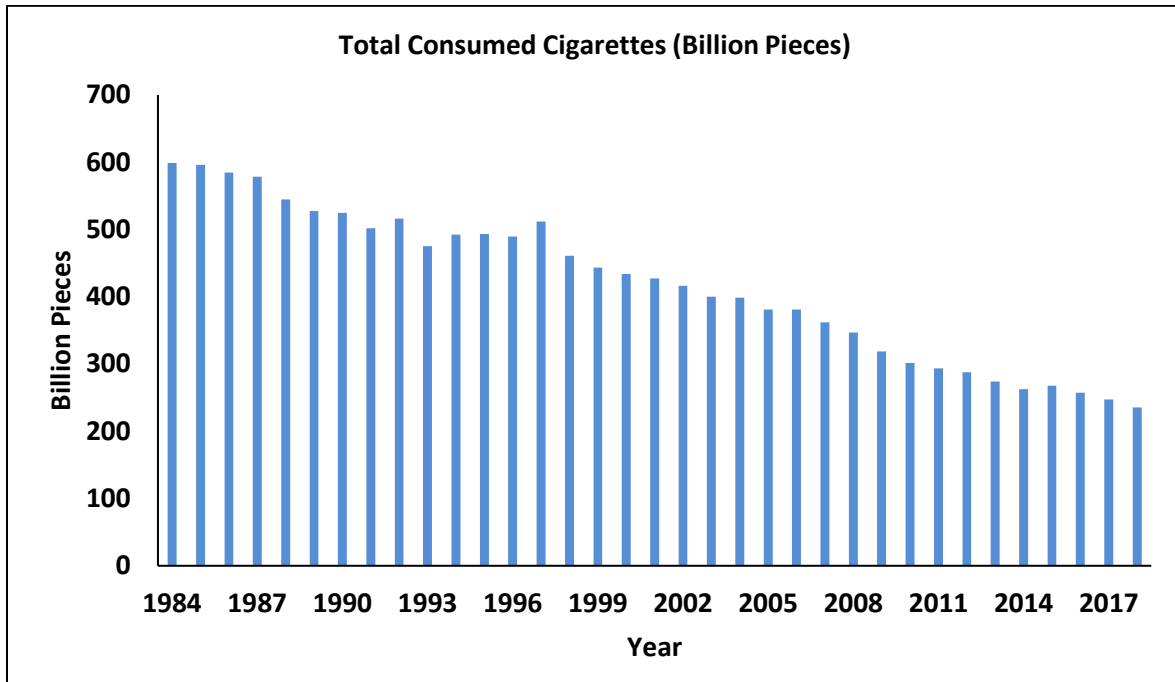
There is no safe level of exposure to SHS (U.S. Department of Health and Human Services, 2006a and 2006b). Even low levels of SHS can harm children and adults in many ways, including the following:

- The U.S. Surgeon General estimates that living with a smoker increases a nonsmoker's chances of developing lung cancer by 20 to 30% (U.S. Department of Health and Human Services, 2014).
- 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 (U.S. Department of Health and Human Services, 2006a and 2006b).
- SHS causes more than 40,000 deaths a year (U.S. Department of Health and Human Services, 2014).

However, the use of cigarettes in the United States is declining, per the U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) Statistical Release reports (Figure 2).⁸ This likely is responsible for the decline in SHS exposure observed in several studies that evaluated the levels of SHS exposure in children and nonsmokers living in homes of smokers (Homa et al., 2015; Yao et al., 2016). Despite the considerable ethnic and racial disparities in SHS exposure in vulnerable populations, data from the National Health and Nutrition Examination Survey showed a decline in SHS exposure from 1999-2000 to 2011-2012 with the highest prevalence of exposure among non-Hispanic subpopulations (46.8%), compared to Mexican Americans (23.9%) and non-Hispanic whites (21.8%) in 2011-2012 (Homa et al., 2015). There were also significant declines in SHS exposure prevalence noted in the 2000 and 2010 National Health Interview Survey Cancer Control Supplements. SHS exposure declined in Hispanics from 16.3% in 2000 to 3.1% in 2010, non-Hispanic Asians from 13.4% in 2000 to 3% in 2010, and non-Hispanic blacks from 31.2% in 2000 to 11.5% in 2010 as compared to exposures in non-Hispanic whites, which declined from 25.8% in 2000 to 9.7% in 2010 (Yao et al., 2016).

⁸ U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) statistical data available at: <https://www.ttb.gov/tobacco/tobacco-stats.shtml>. Accessed April 18, 2019.

Figure 2. Use of Cigarettes in the United States, 1984 – 2018



As of March 2019, 28 states and the District of Columbia have implemented comprehensive smoke-free laws (American Lung Association, 2019). Such laws are expected to reduce the levels of non-user exposure to SHS and THS.

5.5. Impacts from the No-Action Alternative

The environmental impacts of the no-action alternative would not change the existing condition of use of cigarettes because many similar tobacco products would continue to be used in the United States.

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

The Agency evaluated potential impacts to resources in the environment that may be affected by disposal of the new products. The Agency found no significant impacts based on publicly available information such as the documented continuous decline in use of cigarettes in the United States, and the applicant’s submitted information, including the projected market volumes for the new products.

6.1. Affected Environment

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

6.2. Air Quality

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

No changes in air quality are anticipated from disposal of the cigarette butts of the new products. The chemicals in the cigarette butts are commonly used in other currently marketed cigarettes. Because the new products are anticipated to be used by consumers of other marketed cigarettes, the butt waste generated from the new products would 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 cigarettes disposed of in the United States.

No changes in air quality from disposal of the packaging materials of the new products would be expected because (1) the paper and plastic components of the packages are more likely to be recycled or at least a portion of the packaging waste is likely to be recycled, (2) the packaging materials are commonly used in the United States, and (3) the waste generated due to disposal of the packaging is a minuscule portion of the municipal solid waste per FDA's experience in evaluating the packaging waste generated from cigarettes.

6.3. 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. Although disposal of smoldering cigarettes has been implicated in many fire incidents,^{9,10} the new products are not expected to change the fire frequency as (1) the disposal of the new products would be the same as the disposal of cigarettes that are currently marketed in the United States, and (2) there would be no anticipated increase in number of cigarettes being disposed of because the new products are anticipated to be used by consumers of other currently marketed cigarettes.

6.4. Water Resources

No changes in impacts on water resources are expected due to disposal of the cigarette butts and packaging from the new products because the chemicals and packaging materials in the new products would be used in currently marketed cigarettes.

6.5. Solid Waste

The Agency does not foresee that the introduction of the new products would notably affect the current cigarette butt and packaging waste generated from all combusted, filtered cigarettes. The waste generated due to disposal of the new products would be released to the environment and disposed of in landfills in the same manner as any other waste generated from any other combusted, filtered cigarettes in the United States. The number of cigarette butts generated is equivalent to the market projections (Confidential Appendix 1) and a portion of those would continue to be littered.

6.6. 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

⁹ National Fire Protection Association. The smoking-material fire problem. Available at: <https://www.nfpa.org/News-and-Research/Data-research-and-tools/US-Fire-Problem/Smoking-Materials>. Accessed April 16, 2019.

¹⁰ UC Davis Health News. Available at: <https://www.ucdmc.ucdavis.edu/publish/news/newsroom/2763>. Accessed April 16, 2019.

would be handled in the same manner as the waste generated from disposal of other cigarettes in the United States. No new emissions are expected due to disposal of the new products; therefore, there would be no disproportionate impacts on minority or low-income populations.

6.7. Cumulative Impacts

A major existing environmental consequence of the use of the new products and other conventional cigarettes is littering of discarded cigarette filters or butts, which can persist in the environment (Novotny and Zhao, 1999). Cigarette butts are among the most common forms of litter found on beaches (Claereboudt, 2004; Smith et al., 1997), near streams, night clubs (Becherucci and Pon, 2014), bus stops (Wilson et al., 2014), roads, and streets (Healton et al., 2011; Patel et al., 2013). Cigarette butts have been found at densities averaging more than four cigarette butts per meter squared of urban environments (Seco Pon and Becherucci, 2012).

Compounds in cigarette butts can leach out into water, potentially threatening human health and the environment, especially marine ecosystems (Kadir and Sarani, 2015). The environmental toxicity of cigarette butts due to air emissions is not well studied. The chemicals in cigarette butts can be the original chemicals in the unsmoked cigarettes or the pyrolysis and distillation products deposited in the cigarette butts. Airborne emissions from cigarette butts after disposal depend on the environmental conditions and the chemicals in the butts. These emissions can be influenced by several factors, such as the cigarette brand, cigarette length, filter material, types of tobacco, ingredients in the cigarette and tobacco filler, number of puffs, and the mass transfer behavior of combustion products along the cigarette.¹¹

However, the cumulative impacts from cigarette butts is declining because the use of cigarettes in the United States is declining.

6.8. Impacts from the No-Action Alternative

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

7. List of Preparers

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

Preparer:

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

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

Experience: Forty-two years in various scientific activities including eight years in NEPA practice

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

¹¹ NIST Technical Report 8147 available at: <http://dx.doi.org/10.6028/NIST.IR.8147>. Accessed January 8, 2019.

Reviewer:

Hoshing W. Chang, Ph.D., Center for Tobacco Products

Education: M.S. in Environmental Science and Ph.D. in Biochemistry

Experience: Ten years in FDA-related NEPA review

Expertise: NEPA analysis, environmental risk assessment, wastewater treatment

8. A Listing of Agencies and Persons Consulted

Not applicable.

9. References

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U.S. Department of Health and Human Services. 2006b. The Health Consequences of Involuntary Exposure to Tobacco Smoke: A Report of the Surgeon General—Secondhand Smoke: What It Means to You (Consumer Booklet). Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Coordinating Center for Health Promotion, Office on Smoking and Health. Atlanta, GA.

Wilson N, Oliver J, Thomson G. Smoking close to others and butt littering at stops: Pilot observational study. *PeerJ*. 2014;2.

Yao T, Sun HY, Wang Y, Lightwood J, Max W. Sociodemographic differences among U.S. children and adults exposed to secondhand smoke at home: National Health Interview Surveys 2000 and 2010. *Public Health Reports*. 2016;131:357-366.

CONFIDENTIAL APPENDIX 1

Current Market Volume for NASCO’s Cigarettes, Market Volume Projections for the New Products, and Percentage of Cigarette Use in the United States Projected to be Attributed to the New Products

Market volume projections for the VLN™ Cigarettes were compared to the total forecasted use of cigarettes in the United States.¹² The projected use of the VLN™ Cigarettes account for a minute fraction of a percent of the forecasted cigarette use in the United States. In addition, the applicant stated that the VLN™ Cigarettes would replace other currently marketed cigarettes.

Product	Current Market Volume	Projected Market Volumes ¹³			
		Year 2020		Year 2025	
	Current Product (# of Cigarettes)	New Product (# of Cigarettes)	New Product as a Percent of Total Cigarettes Used ¹⁴	New Product (# of Cigarettes)	New Product as a Percent of Total Cigarettes Used ¹⁵
NASCO’s Cigarettes	(b)(4)				
VLN™ King					
VLN™ Menthol King					
Total					

¹² The Agency used historical data regarding total use of cigarettes from 2002 to 2018 to mathematically estimate the total number of cigarettes used in the United States. Using the best-fit trend line with an R² value of 0.9814, the forecasted number of cigarettes that would be used in the United States is estimated at 221.946 billion cigarettes in 2020 and 196.411 billion cigarettes in 2025.

¹³ The applicant provided market volume projections for VLN™ Cigarettes in 2020 and 2025.

¹⁴ Projected Market Occupation of the New Product in the United States (%) = $\frac{\text{Projected Market Volume of the New Products (cigarette pieces)}}{\text{Projected Use of Cigarettes in United States (cigarette pieces)}} \times 100$

¹⁵ Ibid