Programmatic Environmental Assessment for Marketing Orders for New Cigars

by
John Middleton Co.

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

1/6/2022

1. Applicant and Manufacturer Information

Applicant's Name:	John Middleton Co.
Applicant's Address:	601 East Jackson Street, Richmond, Virginia, 23219
Manufacturer's Name:	John Middleton Co.
Address Where the Products Will be Manufactured:	JMC Bay 8 Building located at 2211 Bells Road, Richmond, Virginia 23234, and Confidential Appendix 1

2. Product Information

New Products (STNs), New Product Names, and Predicate Product Names

New Product STN	New Product Name	Predicate Product Name
SE0016588	Black & Mild® Red Label	Prince Albert Soft Cherry Vanilla
SE0016589	Black & Mild® Red Label FT	Black & Mild FT
SE0016590	Black & Mild® Red Label Wood Tip	Prince Albert Soft Cherry Vanilla
SE0016754	Black & Mild® Casino	Black & Mild
SE0016755	Black & Mild® Casino Wood Tip	Black & Mild

Product Identification

Product Type	Cigar	
Product Subcategory	SE0016589	Filtered Sheet-Wrapped Cigar
	SE0016588 SE0016590 SE0016754 SE0016755	Unfiltered Sheet-Wrapped Cigars
Quantity per Retail Sale Unit	SE0016588 SE0016589 SE0016590 SE0016754 SE0016755	Single cigars and five cigars per pack
Product Package	Individual polypropylene wrapped cigars, which are also co-packaged as five individually wrapped cigars per cardboard box. The cardboard boxes are packed in 10-pack paperboard display trays. The trays are shipped in 30-tray corrugated board shipping cases.	

3. The Need for the Proposed Actions

The proposed actions, requested by the applicant, are for FDA to issue marketing orders under the provisions of sections 910 and 905(j) of the Food, Drug, and Cosmetic Act after finding the new products substantially equivalent to the corresponding predicate products. The applicant wishes to market the

new products into interstate commerce for commercial distribution in the United States and submitted to the Agency five substantial equivalence (SE) reports to obtain marketing orders. The Agency shall issue the marketing orders if the new products are found substantially equivalent to the predicate products. The new and predicate products are currently not marketed.

The new products differ in length, diameter, ingredients, cigar tip and filter from the corresponding predicate products (Confidential Appendix 2).

4. Alternative to the Proposed Actions

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

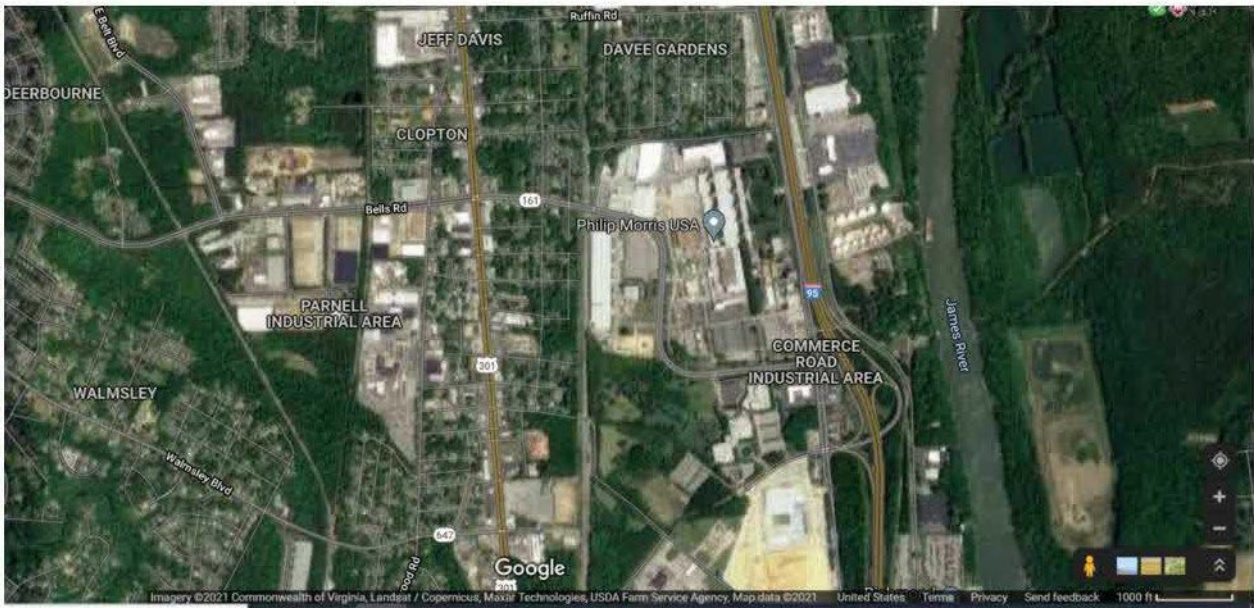
S. Potential Environmental Impacts of the Proposed Actions and the Alternatives - Manufacturing the New Products

The Agency considered potential environmental impacts that may be caused by manufacturing the new products and found no significant impacts. Included in the information the Agency considered were the projected market volumes for the new products. The new products are currently not on the market. The new products will be manufactured inside the United States and at a location outside the United States, at the address listed in Section 1 and Confidential Appendix 1 of this document.

5.1 Affected Environment

The affected environment includes human and natural environments surrounding the manufacturing facility in the United States. The new products would be manufactured at JMC Bay8 Building located at 2211 Bells Road, Richmond, Virginia 23234(Figure 1).

Figure 1. Location of the Manufacturing Facility



The manufacturing facility is surrounded by a residential development to the North, a two-lane divided road, and an interstate freeway (I-95) to the east, undeveloped forested land, petroleum product pumping station and delivery terminal to the south, and a railroad to the west with a spur into the manufacturing facility.[1] The facility is in the James River watershed, which occupies the central portion of Virginia and covers 24% of total land area in the state of Virginia.[2,3]

5.2 Air Quality

The Agency does not anticipate that manufacturing the new products would cause the release of any new chemicals or new type of emissions into the environment. The applicant stated that manufacturing the new products is not expected to 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.

5.3 Water Resources

The Agency does not anticipate that manufacturing the new products would cause the discharge of any new chemicals into water. The new and predicate products will not be marketed simultaneously. The applicant also stated that manufacturing the new products would not require any additional environmental controls for water discharges.

5.4 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. The applicant stated that there would be no expected facility expansion or new construction due to manufacturing the new products. Therefore, there would 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 applicant stated that there would be no facility expansion. The applicant reviewed the U.S. Fish and Wildlife Service's (U.S. FWS) critical habitat and endangered species maps. According to the maps, three threatened species (two plants, and one northern long-eared bat), and one endangered freshwater mussel species are listed in the city of

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[1]JMC Bay 8 Building located at 2211 Bells Road, Richmond, Virginia 23234. Google Maps: www.google.com/maps, Accessed October 1, 2021.

[2]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; underlying ground water; and rainfall. See https://water.usgs.gov/edu/watershed.html and http://www.dcr.virginia.gov/soil-and-water/document/wshedguideb2b.pdf. Accessed October 1, 2021.

[3]www.deq.virginia.gov
https://www.google.com/search?q=James+River+watershed%2C+which+occupies+the+central+portion+of+Virginia+and+covers+24%25+of+total+land+area+in+the+state+of+Virginia. Accessed October 1, 2021.

Richmond and the bordering counties (Henrico and Chesterfield Counties).[4,5] However, the applicant stated that none of these species are found near the manufacturing facility. The Agency searched the U.S. FWS maps and verified the accuracy of the listed species.

5.6 Regulatory Compliance

The Agency does not anticipate that the manufacturing facility would not be in compliance with all federal, state, and local environmental regulations. The applicant stated that the manufacturing facility complies with the Clean Air Act, the Clean Water Act and the Resource Conservation and Recovery Act. The manufacturing facility is registered for waste generation under EPA ID# VAD000819466. The applicant provided detailed information for the following air emission and wastewater permits:

(1) Air permits: Title V Air Permit number PRO52608 and a Stationary Source Permit, issued in accordance with applicable U.S. Environmental Protection Agency (EPA) and Virginia Department of Environmental Quality (VA DEQ) regulations.

(2) Wastewater permit: Industrial User Permit number 2149 from the local publicly owned treatment works (POTW) in the City of Richmond. The permit requires compliance with the relevant effluent limitations (40 C.F.R. §§ 400 – 699) to ensure the wastewater is of a certain quality for effective treatment at the POTW facility. The applicant stated that the facility submits regular discharge monitoring reports to VA DEQ.

The Agency's search of the EPA's Enforcement and Compliance History Online (ECHO) database did not reveal any violations of the environmental laws and regulations at the facility.[6]

The applicant also stated that they did not identify any adverse effects on species or critical habitats of species identified under ESA. The applicant stated that the manufacturing facility is in compliance with all applicable environmental regulations.

5.7 Socioeconomics and Environmental Justice

No changes on socioeconomics are anticipated due to manufacturing the new products. The Agency does not anticipate any impacts on employment, revenue, or taxes because the new products and predicate products will not be marketed simultaneously. The applicant stated that for SE0017350 and SE0017354, the predicate product is not currently on the market; however, PM USA reserves all rights to market the predicate product in the future.

Manufacturing the new products would not disproportionately impact minority populations. In addition, the facility is not located in or near a Native American land.

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[4] U.S. Fish and Wildlife Services (U.S. FWS), available at: https://www.fws.gov/endangered/. Accessed October 7, 2021.

[5] Critical habitat maps available at: https://databasin.org/datasets/d579d87eb54f4374a77ea53e7ef66449. Accessed October 7, 2021.

[6] EPA ECHO Detailed Facility Report: Philip Morris USA Facility, Richmond, VA. Available at: https://echo.epa.gov/detailed-facility-report?fid=110000869793. Accessed October 7, 2021.

5.8 Solid Waste and Hazardous Materials

The Agency does not foresee that the introduction of the new products would notably affect the current manufacturing waste generated from the facility production of all combusted, filtered and unfiltered cigars. 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 applicant stated that manufacturing the new products would not require any additional environmental controls for solid waste disposal. Therefore, no new or revised waste permit or construction of new waste management facility is expected.

A search in the EPA's Toxic Release Inventory (TRI) database showed that in 2020 Philip Morris USA Inc.'s, owners of John Middleton Co., manufacturing facility in Richmond, Virginia, released 32,811 pounds of nicotine and nicotine salts to air (Table 1).[7] Nicotine and nicotine salts have known adverse developmental effects.[8] The TRI database search did not show that the Philip Morris USA manufacturing facility disposed of, treated, or released into the environment any other reportable toxicants associated with manufacturing tobacco products. In addition, EPA's ECHO database did not show that the facility released the following reportable criteria pollutants: ozone, lead, particulate matter, or sulfur dioxide, at or above the reportable threshold levels to air.

Table 1 Management of Chemical Waste Associated with Manufacturing Tobacco Products at Philip Morris USA Facility in 2020

Production-Related Waste Managed or Released			Chemical Mass (Pounds)
Recycled			123,283
Energy Recovery			0
Treated			129,653
Subtotal Waste Managed			*252,936*
On-Site Release	Air	Nicotine and Nicotine Salts	9,628
Off-Site Disposal/Release			23,183
Subtotal Waste Released			*32,811*
Total Production-Related Waste			**285,747**

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 would be no effects on floodplains, wetlands, or coastal zones.

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[7] U.S. Environmental Protection Agency (EPA). TRI Data Form R & A Download. Available at: https://www3.epa.gov/enviro/facts/tri/form_ra_download.html. Searched on October 7, 2021.

[8] EPA. myRight-to-Know, available at: https://www.epa.gov/toxics-release-inventory-tri-program/my-right-know-application. The site allows for searching the industrial facilities that manage toxic waste chemicals by entering the facility address and clicking on the facility location on the map. Accessed October 7, 2021.

5.10 Impacts of the No-Action Alternative

The environmental impacts of the no-action alternative would not change the existing condition of manufacturing cigar products at the listed facility, as many similar tobacco products would 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 impact 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 (Confidential Appendix 3) and the documented use of cigars in the United States (Figure 2).

6.1 Affected Environment

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

6.2 Air Quality

The impact from use of combusted tobacco products include exposure to secondhand smoke (SHS) produced from burned cigars, cigarettes, cigarillos and pipes. 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 a mixture 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:

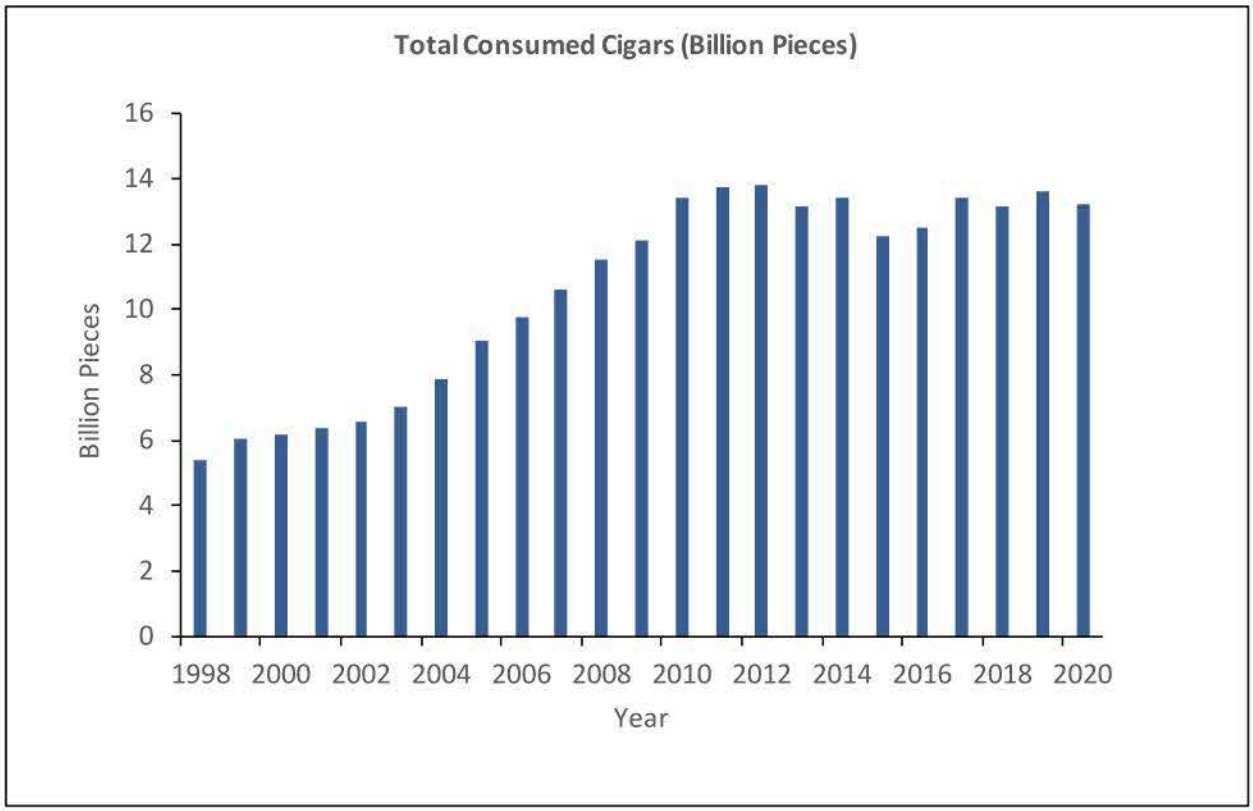
- The U.S. Surgeon General estimates that living with a smoker increases a nonsmoker's chances of developing lung cancer by 20-30% (U.S. Department of Health and Human Services, 2014).
- Exposure to SHS increases school children's risk for ear infections, lower respiratory illnesses, more frequent and more severe asthma attacks, and slowed lung growth. Such exposure 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).

The consumption of cigars in the United States increased significantly from 1997 to 2011. Since 2011 through 2020, the trend of cigar usage has stabilized with a minor decrease overall, per the U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) Statistical Release reports (Figure 2). In combination with declines in use of other tobacco products, a decline in SHS exposure was observed in several studies that evaluated the levels of SHS exposure in children and nonsmokers living in homes of smokers (U.S. Alcohol and Tobacco Tax and Trade Bureau., 2021; 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. Exposure to SHS 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).

Figure 2. Use of Cigars in the United States, 1997 – 2020.



As of December 2020, 28 states and the District of Columbia had implemented comprehensive smoke-free laws (American Lung Association, 2020). Such laws are also expected to reduce the levels of non-users' exposure to SHS and THS.

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 cigars already on the market, because (1) the combustion products from the new products would be released in the same manner as the combustion products of other marketed cigars; (2) the new products are expected to compete and replace other currently marketed cigars; (3) the ingredients in the new products are used in other currently marketed tobacco products; and (4) the new and predicate products have similar characteristics except that the new products will be marketed in a larger quantity compared to the predicate products.

6.3 Environmental Justice

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

6.4 Impacts of the No Action Alternative

The environmental impact of the no-action alternative would not change the existing condition of use of cigars, as many similar tobacco products would continue to be marketed.

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 TTB data[9], which shows relatively stable rates of cigar use in the United States since 2010[1] and the applicant's submitted information, including market volume projections for the new products, the Agency found no significant impacts (Figure 2 and Confidential Appendix 3).

7.1 Affected Environment

The affected environment includes human and natural environments in the United States because the marketing order would allow for the applicant to distribute and sell the new products to consumers in the United States.

7.2 Air Quality

The Agency does not anticipate disposal of the new 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 cigar butts of the new products. The chemicals in the cigar butts are commonly used in other currently marketed cigars. The new products will not replace the predicate products as the predicate products are not marketed. The new products will compete with other cigars currently on the market. Because the market for cigars is not expected to materially increase and may instead decrease over time (Figure 2), 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 cigars disposed of in the United States.

No changes in air quality from disposal of the packaging materials in the new products would be expected because; (1) the packaging materials are commonly used in the United States, and (2) the paper and plastic components of the packaging would either enter the recycling stream or be disposed of in municipal solid waste landfills or as litter and as such, the waste generated due to disposal of the

[9] U.S. Alcohol and Tobacco Tax and Trade Bureau (https://www.ttb.gov/tobacco/tobacco-stats.shtml; Accessed September 20, 2021)

packaging is a minuscule portion of the municipal solid waste per FDA's experience in evaluating the packaging waste generated from tobacco products (U.S. Environmental Protection Agency, 2020).

7.3 Water Resources

No new impacts on water resources are expected due to disposal of the unburned cigars and packaging from the new products because the chemicals in the new products would be the same or similar as in currently marketed cigars and the new products would compete with or replace other cigars currently on the market.

7.4 Biological Resources

The proposed action is 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 ESA because (1) the disposal of the new products would be similar to the disposal of cigar tobacco products that are currently marketed in the United States, and (2) there would be no anticipated increase in number of cigar tobacco products being disposed of as the new products are anticipated to compete and replace similar marketed tobacco products.

7.5 Solid Waste

The use of the new products may impact the environment similarly through littering of discarded non-combusted cigar butts. The environmental impacts from cigar litter are not well studied, and potentially poses similar environmental risk as cigarette butts, which can persist in the environment (Novotny and Zhao, 1999; Kurmus and Mohajerani, 2019).

Like cigarettes, compounds in cigar butts can leach out into water, potentially threatening human health and the environment, especially aquatic and marine ecosystems (Kadir and Sarani, 2015). The environmental toxicity of cigar butts due to air emissions is not well studied. Airborne emissions from cigar butts are likely to resemble those emissions from cigarette butts. Airborne emissions after disposal of cigarette butts depend on the environmental conditions and the chemicals in the butts. These emissions can be influenced by several factors, such as the brand, length, types of tobacco, ingredients in the cigarette tobacco filler, number of puffs, and the mass transfer behavior of combustion products along the cigarette.[10]

The Agency does not foresee the introduction of the new products would notably affect the current and packaging waste generated from all cigars. The waste generated due to disposal of the new products would be handled in the same manner as any other waste generated from any other cigars disposed of in the United States. The number of cigar butts generated is equivalent to the market projections (Confidential Appendix 3) and a portion of those would 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 is expected to be handled in the same manner as the waste generated from other cigars in the United

[10] NIST Technical Report 8147 available at: http://dx.doi.org/10.6028/NIST.IR.8147. Accessed June 1, 2021.

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

7.7 Impact of the No-Action Alternative

The no-action alternative would not change the existing condition of disposal of cigars and cigar packaging, as similar tobacco products would continue to be disposed of in the United States.

8. List of Preparers

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

Preparer:

Vyomesh Patel, Ph.D., Center for Tobacco Products

Education: PhD in Head and Neck Cancer
Experience: Twenty-four years in pharmaceutical toxicology and experimental carcinogenesis
Expertise: Preclinical drug evaluation, regulatory toxicology, animal models of human cancers

Reviewer:

Ronald L. Edwards Jr., MS, Center for Tobacco Products

Education: MS in Biology
Experience: Twenty-seven years in environmental regulation and laboratory toxicology
Expertise: NEPA analysis, heavy metal analysis, water quality, environmental remediation, FDA, EPA, and USDA investigator

9. A Listing of Agencies and Persons Consulted

Not applicable.

10. References

American Lung Association. (2020). Smoke free Air Laws. www.lung.org/our-initiatives/tobacco/smokefree-environments/smokefree-air-laws.html (December 10, 2020). Accessed August 31, 2021.

Burton B. (2011). Does the smoke ever really clear? Thirdhand smoke exposure raises new concerns. *Environmental Health Perspectives*, *119*(2), A70-A74.

Homa DM, Neff LJ, King BA, Caraballo RS, Bunnell RE, Babb SD, Garrett BE, Sosnoff CS, Wang L. Vital signs: disparities in nonsmokers' exposure to secondhand smoke —United States, 1999–2012. *MMWR Morbidity Mortality Weekly Report. 2015;64(4), 103-108.*

Kurmus H, Mohajerani A. The toxicity and valorization options of cigarette butts. Waste Management. 2020; 104:104-118

Kadir AA, Sarani NA. Cigarette butts pollution and environmental impact – A review. Appl Mechanics and Materials. 2015;773-774:1106-1110.

Matt GE, Quintana PJE, Destaillats H, Gundel LA, Sleiman M, Singer BC, Jacob P, Benowitz N, Winickoff JP, Rehan V, Talbot P, Schick SF, Samet J, Wang Y, Hang B, Martins-Green M, Pankow JF, Hovell ME. Thirdhand tobacco smoke: emerging evidence and arguments for a multidisciplinary research agenda. *Environmental Health Perspectives.* 2011;119(9):1218-1226.

Novotny TE, Zhao, F. Consumption and production waste: Another externality of tobacco use. Tobacco Control. 1999;8(1):75-80.

U.S. Alcohol and Tobacco Tax and Trade Bureau. (2021). Tobacco Statistics. U.S. Department of the Treasury. https://www.ttb.gov/tobacco/tobacco-stats.shtml (Updated June 3, 2021) Accessed June 10, 2021.

U.S. Department of Health and Human Services. 2014. *The Health Consequences of Smoking—50 Years of Progress. A Report of the Surgeon General.* Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, 2014. Printed with corrections, January 2014.

U.S. Department of Health and Human Services. 2006a. *The Health Consequences of Involuntary Exposure to Tobacco Smoke. A Report of the Surgeon General.* Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, 2006.

U.S. Department of Health and Human Services. 2006b. *The Health Consequences of Involuntary Exposure to Tobacco Smoke: A Report of the Surgeon General: What it Means to You.* Consumer Booklet. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, 2006.

U.S. Environmental Protection Agency. 2020. *Advancing Sustainable Materials Management: 2017 Fact Sheet*. Washington, DC: U.S. Environmental Protection Agency, Office of Land and Emergency Management. July 2018.

Confidential Appendix 1. Manufacturer and Location of Manufacturing Facility of the New Products

The manufacturing of the new products is also contracted to (b) (4) at (b) (4) (see below), and by subcontractors, (b) (4) located at (b) (4)

(b) (4)

(b) (4) located at (b) (4) is in a commercial lot, with residential and park aera to the East and a commercial aera to the South (Google Map. Accessed October 1, 2021).

Confidential Appendix 2: Changes in the New Products as Compared with the Predicate Products

STN	Change from the Predicate Product
SE0016588 SE0016590	• Reduced cigar rod diameter and length, • Differences in tobacco filler • Added ingredients • (b) (4) and (b) (4) removed • Change in the tip (a non-burned material)
SE0016589	• Reduced cigar rod diameter and length, • Differences in tobacco filler • Added ingredients • (b) (4) and (b) (4) removed • Increase in filter length
SE0016754 SE0016755	• Reduced cigar rod diameter, length, and ingredients • Added ingredients • (b) (4) and (b) (4) removed • Change in the tip (a non-burned material)

Confidential Appendix 3: First- and Fifth-Year Market Volume Projections for the New Products.

First- and fifth-year market volume projections for the new products were compared to the total forecasted use of cigars in the United States[1,2]. The projected use of the new products in the first- and fifth year of marketing after marketing orders are issued account for approximately (b)(4) % and (b)(4) % respectively, of the forecasted cigar use in the United States. The new products are expected to replace and compete with similar tobacco products already on the market.

STN	Projected Market Volume			
	First-Year		Fifth Year	
	New Product (Number of Cigars)	% of Total Cigars Used[3]	New Product (Number of Cigars)	% of Total Cigars Used[3]
SE0016588	(b)(4)			
SE0016589				
SE0016590				
SE0016754				
SE0016755				
Total				

[1]The Agency used historical data regarding total use of cigars from 1997 to 2020 to mathematically estimate the total number of cigars used in the United States. Using the best-fit trend line with an R^2 value of 0.926, the forecasted number of cigars that would be used in the United States is estimated at 13.42 billion cigars in the first year and 12.75 billion cigars in the fifth year of marketing the new products.

[2]U.S. Alcohol and Tobacco Tax and Trade Bureau (https://www.ttb.gov/tobacco/tobacco-stats.shtml; Accessed September 20, 2021)

[3]Projected Market Occupation of the New Product in the United States (%) =

$$\frac{\text{Projected Market Volume of the New Product (cigar pieces)}}{\text{Projected Use of Cigars in United States (cigar pieces)}} x\ 100$$