

**Programmatic Environmental Assessment for Marketing
Orders for New Cigars Manufactured by Cheyenne
International, LLC**

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

October 20, 2020

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1. Applicant and Manufacturer Information

Applicant Name:	Cheyenne International, LLC
Applicant Address:	701 South Battleground Avenue Grover, NC 28073
Manufacturer Name:	Cheyenne International, LLC
Product Manufacturing Location:	701 South Battleground Avenue Grover, NC 28073

2. Product Information

New Product Names, Submission Tracking Numbers (STN), and Original Product Names

New Product Name	STN	Original Product Name	STN
Cheyenne Cigars Xotic Berry	EX0001260	Cheyenne Little Cigars Xotic Berry Box 100's	GF2009807
Cheyenne Cigars Full Flavor	EX0001261	Cheyenne Little Cigars Full Flavor Box 100's	GF2009805
Cheyenne Cigars Peach	EX0001262	Cheyenne Little Cigars Peach Flavor Box 100's	GF2009804
Cheyenne Cigars Vanilla	EX0001263	Cheyenne Little Cigars Vanilla Flavor Box 100's	GF2009809
Cheyenne Cigars Menthol	EX0001264	Cheyenne Little Cigars Menthol Flavor Box 100's	GF2009803
Cheyenne Cigars Wild Cherry	EX0001265	Cheyenne Little Cigars Wild Cherry Flavor Box 100's	GF2009808
Cheyenne Cigars Classic	EX0001266	Cheyenne Little Cigars Light Flavor Box 100's	GF2009806

Product Identification

Product Category:	Cigars
Product Subcategory:	Filtered, Sheet-Wrapped Cigar
Product Number per Retail Unit:	Twenty cigars per pack with ten packs per carton and sixty cartons per case.
Product Package:	The packaging materials consist of a cigar pack, foil insert, plastic outer wrap, and carton.

3. The Need for the Proposed Actions

The proposed actions, requested by the applicant, are for the Food and Drug Administration (FDA) to issue exemptions from substantial equivalence (SE) reporting for marketing orders under section 905(j)(3) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for seven filtered, sheet-wrapped cigars. 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 tobacco products into interstate commerce for commercial distribution in the United States. The applicant must obtain written notification that FDA has granted the products exemptions from demonstrating substantial equivalence under section 905(j)(3) before submitting an abbreviated report. Ninety days after FDA receipt of the abbreviated report, the applicant may introduce or deliver for introduction into interstate commerce for commercial distribution the new products for which the applicant has obtained exemptions from demonstrating substantial equivalence.

The new products differ from the corresponding original products by eliminating or adding a flavor and by the modification to the filter (Confidential Appendix 1).

4. Alternatives to the Proposed Actions

The no-action alternative is FDA does not issue marketing orders for the new tobacco products.

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

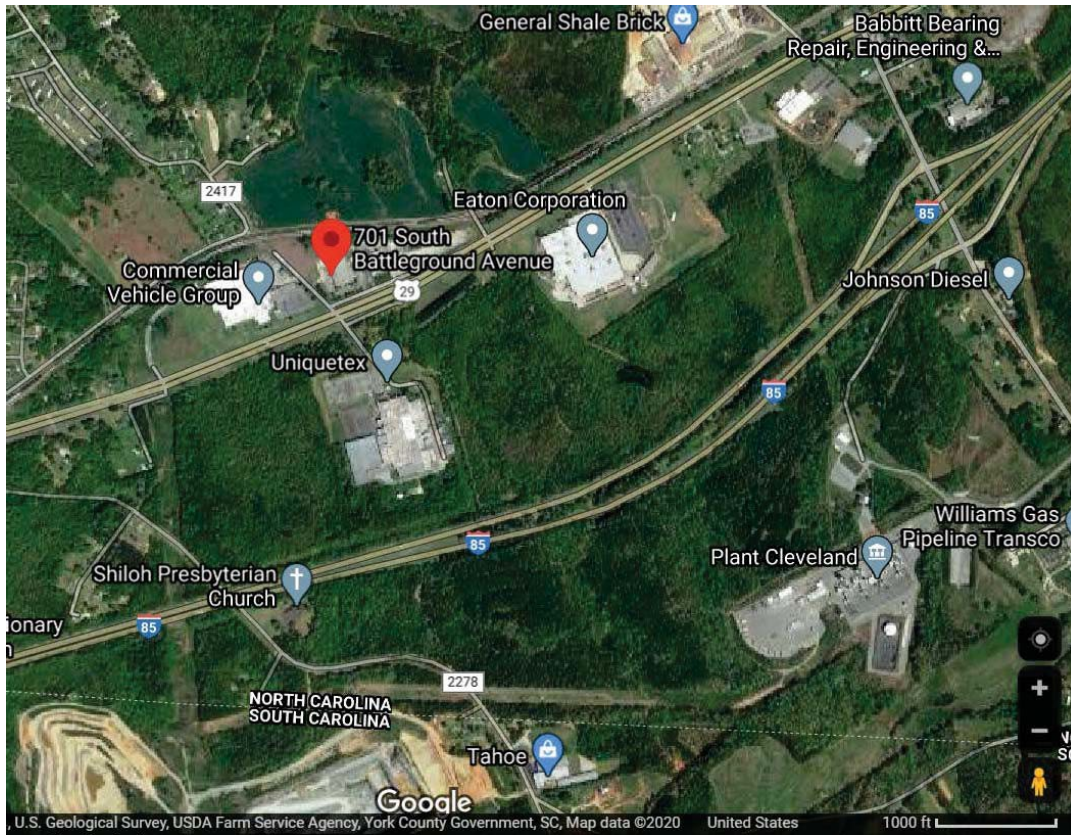
The Agency considered potential impacts to resources in the environment that may be affected by manufacturing the new products and found no significant impacts based on the Agency-gathered information and the following applicant-submitted information:

- Ingredients added to the new products are commonly used in other products currently manufactured at the facility.
- No facility expansion is expected due to manufacturing the new products.
- The new products would replace the original products and compete with other cigars currently on the market.

5.1 Affected Environment

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

Figure 1. Location of the Manufacturing Facility¹



The manufacturing facility is surrounded to the north by high quality agricultural farmland according to the North Carolina Natural Heritage Program.² Forest to the east and south of the manufacturing facility is considered under Major Forest Health Threat of very high priority and the surrounding forest as Maintaining Viable Urban Forest of high to very high priority, according to the North Carolina Forest Action Plan.³ A freeway is located to the south and a railroad to the north. Residential areas are located to the west and northwest.⁴

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 no new compounds or increased amounts of compounds would be emitted due to manufacturing the new products.

¹ Google Maps. 2020. Map of 701 South Battleground Avenue, Grover, NC 28073. Retrieved from Google Maps. Accessed September 25, 2020.

² North Carolina Natural Heritage Program Conservation Planning Tool. Available at <https://www.ncnhp.org/cpt-report-2018/open>. Accessed September 25, 2020; North Carolina Natural Heritage Data Explorer. Available at <http://ncnhde.natureserve.org/content/map>. Accessed September 25, 2020.

³ North Carolina Forest Action Plan. Available at https://www.ncforestactionplan.com/assessment_document.htm; North Carolina Forest Action Plan Priority Layer Map Viewer. Available at <https://www.ncforestactionplan.com/>. Accessed September 25, 2020.

⁴ See footnote 1

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 products are intended to replace similar tobacco products currently manufactured at the facility. Additionally, the applicant stated that no new compounds or increased amounts of compounds would be emitted due to manufacturing the new products.

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 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 manufacturing the new products would not require expansion of the manufacturing facility. Additionally, U.S. Fish and Wildlife Service (FWS) maps show that the facility is not within or near a critical habitat, or endangered animal and plant species.⁵ The U.S. FWS identifies the Dwarf-flowered heartleaf (*Hexastylis naniflora*) and the Northern Long-eared Bat (*Myotis septentrionalis*), both of which are threatened, as being present in Cleveland County.⁶ The National Wetlands Inventory identified a Riverine habitat adjacent to the facility.⁷ Because the proposed actions do not require expansion of the manufacturing facility, and the listed species are not found in the immediate vicinity of the facility, there would be no impacts to protected species or their potential habitat.

5.6 Regulatory Compliance

A search in EPA's Toxic Release Inventory (TRI) database showed that the Cheyenne International, LLC manufacturing facility is not listed, indicating that it does not release TRI listed chemicals in quantities above threshold levels in a given year.⁸

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

⁵ Critical habitat map available at: <https://databasin.org/maps/new#datasets=d579d87eb54f4374a77ea53e7ef66449>. Accessed September 25, 2020.

⁶ U.S. Fish and Wildlife Services (U.S. FWS), Information for Planning and Consultation, available at: <https://ecos.fws.gov/ipac/location/EIS36WWNONAVNKYCKO7VJSQOQ/resources#endangered-species>. Accessed September 25, 2020.

⁷ U.S. Fish and Wildlife Services National Wetlands Inventory (NWI), Wetlands Mapper, available at: <https://fwsprimary.wim.usgs.gov/wetlands/apps/wetlands-mapper/>. Accessed September 25, 2020.

⁸ U.S. Environmental Protection Agency (EPA) TRI Search <https://www.epa.gov/enviro/tri-search>. Accessed September 25, 2020.

5.7 Socioeconomics and Environmental Justice

No changes in 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 are intended to replace similar tobacco products currently manufactured at the facility.

No changes in impacts on environmental justice are anticipated. The applicant stated that no new or increased compounds would be emitted, and no facility expansion would occur due to manufacturing the new products. Thus, no disproportionate impacts to environmental justice populations would 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 would notably affect the current manufacturing waste generated from the facility production of all filtered 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.

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.

5.10 Impacts of the No-Action Alternative

The environmental impacts of the no-action alternative would not change the existing condition of manufacturing cigars 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 impacts based on Agency-gathered information and the applicant's submitted information. Included in the information the Agency considered were the projected market volumes (Confidential Appendix 2) for the new products and the documented cigar use in the United States.

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 impacts 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).

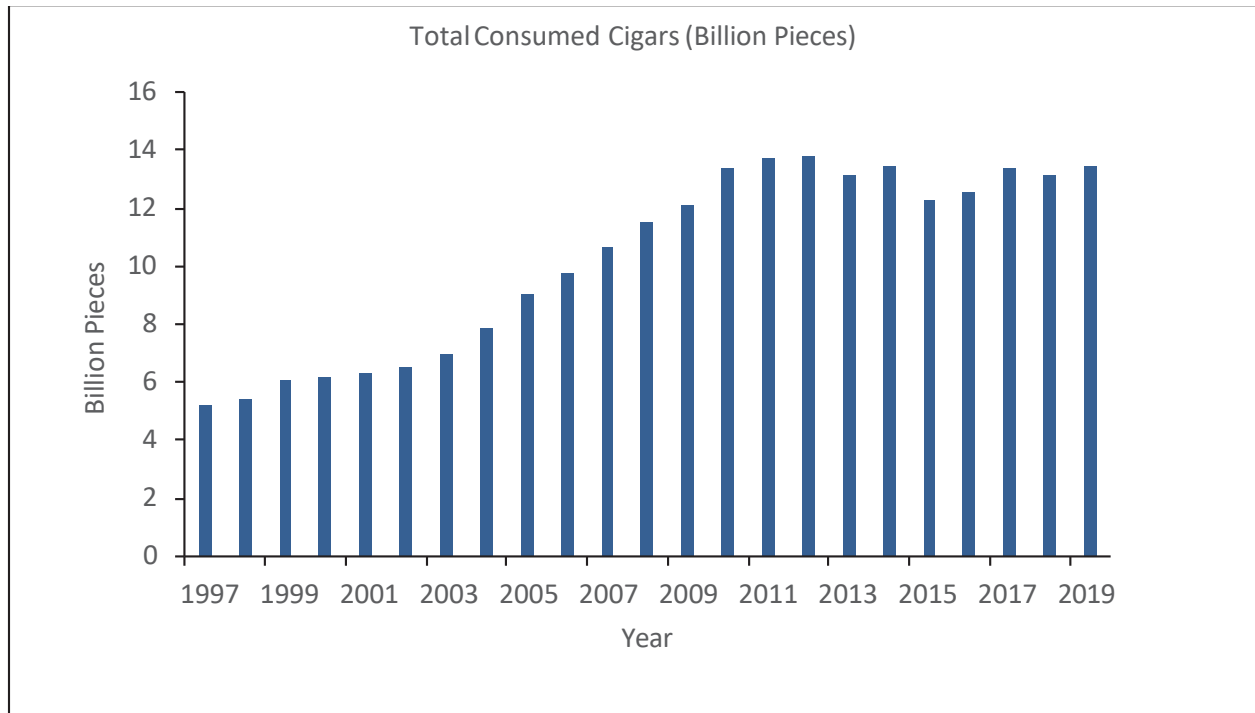
There is no safe level of exposure to SHS (DHHS, 2006a and 2006b). Even low levels of SHS can harm children and adults in many ways, including the following:

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

The consumption of cigars in the United States increased significantly during 1997 to 2011. Since 2011 through 2019, the trend of cigar usage has stabilized with minor decrease overall, per the U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) Statistical Release reports (Figure 2).⁹ In combination with declines in use of other tobacco products, 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; other studies). 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).

⁹ U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) statistical data available at: <https://www.ttb.gov/tobacco/tobacco-stats.shtml>. Accessed March 17, 2020.

Figure 2. Use of Cigars in the United States, 1984 – 2019



As of March 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 that 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 the original products and any other marketed cigars, (2) the new products are expected to compete with, or replace, other currently marketed cigars, and (3) the ingredients in the new products are used in other currently marketed tobacco products.

6.3. 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.

6.4. Impacts of the No-Action Alternative

The environmental impacts of the no-action alternative would not change the existing condition of use of cigars, as many similar tobacco products would 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 TTB data, which shows relatively stable rates of cigar use in the United States since 2010, and 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 would allow for the applicant to distribute and sell the new tobacco products to consumers in the United States.

7.2. Air Quality

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

No changes in air quality are anticipated from disposal of the unburned cigars and cigar tips of the new products. The chemicals in the new products and cigar tips are commonly used in other currently marketed cigars. Because the new products are anticipated to compete with or replace other currently marketed cigars, the tip 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 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 (U.S. Environmental Protection Agency, 2019) 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. Although disposal of smoldering tobacco products like cigars and cigarettes has been implicated in many fire incidents,¹⁰ the disposal of the new products is not expected to change the fire frequency because (1) the disposal of the new products would be similar to the disposal of cigars that are currently marketed in the United States, and (2) there would be no anticipated increase in number of cigars being disposed of as the new products are anticipated to replace similar marketed cigars.

¹⁰ National Fire Protection Association. The smoking-material fire problem. Available at: <https://www.nfpa.org/News-and-Research/Fire-statistics-and-reports/Fire-statistics/Fire-causes/Smoking-Materials>. Accessed September 30, 2020.

7.4. Water Resources

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

7.5. Solid Waste

The use of the new products may impact the environment through littering of discarded cigar butts. The environmental impacts from cigar butt litter is not well studied, and potentially pose similar environmental risk as cigarette butts, which can persist in the environment for more than 18 months (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, filter material, types of tobacco, ingredients in the cigarette tobacco filler, number of puffs, and the mass transfer behavior of combustion products along the cigarette.¹¹

The Agency does not foresee the introduction of the new products would notably affect the current cigar butt 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 2); 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 would be handled in the same manner as the waste generated from disposal of other cigars 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.

7.7. Impacts of the No-Action Alternative

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

¹¹ NIST Technical Report 8147 available at: <http://dx.doi.org/10.6028/NIST.IR.8147>. Accessed September 30, 2020.

8. List of Preparers

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

Preparer:

Hermes Reyes Caballero, Ph.D., Center for Tobacco Products
Education: Ph.D. in Biochemistry
Experience: Twenty years in various scientific activities
Expertise: Environmental toxicology, tobacco toxicology

Reviewer:

Shannon K. Hanna, Ph.D., Center for Tobacco Products
Education: Ph.D. in Environmental Science and Management
Experience: Four years in environmental science, three years in toxicology
Expertise: Ecotoxicology of new substances and materials, bioaccumulation of chemicals including heavy metals, soil/sediment and water quality

9. A Listing of Agencies and Persons Consulted

Not applicable.

10. References

American Lung Association. 2020. Smokefree Air Laws. Available at: <http://www.lung.org/our-initiatives/tobacco/smokefree-environments/smokefree-air-laws.html> (updated March 10, 2020). Accessed September 29, 2020.

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Kadir AA, Sarani NA. Cigarette butts pollution and environmental impact - a review. *Applied Mechanics and Materials*. 2015;773-774:1106-1110.

Matt GE, Quintana PJE, Destailats 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.

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

U.S. Department of Health and Human Services. 2006a. The Health Consequences of Involuntary Exposure to Tobacco Smoke: A Report of the Surgeon General. 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.

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.

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

U.S. Environmental Protection Agency. (2019). Advancing Sustainable Materials Management: 2017 Fact Sheet. Washington, DC: U.S. Environmental Protection Agency, Office of Land and Emergency Management. November 2019.

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. Modifications: New Products as Compared with the Corresponding Original Products

STN	Modification
EX0001260	<ul style="list-style-type: none"> • Elimination of the (b) (4) filter • Addition of the (b) (4) filter
EX0001261	<ul style="list-style-type: none"> • Elimination of the (b) (4) filter • Addition of the (b) (4) filter
EX0001262	<ul style="list-style-type: none"> • Elimination of the (b) (4) filter • Addition of the (b) (4) filter
EX0001263	<ul style="list-style-type: none"> • Elimination of the (b) (4) filter • Addition of the (b) (4) filter
EX0001264	<ul style="list-style-type: none"> • Elimination of the (b) (4) filter • Addition of the (b) (4) filter • Elimination of (b) (4) flavor in the filter • Addition of (b) (4) flavor to the tobacco
EX0001265	<ul style="list-style-type: none"> • Elimination of the (b) (4) filter • Addition of the (b) (4) filter
EX0001266	<ul style="list-style-type: none"> • Elimination of the (b) (4) filter • Addition of the (b) (4) filter

CONFIDENTIAL APPENDIX 2. First- and Fifth-Year Market Volume Projections for the New Products and Percentage of Cigar Use in the United States Projected to be Attributed to the New Products

First- and fifth-year market volume projections of the new products were compared to the total forecasted use of cigars in the United States.¹² The projected use of the new products in the first and fifth year of marketing after marketing orders are issued account for about (b) (4) % and (b) (4) %, respectively, of the forecasted cigar use in the United States. The applicant stated that the new products would replace the original products and would compete with similar tobacco products currently on the market.

STN	Projected Market Volume			
	First Year		Fifth Year	
	New Product (Cigars)	New Product as a Percent of Total Cigars Used ¹³	New Product (Cigars)	New Product as a Percent of Total Cigars Used ¹⁴
EX0001260	(b) (4)			
EX0001261				
EX0001262				
EX0001263				
EX0001264				
EX0001265				
EX0001266				
Total				

¹² The Agency used historical data regarding total use of cigars from 1997 to 2019 to mathematically estimate the total number of cigars used in the United States. Using the best-fit trend line with an R² value of 0.926, the forecasted number of cigars that would be used in the United States is estimated at 13.56 billion cigars in the first year and 13.11 billion cigars in the fifth year of marketing the new products.

¹³ Projected Market Occupation of the New Product in the United States (%) = $\frac{\text{Projected Market Volume of the New and Original Products (\# of cigars)}}{\text{Projected Use of Cigars in United States (\# of cigars)}} \times 100$

¹⁴ Ibid.