

**Environmental Assessment
for Marketing Order for a New Cigar
Manufactured by
Davidoff of Geneva USA, Inc.**

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

March 31, 2022

Table of Contents

Table of Contents.....	2
1. Applicant and Manufacturer Information.....	3
2. Product Information.....	3
3. The Need for the Proposed Action.....	3
4. Alternative to the Proposed Action.....	3
5. Potential Environmental Impacts of the Proposed Action and Alternative - Manufacturing the New Product.....	4
6. Potential Environmental Impacts of the Proposed Action and Alternative – Use of the New Product.....	4
6.1 Affected Environment.....	4
6.2 Air Quality.....	4
6.3 Environmental Justice.....	6
6.4 Impact of the No Action Alternative.....	6
7. Potential Environmental Impacts of the Proposed Action and Alternative – Disposal of the New Product.....	6
7.1 Affected Environment.....	6
7.2 Air Quality.....	6
7.3 Water Resources.....	7
7.4 Biological Resources.....	7
7.5 Solid Waste.....	7
7.6 Socioeconomics and Environmental Justice.....	7
7.7 Impact of the No-Action Alternative.....	7
8. List of Preparers.....	8
9. A Listing of Agencies and Persons Consulted.....	8
10. References.....	9
Appendix 1. Product Quantity of the New Product Compared to the Predicate Product... ..	10
Confidential Appendix 1. Contracted Manufacturing Facility.....	11
Confidential Appendix 2. Changes in the New Product as Compared with the Predicate Product.....	12
Confidential Appendix 3. Current Year, First- and Fifth-Year Market Volumes and Projections for the New Product	13

1. Applicant and Manufacturer Information

Applicant Name:	Davidoff of Geneva USA, Inc.
Applicant Address:	3001 Gateway Centre Parkway Pinellas Park, Florida 33782
Manufacturer Name:	See Confidential Appendix 1
Product Manufacturing Location:	See Confidential Appendix 1

2. Product Information

New Product (STN), New Product Name, and Predicate Product Name

New Product STN	New Product Name	Predicate Product Name
SE0017370	Davidoff Colorado Claro Special T	Zino Platinum Scepter Grand Master Tin-12

Product Identification

Product Type	Cigar
Product Subcategory	Unfiltered, leaf-wrapped
Quantity per Retail Sale Unit	Ten cigars per pack
Product Package	Each cigar is wrapped in cellophane wrap and packaged 10-cigars per wooden box.

3. The Need for the Proposed Action

The proposed action, requested by the applicant, is for FDA to issue a marketing order under the provisions of sections 910 and 905(j) of the Food, Drug, and Cosmetic Act after finding the new product substantially equivalent to the corresponding predicate product. The new product is currently marketed in the United States. The applicant wishes to continue marketing the new product into interstate commerce for commercial distribution in the United States and submitted to the Agency one substantial equivalence (SE) report to obtain a marketing order. The Agency shall issue the marketing order if the new product is found substantially equivalent to the predicate product.

The new product differs from the predicate product in the number of cigars, length, and weight (Appendix 1 and Confidential Appendix 2).

4. Alternative to the Proposed Action

The no-action alternative is FDA does not issue a marketing order for the new tobacco product.

5. Potential Environmental Impacts of the Proposed Action and Alternative - Manufacturing the New Product

The new product is currently manufactured outside of the United States as indicated in Confidential Appendix 1. However, the applicant stated that manufacturing the new product would not (i) require an expansion of the manufacturing facility, (ii) require additional environmental controls, or (iii) lead to changes in air emission or wastewater discharges. The applicant also stated that the manufacturing facility complies with all applicable environmental regulations and is not located within or near a habitat, critical or otherwise, of a threatened or endangered species. The applicant also stated that the manufacturing facility holds all environmental permits necessary to manufacture premium cigars in the manufacturing country.

6. Potential Environmental Impacts of the Proposed Action and Alternative – Use of the New Product

The Agency evaluated potential impacts to resources in the environment that may be affected by use of the new product 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 first- and fifth-year of marketing of the new product (Confidential Appendix 3) and the documented use of cigars in the United States (Figure 1).

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 product 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 (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:

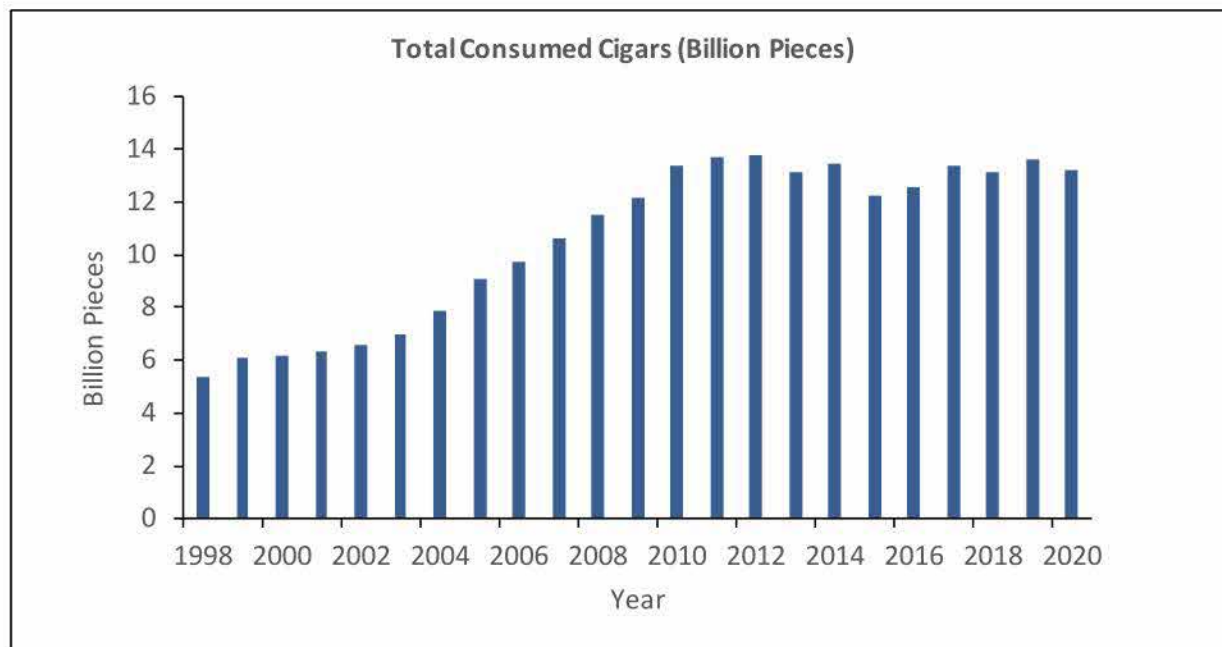
- The U.S. Surgeon General estimates that living with a smoker increases a nonsmoker's chances of developing lung cancer by 20 to 30% (U.S. Department of Health and Human Services, 2014).
- Exposure to SHS increases school children's risk for ear infections, lower respiratory illnesses, more frequent and more severe asthma attacks, and slowed lung growth. 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 1).¹ 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 (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 1. Use of Cigars in the United States, 1998 – 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.

¹U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) statistical data available at: <https://www.ttb.gov/tobacco/tobacco-stats.shtml>. March 30, 2022.

The Agency does not anticipate new chemicals would be released into the environment as a result of use of the new product, 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 product would be released in the same manner as the combustion products of other marketed cigars; (2) the new product will compete with other currently marketed cigars; and (3) the ingredients in the new product are used in other currently marketed tobacco products.

6.3 Environmental Justice

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

6.4 Impact 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 Action and Alternative – Disposal of the New Product

The Agency considered potential impacts to resources in the environment that may be affected by disposal of the new product. Based on TTB data¹, 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 product, 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 order would allow for the applicant to distribute and sell the new product to consumers in the United States.

7.2 Air Quality

The Agency does not anticipate disposal of the new product, 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 product. The chemicals in the cigar butts are commonly used in other currently marketed cigars. The new and predicate products are currently marketed. The new product will compete with or replace other cigars on the market. Because the market for cigars is not expected to materially increase and may instead decrease over time (Figure 1), the butt waste generated from the new product would replace the same type of waste. Therefore, the fate and effects of any materials emitted into the air from disposal of the new product is 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 product would be expected because; (1) the packaging materials are commonly used in the United States, and (2) 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 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, packaging, or cigar butts because the chemicals in the new product would be the same or similar as in currently marketed cigars and the new product would compete with or replace other cigars currently on the market.

7.4 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. Endangered Species Act because (1) the disposal of the new product 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 cigar tobacco products being disposed of as the new product is anticipated to compete or replace similar marketed tobacco products.

7.5 Solid Waste

The Agency does not foresee the introduction of the new product would notably affect the current cigar and packaging waste generated from all cigars. The waste generated due to disposal of the new product would be released to the environment and disposed of and handled in the same manner as any other waste generated from any other cigars disposed of in the United States. The number of cigars 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 product. The waste generated due to disposal of the new product is expected to be handled in the same manner as the waste generated from other cigars in the United States. No new emissions are expected due to disposal of the new product 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 environmental assessment (EA):

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. Smokefree Air Laws. www.lung.org/our-initiatives/tobacco/smokefree-environments/smokefree-air-laws.html (updated March 10, 2020). Accessed September 25, 2020.

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

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. *Enviro Health Perspectives*. 2011;119(9):1218-1226.

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 Morb Mortal Wkly Rep*. 2015;64(4), 103-108.

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.

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.

Appendix 1. Product Quantity of the New Product Compared to the Predicate Product

The applicant provided information on the quantity of cigars per box for both the new and predicate products.

STN	Product Quantity	
	Cigars per Box ¹	
	New Product	Predicate Product
SE0017370	10	12

¹The new products are packaged 10 per wooden box and the predicate product is packaged 12 per aluminum box.

Confidential Appendix 2. Changes in the New Product as Compared with the Predicate Product

STN	New Product			Predicate Product		
	Length ¹	Ring Gauge ²	Weight ³	Length ¹	Ring Gauge ²	Weight ³
SE0017370	(b) (4)					

¹Inch²Unit of measure is 1/64 inch.³Lbs per 1000 cigars.

Confidential Appendix 3. Current Year, First- and Fifth-Year Market Volumes and Projections for the New Product¹.

Both the new and predicate products are currently marketed in United States. In addition, the new product is expected to replace the predicate product. Also, the new product is expected to compete with and replace similar tobacco products already on the marketplace. Current year, First- and fifth year market volume and projections for the new and predicate products were compared to the total forecasted use of cigars in the United States^{2,3}. The projected use of the new product in the first and fifth year of marketing after a marketing order is issued would account for a small fraction, respectively, of the forecasted cigar use in the United States.

STN	Current Year Market Volume		Projected Market Volume			
			First Year		Fifth Year	
	Number of Cigars	% of Total Cigars Used ³	Number of Cigars	% of Total Cigars Used ³	Number of Cigars	% of Total Cigars Used ³
SE0017370	(b) (4)					
Predicate						

¹The 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 R² 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 product.

²U.S. Alcohol and Tobacco Tax and Trade Bureau (<https://www.ttb.gov/tobacco/tobacco-stats.shtml>; Accessed September 26, 2021)

³Projected Market Occupation of the New Product in the United States (%) =
$$\frac{\text{Projected Market Volume of the New Product (cigar pieces)}}{\text{Projected Use of Cigars in United States (cigar pieces)}} \times 100$$