

**Programmatic Environmental Assessment for Marketing
Orders for New Pipe Tobacco Filler Manufactured by
Friedman-Klinge Cigars Co.**

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

September 28, 2021

Table of Contents

Table of Contents..... 2

1. Applicant and Manufacturer Information..... 4

2. Product Information..... 4

3. The Need for the Proposed Actions 4

4. Alternatives to the Proposed Actions 4

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

 5.1 Affected Environment..... 5

 5.2 Air Quality 6

 5.3 Water Resources..... 6

 5.4 Soil, Land Use, and Zoning 6

 5.5 Regulatory Compliance 6

 5.6 Socioeconomics and Environmental Justice 6

 5.7 Solid Waste and Hazardous Materials 6

 5.8 Floodplains, Wetlands, and Coastal Zones 7

 5.9 Impacts of the No-Action Alternative 7

6. Potential Environmental Impacts of the Proposed Action and Alternatives – Use of the New Products 7

 6.1 Affected Environment..... 7

 6.2 Air Quality 7

 6.3 Environmental Justice 9

 6.4 Impacts of the No-Action Alternative 9

7. Potential Environmental Impacts of the Proposed Action and Alternatives – Disposal of the New Product..... 9

 7.1 Affected Environment..... 9

 7.2 Air Quality 9

 7.3 Water Resources..... 9

 7.4 Biological Resources 10

 7.5 Solid Waste 10

 7.6 Socioeconomics and Environmental Justice 10

 7.7 Impacts of the No-Action Alternative 10

8. List of Preparers 10

9. A Listing of Agencies and Persons Consulted..... 11

10. References..... 11

CONFIDENTIAL APPENDIX 1. Comparison of the New Products to the Predicate Products..... 13

CONFIDENTIAL APPENDIX 2. First- and Fifth-Year Market Volume Projections for the New and Predicate
Products. 14

1. Applicant and Manufacturer Information

Applicant Name:	Friedman-Klinge Cigar Co
Applicant Address:	6724 Olive Boulevard St. Louis, Missouri 63130
Manufacturer Name:	(b) (4)
Address Where the Product are Manufactured:	(b) (4)

2. Product Information

Submission Tracking Number (STN), New Product Name, Predicate Product Name

Table 1: Identification of the New and Products

STN	New Product	Predicate Product
SE0018301	Svenborg Danish Mixture	Svenborg Danish Mixture
SE0018302	Svenborg English	Svenborg English

Product Identification

Product Category	Pipe Tobacco Products
Product Subcategory	Pipe Tobacco Filler
Quantity per Retail Sale Unit	100 g
Product Package	Tin

3. The Need for the Proposed Actions

The proposed actions, requested by the applicant, are for Food and Drug Administration (FDA) to issue marketing orders under the provisions of sections 910 and 905(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) after finding the new products substantially equivalent to the predicate products. The applicant wishes to introduce the new products into interstate commerce for commercial distribution in the United States and submitted to the Agency two 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 products differ from the predicate products in the product quantity (Confidential Appendix 1).

4. Alternatives to the Proposed Actions

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

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

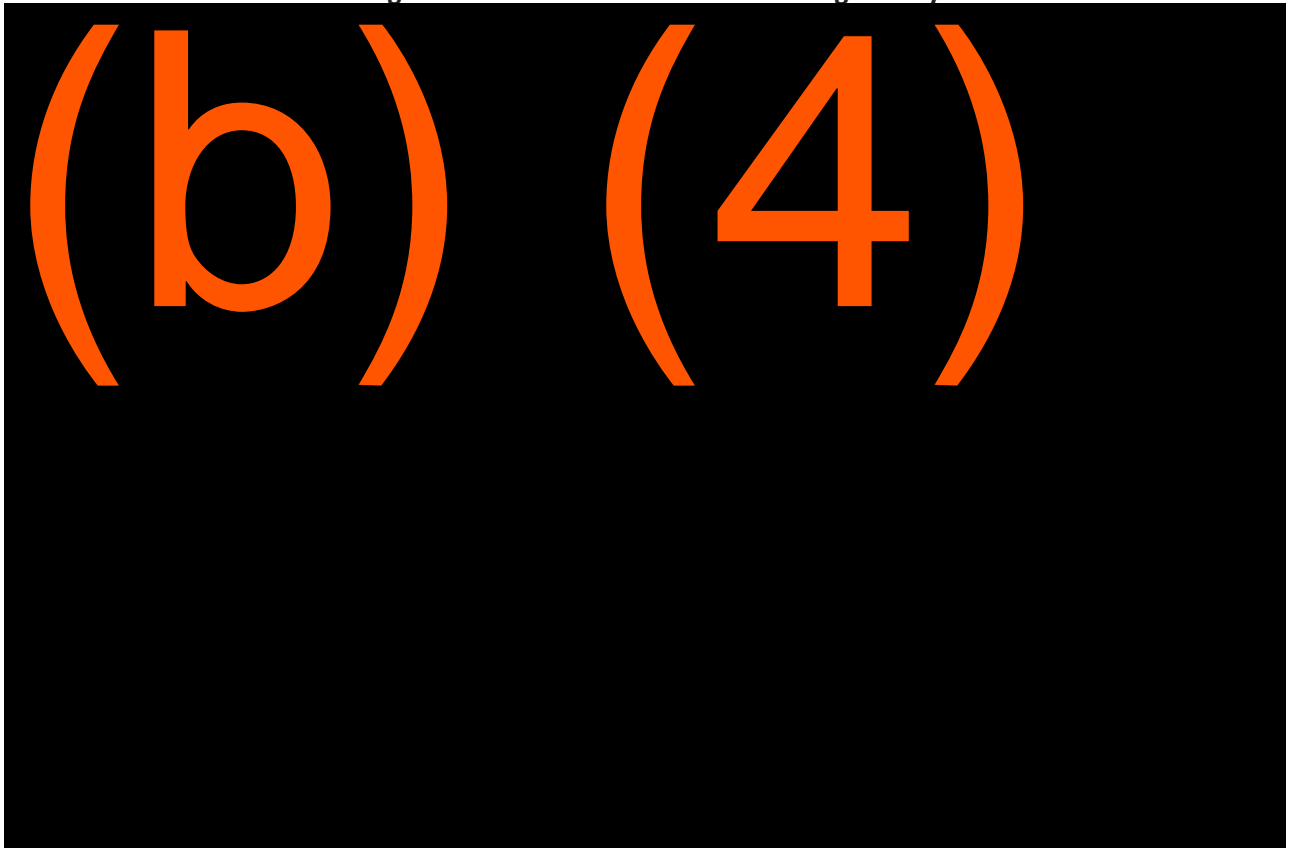
The Agency considered potential impacts to resources in the environment that may be affected by manufacturing the new products and found no significant impacts, based on Agency-gathered information and the following information submitted by the applicant:

- No increase in the facility production beyond its current permitted production capacity is expected due to manufacturing the new products.
- No facility expansion or new construction is expected due to manufacturing the new products.

5.1 Affected Environment

The new products are manufactured outside of the United States. The manufacturing facility for SE0018301 and SE0018302 is located at (b) (4). The facility is situated among commercial, residential and farming areas.

Figure 1. Location of the Manufacturing Facility



¹ Map from www.google.com, accessed 6/8/2021.

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 would not require 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 applicant stated that manufacturing the new products would not require additional environmental controls for water discharge.

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 Regulatory Compliance

The applicant stated that the manufacturing facility complies with all applicable environmental regulations.

The applicant also stated that the facility complies with the ESA and the Convention on International Trade in Endangered Species of Wild Fauna and Flora.

5.6 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 applicant stated that manufacturing the new products would lead to no more than an incremental increase in production at the manufacturing facility.

5.7 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 pipe tobacco. 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 waste disposal. Therefore, no new or revised waste permit or construction of new waste management facility is expected.

5.8 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.

5.9 Impacts of the No-Action Alternative

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

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

The Agency evaluated potential impacts to resources in the environment that may 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 first- and fifth-year of marketing of the new products and the documented pipe tobacco filler 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 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).

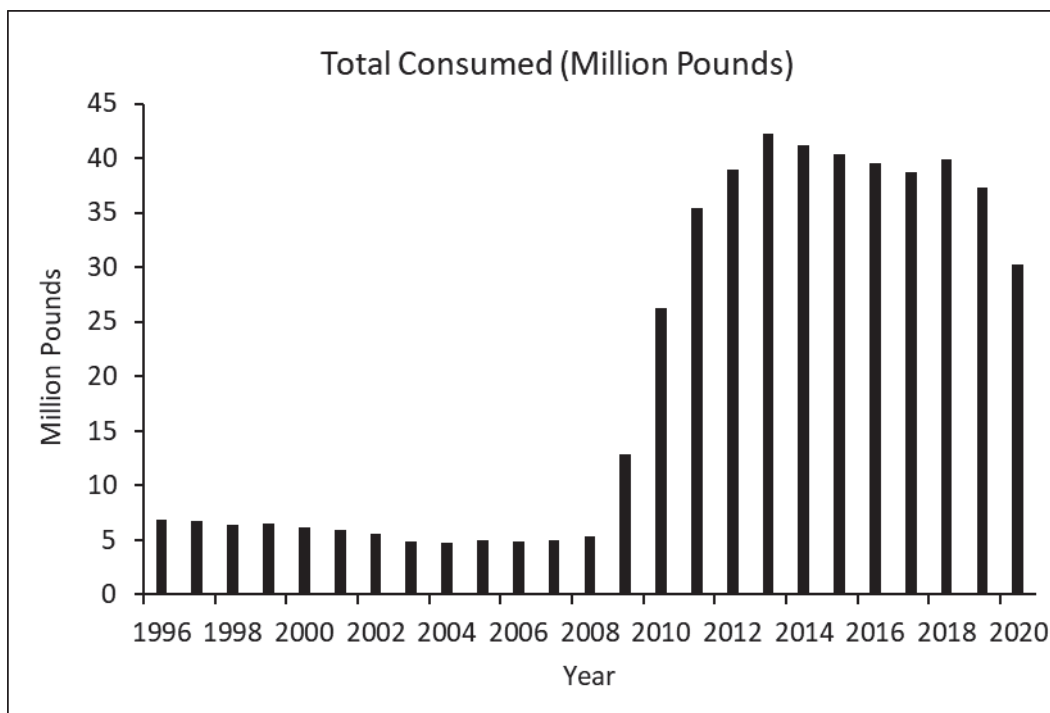
There is no safe level of exposure to SHS (U.S. Department of Health and Human Services, 2006a and 2006b). Even low levels of SHS can harm children and adults in many ways, including the following:

- 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 pipe tobacco in the United States increased significantly from 2008 to 2013. From 2013 through 2020, the trend of pipe tobacco use has stabilized with minor decrease overall, per the

U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) Statistical Release reports (Figure 2).² 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). 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 Pipe Tobacco in the United States, 1996 – 2020.



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 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 tobacco products already on the market because (1) the combustion products from the new products

² Pipe tobacco consumption in the United States. Data from the U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB). Data available at: <https://www.ttb.gov/tobacco/tobacco-stats.shtml>. Accessed April 2021.

would be released in the same manner as the combustion products of other marketed tobacco products; (2) the new products compete with other currently marketed pipe tobacco filler; 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 new disproportionate impacts on minority or low-income populations.

6.4 Impacts of the No-Action Alternative

The no-action alternative would not change the existing condition of use of pipe tobacco filler, as similar products would continue to be marketed.

7. Potential Environmental Impacts of the Proposed Action and Alternatives – Disposal of the New Product

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 pipe tobacco filler 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 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 tin packaging of the new products. The chemicals in the packaging are commonly used in other currently marketed pipe tobacco filler. 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 pipe tobacco filler products and their packaging 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 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 Water Resources

No new impacts on water resources are expected due to disposal of the unburned pipe tobacco filler and packaging from the new products because the chemicals in the new products would be the same or

similar as in currently marketed tobacco pipe filler and the new products would compete with or replace other filler products 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. ESA because the disposal of the new products would be similar to the disposal of pipe tobacco filler that are currently marketed in the United States.

7.5 Solid Waste

The use of the new products may impact the environment through littering of discarded non-combusted pipe tobacco filler

The Agency does not foresee the introduction of the new products would notably affect the current pipe tobacco filler and packaging waste generated from all pipe tobacco filler. 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 pipe tobacco filler disposed of in the United States. The amount of pipe tobacco filler generated is equivalent to the market projections; 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 other pipe tobacco filler products in the United States. No new emissions are expected due to disposal of the new products; therefore, there would be no new disproportionate impacts on minority or low-income populations.

7.7 Impacts of the No-Action Alternative

The no-action alternative would not change the existing condition of disposal of pipe tobacco filler and tin 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:

Preparer:

Alex Lowe, Ph.D., Center for Tobacco Products

Education: Ph.D. in Biology

Experience: Twelve years in environmental science

Expertise: Ecosystem science, human impacts, and water quality

Reviewer:

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

Education: B.S. in Biology

Experience: Seven years in various scientific activities

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

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 28, 2021.
- Burton, B. (2011). Does the smoke ever really clear? Thirdhand smoke exposure raises new concerns. *Environmental Health Perspectives*, 119(2), A70-A74.
- Homa, D.M., Neff, L.J., King, B.A., Caraballo, R.S., Bunnell, R.E., Babb, S.D., Garrett, B.E., Sosnoff, C.S., & Wang, L. (2015). Vital signs: disparities in nonsmokers' exposure to secondhand smoke —United States, 1999–2012. *MMWR Morbidity Mortality Weekly Report*, 64(4), 103-108.
- Kadir, A. A., and N. A., Sarani. (2015). Cigarette butts pollution and environmental impact - a review. *Applied Mechanics and Materials*, 773-774: 1106-1110.
- Matt, G.E., Quintana, P.J.E., Destailats, H., Gundel, L.A., Sleiman, M., Singer, B.C., Jacob, P., Benowitz, N., Winickoff, J.P., Rehan, V., Talbot, P., Schick, S.F., Samet, J., Wang, Y., Hang, B., Martins-Green, M., Pankow, J.F., & Hovell, M.E. (2011). Thirdhand tobacco smoke: emerging evidence and arguments for a multidisciplinary research agenda. *Environmental Health Perspectives*, 119(9), 1218-1226.
- 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. 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. 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. 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—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. 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, H.Y., Wang, Y., Lightwood, J., & Max, W. (2016). Sociodemographic differences among U.S. children and adults exposed to secondhand smoke at home: National Health Interview Surveys 2000 and 2010. *Public Health Reports*, 131, 357-366.

CONFIDENTIAL APPENDIX 1. Comparison of the New Products to the Predicate Products.

STN	New Product Name	Difference From Predicate
SE0018301	Svenborg Danish Mixture	Increase in product quantity from 50 to 100 g.
SE0018302	Svenborg English	Increase in product quantity from 50 to 100 g.

CONFIDENTIAL APPENDIX 2. First- and Fifth-Year Market Volume Projections for the New and Predicate Products.

The applicant states the applicant intends to (b) (4) [REDACTED]

STN	First-Year Market Volume Projection (lbs)		Fifth-Year Market Volume Projection (lbs)	
	New Product	Predicate Product	New Product	Predicate Product
SE0018301	(b) (4)			
SE0018302				