U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

January 26, 2022

SUBSTANTIALLY EQUIVALENT

Friedman-Klinge Cigar Co.
Attention: Beth Oliva, Esq.
Fox Rothschild LLP
101 Park Avenue, 17th Floor
New York, NY 10178

FDA Submission Tracking Numbers (STNs): Multiple STNs**,** see Appendix A

Dear Beth Oliva:

We completed our review of your SE Reports[1] and determined that the new tobacco products are substantially equivalent to the corresponding predicate tobacco products listed in Appendix A[2] and are in compliance with the requirements of the FD&C Act. Under the provisions of section 910 and 905(j) of the FD&C Act, you may introduce or deliver for introduction into interstate commerce the new tobacco products subject of this letter.

Our finding does not mean we "approved" the new products specified in Appendix A; therefore, you may not promote or in any way represent the new tobacco products specified in Appendix A, or the labeling, as being "approved" by FDA (see Section 301(tt) of the FD&C Act).

For information on how to fulfill the provisions of section 910(a)(4) of the FD&C Act, refer to Appendix B.

In accordance with 40 CFR 1506.6, we will make your Environmental Assessment (EA) publicly available.

All regulated tobacco products, including the tobacco products specified in Appendix A, are subject to the requirements of the FD&C Act and its implementing regulations. It is your responsibility to ensure the tobacco products specified in Appendix A complies with all applicable statutory and regulatory requirements. FDA will monitor your compliance with all applicable statutes and regulations.

[1] Substantially Equivalent (SE) Reports submitted under section 905(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)
[2] In addition to comparing the new tobacco products to the predicate tobacco products named by the applicant, FDA also compared the new tobacco products in these SE Reports to the grandfathered tobacco products. Although the new products have different characteristics than the grandfathered tobacco products, FDA found that those differences do not cause the new tobacco products to raise different questions of public health, and thus the new tobacco products are also substantially equivalent to the grandfathered products.

If you have any questions, please contact Raquel Jarrett, Regulatory Health Project Manager, at (240) 402-4211 or Raquel.Jarrett@fda.hhs.gov.

Sincerely,

Digitally signed by Todd L. Cecil -S
Date: 2022.01.26 14:48:29 -05'00'

Todd Cecil, Ph.D.
Deputy Director
Office of Science
Center for Tobacco Products

Enclosures:

Appendix A – New and Corresponding Predicate Tobacco Products Subject of This Letter
Appendix B – Health Information Summary

Appendix A[3]

New and Corresponding Predicate Tobacco Products Subject of This Letter

Common Attributes of SE Reports		
Submission date	September 4, 2020	
Receipt date	September 4, 2020	
Product manufacturer	Kohlhase, Kopp & Co. GmbH & Co. KG "Kohlhase Kopp"	
Product category	Pipe Tobacco Products	
Product subcategory	Pipe Tobacco Filler	
Attributes	**New Tobacco Product**	**Predicate Tobacco Product**
STN	**SE0018301**	**N/A**
Product name	Svenborg Danish Mixture[3]	Svenborg Danish Mixture[3]
Eligibility status	Not Applicable (N/A)	Grandfathered
Package type	Tin	Tin
Package quantity	100 Grams	50 Grams
Characterizing flavor	None	None
STN	**SE0018302**	**N/A**
Product name	Svenborg English[3]	Svenborg English[3]
Eligibility status	N/A	Grandfathered
Package type	Tin	Tin
Package quantity	100 Grams	50 Grams
Characterizing flavor	None	None

[3] Brand/sub-brand or other commercial name used in commercial distribution.

Appendix B

Health Information Summary

Your SE Reports did not provide a summary of any health information related to the new tobacco products, required by section 910(a)(4) of the FD&C Act; however, your SE Reports stated that such information will be available upon request to any person. Consistent with the requirements of section 910(a)(4), you may wish to consider providing the following when information is requested:

A. A copy of your final SE Reports upon which the Substantially Equivalent order was based, redacted only to the extent necessary to exclude patient identifiers and trade secret and confidential commercial information as defined in 21 CFR 20.61 and 20.63.
B. Any research or data you have in your possession or otherwise know of specifically regarding the adverse health effects of the new tobacco products, or the following statement if such statement is accurate: "[Insert manufacturer name] does not have or know of any research or data regarding any adverse health effects specifically related to [insert tobacco product name]."

Alternatively, you may provide the following when information is requested:

- Description of the new tobacco products
- Description of the predicate tobacco products
- List of all differences in characteristics between the new and predicate tobacco products
- Summary of the evidence and scientific rationale concerning why the differences in characteristics do not raise different questions of public health
- Any research or data you have in your possession or otherwise know of regarding the adverse health effects of the new tobacco product, or the following statement if such statement is accurate: "[Insert manufacturer name] does not have or know of any research or data regarding any adverse health effects specifically related to [insert tobacco product name]."

There may be other accurate, complete, and not false or misleading ways to satisfy the requirements of section 910(a)(4) not included above. If you wish to discuss other ways to meet the requirements of section 910(a)(4), submit a meeting request to us.