FDA U.S. FOOD & DRUG ADMINISTRATION

Technical Project Lead (TPL) Review of SE Reports

New Products Subject of this Review	
Submission tracking numbers (STNs)	SE0018301-SE0018302
Common Attributes	
Submission date	September 4, 2020
Receipt date	September 4, 2020
Applicant	Friedman-Klinge Cigar Co.
Product manufacturer	Kohlhase, Kopp & Co. GmbH & Co. KG "Kohlhase Kopp"
Application type	Regular Product Quantity
Product category	Pipe Tobacco Products
Product subcategory	Pipe Tobacco Filler
Cross-Referenced Submissions	
All STNs	None
Supporting FDA Memoranda Relied Upon in this Review	
All STNs	Internal Memo Addendum: Product quantity changes in Substantial Equivalence Reports (SE Reports) for statutorily regulated tobacco products.
Recommendation	
Issue Substantially Equivalent (SE) orders for the new tobacco products subject of this review.	

Technical Project Lead (TPL):

Digitally signed by Melissa Mcculloch -S
Date: 2022.01.26 14:36:44 -05'00'

Melissa McCulloch, Ph.D.
Senior Regulatory Scientist, Division of Product Science
Office of Science

Signatory Decision:

Concur with TPL recommendation and basis of recommendation

Digitally signed by Todd L. Cecil -S
Date: 2022.01.26 14:47:27 -05'00'

Todd L. Cecil, Ph.D.
Deputy Director
Office of Science

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1. BACKGROUND

1.1. NEW AND PREDICATE PRODUCTS

The applicant submitted information for the new and predicate products listed in detail in the Appendix.

1.2. REGULATORY ACTIVITY

FDA issued an Acceptance letter to the applicant on September 23, 2020. See Appendix for products and amendments.

1.3. SCOPE OF REVIEW

This review captures all compliance, regulatory, and scientific reviews completed for the new products that are the subject of this review.

Table 1. Disciplines reviewed

Discipline	Cycle 1	
	Reviewer(s)	Review Date
Environmental Science	Alexander Lowe	8/27/2021
Chemistry	Melis Coraggio	9/10/2021
Engineering	Chukwuazam Nwasike	9/13/2021
Microbiology	Amma Baidoo	9/10/2021
Toxicology	Jiaqi Fu	9/9/2021

2. COMPLIANCE REVIEW

The Office of Compliance and Enforcement (OCE) completed reviews to determine whether the applicant established that the predicate products are grandfathered products (i.e., were commercially marketed in the United States as of February 15, 2007). The OCE reviews dated August 21, 2021, and August 24, 2021, conclude that the evidence submitted by the applicant is adequate to demonstrate that the predicate products are grandfathered and, therefore, are eligible predicate products.

OCE also completed a review to determine whether the new products are in compliance with the Federal Food, Drug, and Cosmetic Act (FD&C Act) (see section 910(a)(2)(A)(i)(II) of the FD&C Act). The OCE review dated October 4, 2021, concludes that the new products are in compliance with the FD&C Act.

3. SCIENTIFIC REVIEW

During scientific review, Office of Science (OS) determined the product characteristics of the new and corresponding predicate tobacco products are identical except for the following change in product quantity:

SE Report	New Product Quantity	Predicate Product Quantity	% Change
SE0018301	100 g	50 g	100%
SE0018302	100 g	50 g	100%

OS prepared memoranda[1] summarizing its current thinking on product quantity changes. Existing data on product quantity changes are limited and do not address the size threshold (i.e., how much of a change in product quantity) necessary to raise different questions of public health. With respect to product quantity decreases, even though some of the currently available scientific evidence is specific to tobacco products, the studies do not separate out the effect of reduced price from size on consumption or initiation. Thus, based upon the currently available science and CTP's experience in reviewing SE Reports, product quantity changes do not cause new tobacco products to raise different questions of public health.

Scientific reviews were completed by the Office of Science (OS) for the following disciplines:

3.1. CHEMISTRY

The chemistry review did not identify any differences in characteristics between the new and corresponding predicate products that could cause the new products to raise different questions of public health from a chemistry perspective.

3.2. ENGINEERING

The engineering review did not identify any differences in characteristics between the new and corresponding predicate products that could cause the new products to raise different questions of public health from an engineering perspective.

3.3. MICROBIOLOGY

The microbiology review did not identify any differences in characteristics between the new and corresponding predicate products that could cause the new products to raise different questions of public health from a microbiology perspective.

3.4. TOXICOLOGY

The toxicology review did not identify any differences in characteristics between the new and corresponding predicate products that could cause the new products to raise different questions of public health from a toxicology perspective.

4. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Luis Valerio, Ph.D. on October 4, 2021. The FONSI was supported by an environmental assessment prepared by FDA on September 28, 2021.

[1] *See* memorandum on product quantity changes, dated December 7, 2017, and addendum for deemed tobacco products, dated December 30, 2019.

5. CONCLUSION AND RECOMMENDATION

The product characteristics of the new and corresponding predicate tobacco products are identical except for a change in product quantity from 50 g to 100 g.

The OS memorandum[2] concludes that based on OS' experience and the currently available evidence, the difference in product quantity does not cause the new tobacco products to raise different questions of public health. I concur with this conclusion.

The predicate products meet statutory requirements because they were determined that they are grandfathered products (i.e., were commercially marketed in the United States as of February 15, 2007).

The new products are currently in compliance with the FD&C Act. I concur with these reviews and recommend that SE order letters be issued.

FDA examined the environmental effects of finding these new products substantially equivalent and made a finding of no significant impact.

[2] *See* memorandum on product quantity changes, dated December 7, 2017, and addendum for deemed tobacco products, dated December 30, 2019.

6. APPENDICES

Appendix A. New and predicate products

Common Attributes		
Submission date	September 4, 2020	
Receipt date	September 4, 2020	
Applicant	Friedman-Klinge Cigar Co.	
Product manufacturer	Kohlhase, Kopp & Co. GmbH & Co. KG "Kohlhase Kopp"	
Product category	Pipe Tobacco Products	
Product subcategory	Pipe Tobacco Filler	
Attributes	**New Product**	Predicate Product
STN	SE0018301	N/A
Product name	Svenborg Danish Mixture[a]	Svenborg Danish Mixture
Eligibility status	Not applicable	Grandfathered
Package type	Tin	Tin
Package quantity	100 Grams	50 Grams
Characterizing flavor[b]	None	None
STN	SE0018302	N/A
Product name	Svenborg English[a]	Svenborg English
Eligibility status	Not applicable	Grandfathered
Package type	Tin	Tin
Package quantity	100 Grams	50 Grams
Characterizing flavor [b]	None	None

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

[b] As provided by the applicant's certification statement. For product quantity change SE Reports, FDA does not conduct substantive scientific review to evaluate the information contained in the applicant's certification statement.

Appendix B. Amendments

Submission Date	Receipt Date	Amendment	Applications being amended	Reviewed	Brief Description
August 11, 2021	August 11, 2021	SE0024819	All STNs	Yes	Response to August 2, 2021 FDA Information Request