FDA U.S. FOOD & DRUG ADMINISTRATION

Technical Project Lead (TPL) Review of SE Report

New Product Subject of this Review	
Submission tracking number (STN)	SE0017370
Common Attributes	
Submission date	August 20, 2020
Receipt date	August 20, 2020
Applicant	Davidoff of Geneva USA Inc.
Product manufacturer	(b) (4)
Application type	Regular
Product category	Cigars
Product subcategory	Leaf-Wrapped Cigar
Cross-Referenced Submission	
SE0017370	None
Supporting FDA Memoranda Relied Upon in this Review	
SE0017370	None
Recommendation	
Issue a Substantially Equivalent (SE) order for the new tobacco product subject of this review.	

Technical Project Lead (TPL):

Digitally signed by Charles Feng -S
Date: 2022.03.31 11:00:07 -04'00'

Charles Feng, Ph.D.
Chemistry Branch Chief, Division of Product Science
Office of Science

Signatory Decision: Concur with TPL recommendation and basis of recommendation

Todd L. Cecil -S
Digitally signed by Todd L. Cecil -S
Date: 2022.03.31 15:03:11 -04'00'

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 Appendix A.

1.2. REGULATORY ACTIVITY

On September 11, 2020, FDA issued an Acceptance letter. On November 30, 2020, FDA issued a Deficiency letter to the applicant. On February 18, 2021, FDA received an extension request for time to repond to the November 30, 2020, Deficiency letter. While reviewing the extension request, FDA found that the Deficiency letter contained incorrect information in Deficiency #4. On April 21, 2021, FDA issued a new Defiency letter with a new response due date to correct Deficiency #4. On April, 21, 2021, FDA also issued an Extension Denied letter.

See Appendix B for amendments.

1.3. SCOPE OF REVIEW

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

Table 1. Disciplines reviewed

Discipline	Cycle 1		Cycle 2	
	Reviewer(s)	Review Date	Reviewer(s)	Review Date
Regulatory	Maria-Cristina Suarez	9/11/2020	Not assigned	N/A
Chemistry	DeLauren Mccauley	11/16/2020	DeLauren Mccauley	3/30/2022
Engineering	Mohammad Ali	11/12/2020	Daniel Fuentes	3/30/2022
Toxicology	Atinuke Seun Ajiboye	11/12/2020	Not assigned	N/A
Microbiology[1]	David Craft	11/12/2020	Cassandra Nelson	3/30/2022
Environmental science	Vyomesh Patel	11/16/2020	Vyomesh Patel	3/31/2022

2. COMPLIANCE REVIEW

The Office of Compliance and Enforcement (OCE) completed review to determine whether the applicant established that the predicate product is grandfathered product (i.e., was commercially marketed in the United States as of February 15, 2007). The OCE review dated October 30, 2020, conclude that the evidence submitted by the applicant is adequate to demonstrate that the predicate product is grandfathered and, therefore, is eligible predicate product.

OCE also completed a review to determine whether the new product is in compliance with the Federal Food, Drug, and Cosmetic Act (FD&C Act) (see section 910(a)(2)(A)(i)(II) of the

[1] A microbiology addendum was signed on March 29, 2021 to correct Deficiency #4 and to support the corrected Deficiency letter dated on April 21, 2021.

FD&C Act). The OCE reviews dated November 19, 2021, and January 24, 2022, conclude that the new product is in compliance with the FD&C Act.

3. SCIENTIFIC REVIEW

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

3.1. CHEMISTRY

The final chemistry review concludes that the new product has different characteristics compared to the predicate product, but the differences do not cause the new product to raise different questions of public health from a chemistry perspective.

The new product has decreased tobacco quantity (↓13%) and adhesive (↓4%), which are not expected to increase the HPHC yields. Engineering deferred several design parameter changes to chemistry, including decreases in tobacco rod density and tobacco mass and an increase in cigar length. The chemistry review concludes that based on the currently available knwoledge, collectively, these differences in tobacco rod density, cigar length, and cigar mass between the new and predicate products in this case are likely to result in lower mainstream smoke yields.

Therefore, the differences in characteristics between the new and predicate products do not cause the new product to raise different questions of public health from a chemistry perspective.

3.2. ENGINEERING

The final engineering review concludes that the new product has different characteristics compared to the predicate product, but the differences do not cause the new product to raise different questions of public health from an engineering perspective.

There was a decrease of 21% for the tobacco rod density between the new and predicate products. A change in tobacco rod density may alter the fuel to air relationship in the combustion zone of the product affecting the combustion temperature and resulting in changes in the yields of TNCO and carbonyls. Additionally, a decrease in rod density may increase the smoke constituents by reducing the filtration efficiency through the tobacco rod. As a result the difference in target specifications for the tobacco rod density was deferred to chemistry for evaluation of the yields of TNCO and carbonyls. Furthermore, the applicant provided the target specifications and range limits for other design parameters including tobacco moisture, binder length, cigar length, diameter, and mass for the new and predicate products. These parameter are either the same or different, however, the differences are deferred to chemistry for evaluation of impact on smoke yields.

Therefore, the differences in characteristics between the new and predicate products do not cause the new product to raise different questions of public health from an engineering perspective.

3.3. TOXICOLOGY

The toxicology review concludes that the new product has different characteristics compared to the predicate product, but the differences do not cause the new product to raise different questions of public health from a toxicology perspective.

The tobacco blend in the new and predicate products is (b) (4) (b) (4) tobacco. The tobacco mass in the new product is 13% lower and the seam adhesive ingredient is also lower. This change is unlikely to be of toxicological concern.

Therefore, the differences in characteristics between the new and predicate products do not cause the new product to raise different questions of public health from a toxicology perspective.

3.4. MICROBIOLOGY

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

4. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Luis Valerio, Ph.D. on March 31, 2022. The FONSI was supported by an environmental assessment prepared by FDA on March 31, 2022.

5. CONCLUSION AND RECOMMENDATION

The new and the predicate products have the following characteristics:

- 13% decrease in tobacco mass
- 4% decrease in (b) (4) cellulose) adhesive
- 9% increase in cigar length
- 21% decrease in tobacco rod density

I concur with the conclusions of all the scientific reviews that the applicant has demonstrated that these differences in characteristics do not cause the new product to raise different questions of public health as described in Section 3.1-3.3 above. The new product has decreases in tobacco mass, adhesive, and tobacco rod density as well as an increase in cigar length. The decreased tobacco rod density resulted from the decreased tobacco mass and increased cigar length. In this case, collectively, the differences between the new and predicate products are likely to result in lower mainstream smoke yields. Therefore, the differences in characteristics between the new and predicate products do not cause the new products to raise different questions of public health.

The predicate product meet statutory requirements because it was determined that it is a grandfathered product (i.e., were commercially marketed in the United States as of February 15, 2007).

The new product is currently in compliance with the FD&C Act. I concur with these reviews and recommend that SE order letter be issued. FDA examined the environmental effects of finding the new product substantially equivalent and made a finding of no significant impact.

6. APPENDICES

Appendix A. New and predicate products

Common Attributes		
Submission date	August 20, 2020	
Receipt date	August 20, 2020	
Applicant	Davidoff of Geneva USA Inc.	
Product manufacturer	(b) (4)	
Product category	Cigars	
Product subcategory	Leaf-Wrapped Cigar	
Attributes	**New Product**	**Predicate Product**
STN	**SE0017370**	**GF1703449**
Product name	Davidoff Colorado Claro Special T[a]	Zino Platinum Scepter Grand Master Tin-12
Eligibility status	Not Applicable (N/A)	Grandfathered
Package type	Cellophane	Cellophane
Package quantity	1 Cigar	1 Cigar
Characterizing flavor	None	None
Length	152.4 mm	139.7 mm
Diameter	Not provided	Not provided
Wrapper material	(b) (4) Tobacco	(b) (4) Tobacco
Additional property	Ring Gauge 52 (1/64 in)	Ring Gauge 52 (1/64 in)
Additional property	Cardboard box	Tin

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

Appendix B. Amendments

Submission Date	Receipt Date	Amendment	Applications being amended	Reviewed	Brief Description
October 30, 2020	October 30, 2020	SE0022439	SE0017370	Yes	Response to October 6, 2020, FDA Information Request
February 18, 2021	February 18, 2021	SE0024343	SE0017370	Yes	Extension request for time to respond to November 30, 2020, FDA Deficiency Letter
July 20, 2021	July 20, 2021	SE0024753	SE0017370	Yes	Response to April 21, 2021, FDA Deficiency Letter