



SUBSTANTIALLY EQUIVALENT

Davidoff of Geneva USA, Inc.
Attention: Diane Kalambokas, Director of Tax, Treasury and Regulatory Affairs
3001 Gateway Centre Parkway
Pinellas Parks, FL 33782

FDA Submission Tracking Number (STN): SE0017370

Dear Diane Kalambokas:

We completed our review of your SE Report¹ and determined that the new tobacco product is substantially equivalent to the predicate tobacco product listed in Appendix A and is 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 product subject of this letter.

Our finding does not mean we “approved” the new product specified in Appendix A; therefore, you may not promote or in any way represent the new tobacco product 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 product 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 product 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) Report submitted under section 905(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)

If you have any questions, please contact Maria Suarez, M.S.H.S., Regulatory Health Project Manager, at (301) 348 -1867 or Maria.Suarez@fda.hhs.gov.

Sincerely,

Todd L. Cecil

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Digitally signed by Todd
L. Cecil -S

Date: 2022.03.31 15:05:13
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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 A²
New and Corresponding Predicate Tobacco Products Subject of This Letter

Common Attributes of SE Report		
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 Tobacco Product	Predicate Tobacco Product
STN	SE0017370	GF1703449
Product name	Davidoff Colorado Claro Special T	Zino Platinum Scepter Grand Master
Eligibility status	Not Applicable	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)

² Brand/sub-brand or other commercial name used in commercial distribution.

Appendix B
Health Information Summary

Your SE Report did not provide a summary of any health information related to the new tobacco product, required by section 910(a)(4) of the FD&C Act; however, your SE Report 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 Report 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 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].”

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.