U.S. FOOD & DRUG ADMINISTRATION

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

September 28, 2021

SUBSTANTIALLY EQUIVALENT

La Aurora S.A.
Attention: Agustin E. Rodriguez, Esq., Counsel
1001 Haxall Point
Po Box 1122 (23218)
Richmond, VA 23219-3940 US

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

Dear Mr. Rodriguez:

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 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)

If you have any questions, please contact Bridgette Hager, M.P.H., Regulatory Health Project Manager, at (240) 402 - 5081 or Bridgette.Hager@fda.hhs.gov.

Sincerely,

Digitally signed by Matthew R. Holman -S
Date: 2021.09.28 11:52:17 -04'00'

Matthew R. Holman, Ph.D.
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[2]

New and Corresponding Predicate Tobacco Products Subject of This Letter

Common Attributes of SE Reports		
Submission date	September 07, 2020	
Receipt date	September 07, 2020	
Product manufacturer	La Aurora S.A.	
Product category	Cigar	
Product subcategory	Leaf-Wrapped Cigar	
Attributes	**New Tobacco Product**	**Predicate Tobacco Product**
STN	**SE0018516**	**GF1907499**
Product name	PRINCIPES CORONA RED (Box of 55)	TATIANA LA VITA CHERRY 5X38 BOX OF 25
Eligibility status	Not applicable	Grandfathered
Package type	Biaxially-oriented polypropylene	Polypropylene
Package quantity	55 cigars	25 cigars
Characterizing flavor	Cherry	Cherry
Length	127 millimeters (mm)	127 mm
Diameter	15 mm	15 mm
Wrapping material	Dark air cured tobacco	Dark air cured tobacco
Attributes	**New Tobacco Product**	**Predicate Tobacco Product**
STN	**SE0019428**	**GF1907499**
Product name	PRINCIPES CORONA RED (Box of 30)	TATIANA LA VITA CHERRY 5X38 BOX OF 25
Eligibility status	Not applicable	Grandfathered
Package type	Biaxially-oriented polypropylene	Polypropylene
Package quantity	30 cigars	25 cigars
Characterizing flavor	Cherry	Cherry
Length	127 mm	127 mm
Diameter	15 mm	15 mm
Wrapping material	Dark air cured tobacco	Dark air cured tobacco
Attributes	**New Tobacco Product**	**Predicate Tobacco Product**
STN	**SE0019429**	**GF1907507**
Product name	PRINCIPES CHICO RED (Box of 30)	TATIANA DOLCE CHERRY 5X30 BOX OF 50
Eligibility status	Not applicable	Grandfathered
Package type	Biaxially-oriented polypropylene	Polypropylene
Package quantity	30 cigars	50 cigars
Characterizing flavor	Cherry	Cherry
Length	116 mm	116 mm
Diameter	12 mm	12 mm
Wrapping material	Dark air cured tobacco	Dark air cured tobacco

[2] 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.