

Technical Project Lead (TPL) Review of SE Reports

New Products Subject of this Review	
Submission tracking numbers (STNs)	SE0019795 – SE0019798
Common Attributes	
Submission date	September 7, 2020
Receipt date	September 7, 2020
Applicant	La Aurora S.A.
Product manufacturer	La Aurora S.A.
Application type	Regular Product Quantity
Product category	Cigars
Product subcategory	Leaf-Wrapped Cigar
Cross-Referenced Submissions	
All STNs	None
Supporting FDA Memoranda Relied Upon in this Review	
All STNs	Addendum to Memorandum: Product quantity changes in Substantial Equivalence Reports (SE Reports) for statutorily regulated tobacco products (December 31, 2019).
Recommendation	
Issue Substantially Equivalent (SE) orders for the new tobacco products subject of this review.	

Technical Project Lead (TPL):

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Date: 2021.11.04 09:34:31 -04'00'

Marcella W. Dolling, M.S., M.B.A.
Chief, Regulatory Project Management Branch
Division of Regulatory Project Management
Office of Science

Signatory Decision:

Concur with TPL recommendation and basis of recommendation

Digitally signed by Matthew R. Holman -S
Date: 2021.11.04 09:43:35 -04'00'

Matthew R. Holman, Ph.D.
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

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	
	Reviewers	Review Date
Regulatory	Maliha Choudhury	10/5/2020
	Fiona Kiprof	9/28/2021
Environmental Science	Christy Leppanen	08/16/2021

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 July 19, 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 reviews 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 reviews dated October 20, 2021, conclude that the new products are in compliance with the FD&C Act.

3. SCIENTIFIC REVIEW

Full scientific review was not initiated by the Office of Science (OS) because the product characteristics of the new and corresponding predicate tobacco products are identical except for the following changes in product quantity:

Change in Product Quantity

SE Report	New Product Quantity	Predicate Product Quantity	% Change
SE0019795 and SE0019797	55 cigars	25 cigars	↑120%
SE0019796 and SE0019798	30 cigars	25 cigars	↑20%

OS prepared memoranda¹ 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. Therefore, scientific review is unnecessary.

4. ENVIRONMENTAL DECISION

The final environmental review found the applicant does not indicate if the predicate products will be marketed simultaneously with the new products. If the predicate products will be marketed with the new products, first and fifth year predicate product market volume information is needed to assess potential environmental impacts. Therefore, additional information is needed to determine whether to prepare an Environmental Impact Statement (EIS) or Finding of No Significant Impact (FONSI).

5. CONCLUSION AND RECOMMENDATION

The product characteristics of the new and corresponding predicate tobacco products are identical except for a change in product quantity and container closure system:

- 120% increase in product quantity - SE0019795 and SE0019797
- 20% increase in product quantity - SE0019796 and SE0019798

The OS memoranda 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 it was 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.

FDA examined the environmental effects of finding these new products substantially equivalent and found additional information is necessary to determine the impact of the action. Without this information, FDA is precluded from issuing an SE order.

An Environmental Information Request letter should be issued requesting the following information:

1. Your SE Reports do not indicate if predicate products will be marketed along with the corresponding new products. This information is needed to evaluate environmental impacts of the new and predicate products.
 - a. State if each predicate product will or will not be simultaneously marketed with the corresponding new product.

¹ See memorandum on product quantity changes, dated December 7, 2017, and addendum for deemed tobacco products, dated December 31, 2019.

- b. If the predicate products will be simultaneously marketed, provide market volume estimates in number of units and weight for the first and fifth years for each predicate product.

If the applicant adequately responds to the request and an EIS or FONSI is completed, SE order letters should be issued for the new products, as identified in the Appendix of this review.

6. APPENDICES

Appendix A. New and predicate products

Common Attributes		
Submission date	September 7, 2020	
Receipt date	September 7, 2020	
Applicant	La Aurora S.A.	
Product manufacturer	La Aurora S.A.	
Product category	Cigars	
Product subcategory	Leaf Wrapped Cigar	
Attributes	New Product	Predicate Product
STN	SE0019795	GF2010117
Product name ²	PRINCIPES CORONA BROWN (Box of 55)	PRINCIPES CORONA CHOCOLATE 5X38 BOX OF 25
Eligibility status	Not applicable	Grandfathered
Package type	Biaxially-oriented polypropylene	Biaxially-oriented polypropylene
Package quantity	55 cigars	25 cigars
Characterizing flavor ³	Chocolate	Chocolate
Length	127 millimeters (mm)	127 mm
Diameter	15.08 mm	15.08 mm
Wrapper Material	Dark air-cured tobacco	Dark air-cured tobacco
STN	SE0019796	GF2010117
Product name ²	PRINCIPES CORONA BROWN (Box of 30)	PRINCIPES CORONA CHOCOLATE 5X38 BOX OF 25
Eligibility status	Not applicable	Grandfathered
Package type	Biaxially-oriented polypropylene	Biaxially-oriented polypropylene
Package quantity	30 cigars	25 cigars
Characterizing flavor ³	Chocolate	Chocolate
Length	127 mm	127 mm
Diameter	15.08 mm	15.08 mm
Wrapper Material	Dark air-cured tobacco	Dark air-cured tobacco

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

³ 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.

STN	SE0019797	GF2012252
Product name ²	PRINCIPES CORONA CARIBBEAN (Box of 55)	PRINCIPES CORONA RUM 5X38 BOX OF 25
Eligibility status	Not applicable	Grandfathered
Package type	Biaxially-oriented polypropylene	Biaxially-oriented polypropylene
Package quantity	55 cigars	25 cigars
Characterizing flavor ³	Rum	Rum
Length	127 mm	127 mm
Diameter	15.08 mm	15.08 mm
Wrapper Material	Dark air-cured tobacco	Dark air-cured tobacco
STN	SE0019798	GF2012252
Product name ²	PRINCIPES CORONA CARIBBEAN (Box of 30)	PRINCIPES CORONA RUM 5X38 BOX OF 25
Eligibility status	Not applicable	Grandfathered
Package type	Biaxially-oriented polypropylene	Biaxially-oriented polypropylene
Package quantity	30 cigars	25 cigars
Characterizing flavor ³	Rum	Rum
Length	127 mm	127 mm
Diameter	15.08 mm	15.08 mm
Wrapper Material	Dark air-cured tobacco	Dark air-cured tobacco

Appendix B. Amendment

Submission Date	Receipt Date	Application being amended	Reviewed	Brief Description
July 6, 2021	July 6, 2021	SE0019797 and SE0019798	Yes	Response to June 24, 2021, FDA Information Request