

Technical Project Lead (TPL) Review of SE Reports

| New Products Subject of this Review | |
|---|--|
| Submission tracking numbers (STNs) | SE0018516, SE0019428, and SE0019429 |
| 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 new tobacco products | MF0000242 |
| Supporting FDA Memoranda Relied Upon in this Review | |
| All new tobacco products | 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):

Digitally signed by Marcella W. Dolling -S
 Date: 2021.09.28 11:27:07 -04'00'

Marcella W. Dolling, M.S., MBA
 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: 2021.09.28 11:34:18 -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 Kiproop | 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, 2021¹ and August 13, 2021² 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 August 23, 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 and container closure system:

Change in Product Quantity

| SE Report | New Product Quantity | Predicate Product Quantity | % Change |
|-----------|----------------------|----------------------------|----------|
| SE0018516 | 55 cigars | 25 cigars | ↑120% |
| SE0019428 | 30 cigars | 25 cigars | ↑20% |

¹ For SE0019429

² For SE0018516 and SE0019428. This addendum review changes the conclusion of the OCE review dated July 20, 2021.

| SE Report | New Product Quantity | Predicate Product Quantity | % Change |
|-----------|----------------------|----------------------------|----------|
| SE0019429 | 30 cigars | 50 cigars | ↓40% |

Change in Container Closure System:

| SE Report | New Product | Predicate Product |
|-------------------------------------|----------------------------------|-------------------|
| SE0018516, SE0019428, and SE0019429 | Biaxially-oriented polypropylene | Polypropylene |

OS prepared memoranda³ 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.

The predicate products' container closure system (CCS) is composed of polypropylene, and the new tobacco products' CCS is composed of biaxially-oriented polypropylene. Both biaxially-oriented polypropylene and polypropylene are thermoplastic polymers (i.e., polyolefins). Given the similarities of these plastics, we do not expect the change in plastics to affect product stability. Consequently, in this particular case, the change from polypropylene to biaxially-oriented polypropylene does not cause the new products to raise different questions of public health.

MF0000242 is referenced for additional information regarding design parameters (i.e., wrapper porosity, binder porosity, and binder length). However, the information in this Tobacco Product Master File (TPMF) is not applicable to these applications because there were no additional modifications outside of product quantity and CCS and the referenced TPMF did not contain relevant information on product quantity and CCS changes; therefore, a TPMF review is not needed.

4. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Luis Valerio, Ph.D. on August 16, 2021. The FONSI was supported by an environmental assessment prepared by FDA on August 16, 2021.

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 - SE0018516
- 20% increase in product quantity - SE0019428
- 40% decrease in product quantity - SE0019429

³ See memorandum on product quantity changes, dated December 7, 2017, and addendum for deemed tobacco products, dated December 31, 2019.

- Change in container closure system composition from polypropylene in the predicate products to biaxially-oriented polypropylene in the new products - SE0018516, SE0019428, and SE0019429

The OS memoranda³ 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. 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.

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 | SE0018516 | GF1907499 |
| Product name ⁴ | 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 ⁵ | Cherry | Cherry |
| Length | 127 millimeters (mm) | 127 mm |
| Diameter | 15 mm | 15 mm |
| Wrapper Material | Dark air-cured tobacco | Dark air-cured tobacco |
| STN | SE0019428 | GF1907499 |
| Product name ⁴ | 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 ⁵ | Cherry | Cherry |
| Length | 127 mm | 127 mm |
| Diameter | 15 mm | 15 mm |
| Wrapper Material | Dark air-cured tobacco | Dark air-cured tobacco |
| STN | SE0019429 | GF1907507 |
| Product name ⁴ | 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 ⁵ | Cherry | Cherry |
| Length | 116 mm | 116 mm |
| Diameter | 12 mm | 12 mm |
| Wrapper Material | Dark air-cured tobacco | Dark air-cured tobacco |

⁴ Brand/sub-brand or other commercial name used in commercial distribution.

⁵ 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. Amendment

| Submission Date | Receipt Date | Application being amended | Reviewed | Brief Description |
|------------------------|---------------------|----------------------------------|-----------------|---|
| July 6, 2021 | July 6, 2021 | SE0019429 | Yes | Response to June 24, 2021 FDA Information Request |