

Technical Project Lead (TPL) Review of SE Report

| New Product Subject of this Review ¹ | |
|---|-------------------|
| STN | SE0023356.PD2 |
| Attributes of SE Report | |
| Submission date | September 9, 2020 |
| Receipt date | September 9, 2020 |
| Applicant | Fronto King LLC |
| Product manufacturer | FK Global |
| Application type | Regular |
| Product category | Cigars |
| Product subcategory | Cigar Component |
| Cross-Referenced Submission | |
| SE0023356.PD2 | None |
| Supporting FDA Memoranda Relied Upon in this Review | |
| SE0023356.PD2 | None |
| Recommendation | |
| Issue a Substantially Equivalent (SE) order for the new tobacco product subject of this review. | |

Technical Project Lead (TPL):

Digitally signed by Jeannie H. Jeong-im -S
 Date: 2022.09.28 18:33:17 -04'00'

Jeannie Jeong-Im, Ph.D.
 Chemistry Branch Chief
 Division of Product Science

Signatory Decision:

Concur with TPL recommendation and basis of recommendation

Todd L. Cecil -S Digitally signed by Todd L. Cecil -S
 Date: 2022.09.29 11:20:10 -04'00'

Todd L. Cecil, Ph.D.
 Acting Director
 Office of Science

¹ Product details, amendments, and dates provided in the Appendix. SE means substantial equivalence (report). STN means submission tracking number.

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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

FDA received the SE Reports on September 9, 2020. On November 12, 2020, FDA issued an Acceptance letter. On February 4, 2022, FDA issued a Deficiency letter. On May 4, 2022 (received by FDA on May 6, 2022), the applicant requested an extension of time to respond to FDA's February 4, 2022, Deficiency letter, and provided partial responses. On May 13, 2022, FDA issued an Extension Granted letter. On May 13, 2022, the applicant responded to FDA's February 4, 2022, Deficiency letter.

See Appendix for products and amendments.

1.3. SCOPE OF REVIEW

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

Table 1. Disciplines reviewed

| Discipline | Cycle 1 | | Cycle 2 | |
|--------------------------|---------------------|-------------|-----------------------|-------------|
| | Reviewer(s) | Review Date | Reviewer(s) | Review Date |
| Chemistry | Ruth Ganunis | 2/1/2022 | Kristin Gagne | 8/9/2022 |
| Engineering | Anjali Verma | 2/3/2022 | Wesley Anderson | 8/29/2022 |
| Microbiology | Kristy Huynh Ngo | 2/1/2022 | Prashanthi Mulinti | 7/1/2022 |
| Environmental Science | Vyomesh Patel | 8/24/2021 | Vyomesh Patel | 6/27/2022 |

2. COMPLIANCE REVIEW

The Office of Compliance and Enforcement (OCE) completed a review to determine whether the applicant established that the predicate product is a Pre-Existing Tobacco Product (i.e., was commercially marketed in the United States as of February 15, 2007). The OCE review dated August 13, 2021, concludes that the evidence submitted by the applicant is adequate to demonstrate that the predicate product is a Pre-Existing Tobacco Product and, therefore, is an eligible predicate product.

OCE also completed a review 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 review dated July 26, 2022, concludes that the new products are 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 does not cause the new product to raise different questions of public health from a chemistry perspective. The applicant provided tobacco type (e.g., (b)(4)), manufacturing location (i.e., (b)(4) for the new product and (b)(4) and (b)(4) for the predicate product), detailed ingredient information, and container closure system ingredients (e.g., (b)(4)). They indicated that the new and predicate products are identical with the exception of size and therefore mass. The applicant provided clarification that the tobacco leaf is an agricultural product that naturally varies in size, and the decrease in (b)(4) in the new product was due to the (b)(4) (b)(4) for use as the predicate product and (b)(4) for use as the new product. The applicant provided additional information regarding the design parameters, including the averages and ranges of tobacco leaf wrapper weight, length, and width. Because the new product is a cigar wrapper that is identical to the predicate product, with exception of a smaller size and mass, and based on the clarifying information that the tobacco leaf is an agricultural product that naturally varies in size and the only ingredients are (b)(4) (b)(4) the applicant does not need to submit tar, carbon monoxide, TSNA mainstream smoke yields or information related to the nicotine yield to demonstrate that the new product does not raise different questions of public health from a chemistry perspective at this time. Therefore, the product size decrease in the new product compared to the predicate product is not expected to 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 does not cause the new product to raise different questions of public health from an engineering perspective. The difference in the length and width target specifications are (b)(4) less respectively between the new and predicate products. The difference in the overall wrapper mass (g) target specification for the new and predicate products is (b)(4) less than the predicate products. A difference in length, width and wrapper mass may affect smoke constituent yields; therefore, the impact of change in length, width and wrapper mass between the new and predicate products are deferred to Chemistry to evaluate tar, nicotine, and carbon monoxide in smoke. 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. 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 June 29, 2022. The FONSI was supported by an environmental assessment prepared by FDA on June 29, 2022.

5. CONCLUSION AND RECOMMENDATION

The new and the predicate products have the following characteristics:

- Decrease in wrapper length (25%)
- Decrease in wrapper width (35%)
- Decrease in wrapper mass (49%)
- Manufacturer difference: (b)(4) for the new product and (b)(4) and (b)(4) for the predicate product

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 is processed and manufactured the same way as the predicate product. The tobacco leaf is an agricultural product that naturally varies in size, and the (b)(4)

(b)(4)

(b)(4)

(b)(4) Since the new product is smaller than the predicate product and the ingredients are identical, with exception of the amount, TNCO and HPHCs are not needed at this time. Based on the information that the applicant has provided in their original submission and amendments (the leaf is an agricultural product that naturally varies in size; only (b)(4) and (b)(4) are ingredients within the new and predicate leaf; the new product is a smaller leaf size than the original product; the size of the wrappers being at the discretion of the consumer because consumers generally cut or tear the leaf to make wrappers), as the TPL, I have determined that the differences in leaf size between the new and predicate products do not cause the new product to raise different questions of public health.

The predicate product meets statutory requirements because it was determined that it is a Pre-Existing Tobacco Product (i.e., was 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 an SE order letter 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 products²**

| Attributes of SE Report | | |
|------------------------------------|--|------------------------------------|
| Submission date | September 9, 2020 | |
| Receipt date | September 9, 2020 | |
| Applicant | Fronto King LLC | |
| Product manufacturer | FK Global | |
| Product category | Cigars | |
| Product subcategory | Cigar Component | |
| Attributes | New Product | Predicate Product |
| STN | SE0023356.PD2 | GF2012754 |
| Product name | Fronto King Mini Leaf | Fronto King Original Whole Leaf |
| Eligibility status | Not applicable | Pre-Existing Tobacco Product |
| Package type | Foil Pouch | Foil Pouch |
| Package quantity | 1 Wrapper | 1 Wrapper |
| Characterizing flavor | None | None |
| Length ³ | 416 millimeters (mm) | 551 mm |
| Width ³ | 188 mm | 289 mm |
| Additional Properties ³ | Whole tobacco leaf; Mass: 6862 grams (g) | Whole tobacco leaf; Mass: 13,581 g |

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

³ Per the applicant, the new and predicate products consist of a single, whole tobacco leaf; as the tobacco leaf is an agricultural product, it naturally varies in size.

Appendix B. Amendments

| Submission Date | Receipt Date | Amendment | Applications being amended | Reviewed | Brief Description |
|------------------------|---------------------|------------------|-----------------------------------|-----------------|--|
| May 4, 2022 | May 6, 2022 | SE0025336 | SE0023356.PD2 | Yes | Response to February 4, 2022 Deficiency Letter and Request for extension to provide a complete response as a result of COVID |
| May 4, 2022 | May 6, 2022 | SE0025347 | SE0023356.PD2 | Yes | Extension Request |
| May 13, 2022 | May 13, 2022 | SE0025343 | SE0023356.PD2 | Yes | Response to February 4, 2022 Deficiency Letter |