FDA U.S. FOOD & DRUG ADMINISTRATION

# Technical Project Lead (TPL) Review of SE Reports

| New Products Subject to this Review | |
|---|---|
| Submission tracking numbers (STNs) | SE0018754.PD1 and SE0018755.PD1 |
| **Common Attributes** | |
| Submission date | September 8, 2020 |
| Receipt date | September 8, 2020 |
| Applicant | Ashton Distributors Inc. |
| Product manufacturer | (b) (4) |
| Application type | Regular Product Quantity |
| Product category | Cigars |
| Product subcategory | Unfiltered, Leaf-Wrapped |
| **Cross-Referenced Submissions** | |
| All new products | None |
| **Supporting FDA Memoranda Relied Upon in this Review** | |
| All new products | Addendum: Product Quantity Changes in Substantial Equivalence Reports (SE Reports) for Deemed Tobacco Products (December 30, 2019) |
| **Recommendation** | |
| Issue Substantially Equivalent (SE) orders for the new tobacco products subject of this review. | |

**Technical Project Lead (TPL):**

Digitally signed by Habibah M. Jackson -S
Date: 2022.03.08 11:55:28 -05'00'

Habibah Jackson
Branch Chief, 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: 2022.03.22 14:30:24 -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 Appendix A.

## 1.2. REGULATORY ACTIVITY

On September 8, 2020, FDA received two Product Quantity Change SE Reports from Ashton Distributors Inc. On October 22, 2020, FDA issued an acceptance letter to the applicant.

See Appendix B for 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 | |
|---|---|---|
| | Reviewer(s) | Review Date |
| Regulatory | Fiona Kiprop | 3/4/2022 |
| Environmental Science | Christy Leppanen | 12/9/2021 |

# 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 November 16, 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 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 January 14, 2022, concludes 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 change in product quantity:

| SE Report | New Product Quantity | Predicate Product Quantity | % Change |
|---|---|---|---|
| SE0018754.PD1 | 50 Cigars | 10 Cigars | ↑400 |
| SE0018755.PD1 | 50 Cigars | 10 Cigars | ↑400 |

OS prepared memoranda[1] 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

A finding of no significant impact (FONSI) was signed by Luis Valerio, Ph.D. on December 21, 2021. The FONSI was supported by an environmental assessment prepared by FDA on December 20, 2021

## 5. CONCLUSION AND RECOMMENDATION

The product characteristics of the new and corresponding predicate tobacco products are identical except for the following change in product quantity:

- 400% increase (10 Cigars to 50 Cigars) - SE0018754.PD1 and SE0018755.PD1

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.

[1] *See* memorandum on product quantity changes, dated December 7, 2017, and addendum for deemed tobacco products, dated December 30, 2019.

## 6. APPENDICES

**Appendix A[2]. New and predicate products**

| **Common Attributes of SE Reports** | | |
|---|---|---|
| Submission date | September 8, 2020 | |
| Receipt date | September 8, 2020 | |
| Product manufacturer | (b) (4) | |
| Product category | Cigars | |
| Product subcategory | Unfiltered, Leaf-Wrapped | |
| **Attributes** | **New Tobacco Product** | **Predicate Tobacco Product** |
| **STN** | **SE0018754.PD1** | **GF1908684** |
| Product name | Ashton Senoritas Bx50 | Ashton Senoritas (10-Cigar Box) |
| Eligibility status | Not Applicable (N/A) | Grandfathered |
| Package type | Paper Box | Paper Box |
| Package quantity | 50 Cigars | 10 Cigars |
| Characterizing flavor | None | None |
| Length | 88.90 millimeters (mm) | 88.90 mm |
| Diameter | 11.91 mm | 11.91 mm |
| Wrapper material | Not Provided | Not Provided |
| **STN** | **SE0018755.PD1** | **GF1908684** |
| Product name | Ashton Connecticut Senoritas Bx50 | Ashton Senoritas (10-Cigar Box) |
| Eligibility status | N/A | Grandfathered |
| Package type | Paper Box | Paper Box |
| Package quantity | 50 Cigars | 10 Cigars |
| Characterizing flavor | None | None |
| Length | 88.90 mm | 88.90 mm |
| Diameter | 11.91 mm | 11.91 mm |
| Wrapper material | Not Provided | Not Provided |

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

**Appendix B. Amendment**

| Submission Date | Receipt Date | Application being amended | Reviewed | Brief Description |
|---|---|---|---|---|
| December 06, 2021 | December 06, 2021 | SE0018754.PD1 and SE0018755.PD1 | Yes | Response to November 29, 2021, FDA Information Request |