FDA U.S. FOOD & DRUG ADMINISTRATION

Technical Project Lead (TPL) Review: SE0006273 and SE0006274

SE0006273: Natural American Spirit 100% US Grown Pouch	
Package Type	Pouch
Package Quantity	40 grams
Characterizing Flavor	None
SE0006274: Natural American Spirit 100% US Grown Tin	
Package Type	Tin
Package Quantity	150 grams
Characterizing Flavor	None
Attributes of SE Reports	
Applicant	Santa Fe Natural Tobacco Company Inc.
Report Type	Provisional
Product Category	Roll-Your-Own Tobacco Products
Product Sub-Category	Roll-Your-Own Tobacco Filler
Recommendation	
Issue Substantially Equivalent (SE) Orders.	

Technical Project Lead (TPL):

Digitally signed by Charles Feng -S
Date: 2019.10.01 13:07:42 -04'00'

Charles Feng, Ph.D.
Chemistry Branch Chief
Division of Product Science

Signatory Decision:

☒ Concur with TPL recommendation and basis of recommendation

☐ Concur with TPL recommendation with additional comments (see separate memo)

☐ Do not concur with TPL recommendation (see separate memo)

Digitally signed by Matthew R. Holman -S
Date: 2019.10.01 13:12:28 -04'00'

Matthew R. Holman, Ph.D.
Director
Office of Science

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1. BACKGROUND

1.1. PREDICATE TOBACCO PRODUCTS

The applicant submitted the following predicate tobacco products:

SE0006273: Natural American Spirit 100% US Grown Pouch	
Product Name	Natural American Spirit 100% U.S. Grown Pouch
Package Type	Pouch
Package Quantity	40 grams
Characterizing Flavor	None
SE0006274: Natural American Spirit 100% US Grown Tin	
Product Name	Natural American Spirit 100% U.S. Grown Tins
Package Type	Tin
Package Quantity	150 grams
Characterizing Flavor	None

The predicate tobacco products are roll-your-own tobacco filler manufactured by the applicant.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

FDA received SE Reports on March 22, 2011. On March 25, 2013, FDA issued Acknowledgement and Advice/Information Request (A/I) letters. On March 21, 2013, FDA received the applicant's 30-day extension request (SE0007894) to collect the information to respond to the A/I letters[1]. On April 1, April 5, April 9, and April 11, 2013, FDA conducted teleconferences to discuss the applicant's timeline and proposal to amend the SE Reports in response to the A/I letters. On April 11, 2013, FDA received the applicant's timeline and proposal to amend the SE Reports (SE0008212). FDA issued an Extension Response letter on April 17, 2013, requesting the applicant submit a complete response to the A/I letter and any additional information prior to the start of scientific review. On February 26, 2013, FDA completed Public Health Impact (PHI) reviews for these SE Reports. FDA assigned SE0006273 and SE0006274 to PHI Tier 1. FDA issued a PHI A/I letter on May 10, 2013. On August 8, 2013 and August 9, 2013, FDA received the applicant's response to the PHI A/I letter (SE0009600, SE0009601). A detailed review of the product composition information in the amendment prompted FDA to conduct another PHI review on October 17, 2013 and reassign the SE Reports to PHI Tier 2. FDA issued a Notification letter on January 11, 2019, indicating that scientific review was expected to begin 180 days from the letter date. On July 3, 2019, FDA received an amendment containing revised SE reports (SE0015338). On July 18, 2019, FDA received the applicant's response to the Office of Compliance and Enforcement (OCE) request for information (SE0015359) noting the correct predicate product names[2].

[1] Applicant submitted amendment in advance of March 25, 2013 A/I letter in response to March 19, 2013 discussion with CTP confirming RAIS would receive additional letters requesting additional information of products listed in the March 22, 2011 submission.

[2] Amendment (SE0015359) was received in response to the Office of Compliance and Enforcement Request for information, the letter identified the predicate product as "Natural American Spirit 100% *U.S.* Grown Pouch".

Product Name	SE Report	Amendments
Natural American Spirit 100% US Grown Pouch	SE0006273	SE0007894 SE0008212 SE0009600 SE0015338 SE0015359
Natural American Spirit 100% US Grown Tin	SE0006274	SE0007894 SE0008212 SE0009601 SE0015338 SE0015359

1.3. SCOPE OF REVIEW

This review captures all regulatory, compliance, and scientific reviews completed for these SE Reports.

2. REGULATORY REVIEW

Regulatory reviews were completed by Marcella White on March 25, 2013, finding the SE Reports administratively incomplete, because of the following information not included in the SE Reports:

1. Unique identification of the new and predicate tobacco products
2. Basis for SE determination
3. Health Information Summary or Statement
4. Heating source of the new and predicate tobacco products
3. Other features
4. Statement of compliance with section 907
5. Environmental assessment
6. First commercial market date for the new tobacco products

This information was provided during the scientific review process. A regulatory review completed by Barbara Banchero on September 25, 2019, concludes the SE Reports are administratively complete.

3. COMPLIANCE REVIEW

The Office of Compliance and Enforcement (OCE) completed reviews to determine whether the applicant established that the predicate tobacco products are grandfathered products (i.e., were commercially marketed as of February 15, 2007). The OCE reviews dated July 29, 2019, conclude that the evidence submitted by the applicant is adequate to demonstrate that the predicate tobacco products are grandfathered and, therefore, are eligible predicate tobacco products.

4. SCIENTIFIC REVIEW

Scientific reviews were completed by the Office of Science (OS) for the following disciplines:

4.1. CHEMISTRY

A chemistry review was completed by Margaret Schmierer on August 19, 2019.

The chemistry review concludes that the new tobacco products have different characteristics related to product chemistry compared to the corresponding predicate tobacco products, but the differences do not cause the new tobacco products to raise different questions of public health. The review identified the following differences:

- 4% increase in (b) (4) tobacco
- Removal of (b) (4) tobacco
- 9% higher NNK quantities
- Replacement of polyethylene pouch material with paper inserted between polypropylene and COEX films (SE0006273)

The new tobacco products only contain (b) (4), whereas the corresponding predicate tobacco products contain a mixture of (b) (4) and (b) (4). The applicant provided filler HPHC data for total nicotine, NNN, and NNK in the new and predicate products, along with sufficient information on the methods and laboratory used for testing. For both SE Reports, although the mean NNK quantities increased by 9% in the new tobacco products, this increase is within the analytical variability and therefore, considered analytically equivalent. Furthermore, the nicotine and NNN quantities are also analytically equivalent. Therefore, the differences in tobacco blend do not cause the new products to raise different questions of public health.

In SE0006273, the pouch materials in the new and predicate tobacco products are different, but in this case, since the products are roll-your-own tobacco filler, this difference is not expected to impact smoke chemistry.

Therefore, the differences in characteristics between the new and corresponding predicate tobacco products do not cause the new tobacco products to raise different questions of public health from a chemistry perspective.

4.2. ENGINEERING

An engineering review was completed by Drew Katherine on August 16, 2019.

The engineering review did not identify any differences in characteristics between the new and corresponding predicate tobacco products that could cause the new tobacco products to raise different questions of public health from an engineering perspective.

4.3. TOXICOLOGY

A toxicology review was completed by Eric Beier on August 19, 2019.

The toxicology review concludes that the new tobacco products have different characteristics related to toxicology compared to the corresponding predicate tobacco products, but the

differences do not cause the new tobacco products to raise different questions of public health. The review identified the following differences:

- 4% increase in (b) (4) tobacco
- Removal of (b) (4) tobacco

The amount of (b) (4) tobacco was increased while (b) (4) was removed in the new tobacco products. The applicant provided nicotine, NNN, and NNK measurements from both new and corresponding predicate tobacco products that showed no significant changes in constituent levels.

Therefore, the differences in characteristics between the new and corresponding predicate tobacco products do not cause the new tobacco products to raise different questions of public health from a toxicology perspective.

5. ENVIRONMENTAL DECISION

Under 21 CFR 25.35(a), issuance of SE orders under section 910(a) of the FD&C Act for these provisional SE Reports (SE0006273 and SE0006274) is categorically excluded and, therefore, normally does not require the preparation of an environmental assessment (EA) or an environmental impact statement. FDA has considered whether there are extraordinary circumstances that would require the preparation of an EA and has determined that none exist.

6. CONCLUSION AND RECOMMENDATION

The following are the key differences in characteristics between the new and corresponding predicate tobacco products:

- 4% increase in (b) (4) tobacco
- Removal of (b) (4) tobacco
- 9% higher NNK quantities
- Replacement of polyethylene pouch material with paper inserted between polypropylene and COEX films (SE0006273)

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco products to raise different questions of public health. The amount of (b) (4) tobacco was increased while (b) (4) tobacco was removed in the new products. The NNK, along with nicotine and NNN measurements from both new and corresponding predicate tobacco products showed analytically equivalent quantities. For SE0006273, pouch materials are different between the new and predicate tobacco product. However, this difference is not expected to impact smoke chemistry. Therefore, the differences in characteristics between the new and corresponding predicate products do not cause the new tobacco products to raise different questions of public health.

The predicate tobacco products meet statutory requirements because it was determined that they are grandfathered tobacco products (i.e., were commercially marketed in the United States other than exclusively in test markets as of February 15, 2007).

Because the proposed action is issuing SE orders for the provisional SE Reports, it is a class of action that is categorically excluded under 21 CFR 25.35(a). FDA has considered whether there are extraordinary circumstances that would require the preparation of an environmental assessment and has determined that none exist. Therefore, the proposed action does not require preparation of an environmental assessment or an environmental impact statement.

SE order letters should be issued for the new tobacco products in SE0006273 and SE0006274, as identified on the cover page of this review.