Technical Project Lead (TPL) Review: SE0005816, SE0005826, SE0005828, and SE0005830

SE0005816: J.D.'s Blend 9 oz	
Package Type	Foil Pouch
Package Quantity	255.15 g
Tobacco Cut Size	(b) (4) mm
Characterizing Flavor	None
SE0005826: Longhorn Fine Cut Natural 408.24 g	
Package Type	Plastic Can and Lid
Package Quantity	408.24 g
Tobacco Cut Size	(b) (4) mm
Characterizing Flavor	None
SE0005828: Longhorn Long Cut Wintergreen 408.24 g	
Package Type	Plastic Can and Lid
Package Quantity	408.24 g
Tobacco Cut Size	(b) (4) mm
Characterizing Flavor	Wintergreen
SE0005830: Longhorn Long Cut Straight 408.24 g	
Package Type	Plastic Can and Lid
Package Quantity	408.24 g
Tobacco Cut Size	(b) (4) mm
Characterizing Flavor	None
Common Attributes of SE Reports	
Applicant	Swedish Match USA Inc.
Report Type	Regular
Product Category	Smokeless Tobacco Product
Product Sub-Category	Loose Chewing Tobacco (SE0005816); Loose Moist Snuff (SE0005826, SE0005828 and SE0005830)
Recommendation	
Issue Substantially Equivalent (SE) orders.	

Technical Project Lead (TPL):

Matthew J. Walters -S
2018.04.25 12:21:29 -04'00'

Matthew J. Walters, Ph.D., MPH
CDR, US Public Health Service
Deputy Director
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: 2018.04.25 12:44:35 -04'00'

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

TABLE OF CONTENTS

1. BACKGROUND 4
1.1. PREDICATE TOBACCO PRODUCTS 4
1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW 4
1.3. SCOPE OF REVIEW 8
2. REGULATORY REVIEW 8
3. COMPLIANCE REVIEW 8
4. SCIENTIFIC REVIEW 8
4.1. CHEMISTRY 8
4.2. ENGINEERING 9
4.3. MICROBIOLOGY 9
4.4. TOXICOLOGY 9
4.5. SOCIAL SCIENCE 10
5. ENVIRONMENTAL DECISION 11
6. CONCLUSION AND RECOMMENDATION 11

1. BACKGROUND

1.1. PREDICATE TOBACCO PRODUCTS

The applicant submitted the following predicate tobacco products:

SE0005816: J.D.'s Blend 9 oz	
Product Name	J.D.'s Blend 3 oz
Package Type	Foil Pouch
Package Quantity	85.05 g
Tobacco Cut Size	(b) (4) mm
Characterizing Flavor	None
SE0005826: Longhorn Fine Cut Natural 408.24 g	
Product Name	Longhorn Fine Cut Natural
Package Type	Plastic Can and Lid
Package Quantity	37.42 g
Tobacco Cut Size	(b) (4) mm
Characterizing Flavor	None
SE0005828: Longhorn Long Cut Wintergreen 408.24 g	
Product Name	Longhorn Long Cut Wintergreen
Package Type	Plastic Can and Lid
Package Quantity	37.42 g
Tobacco Cut Size	(b) (4) mm
Characterizing Flavor	Wintergreen
SE0005830: Longhorn Long Cut Straight 408.24 g	
Product Name	Longhorn Long Cut Straight
Package Type	Plastic Can and Lid
Package Quantity	37.42 g
Tobacco Cut Size	(b) (4) mm
Characterizing Flavor	None

The predicate tobacco products are loose chewing tobacco (SE0005816) or loose moist snuff (SE0005826, SE0005828, and SE0005830) smokeless tobacco products manufactured by the applicant.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

FDA received the SE Reports on March 10, 2011. On July 5, 2012, FDA received an unsolicited amendment (SE0004654) containing Environmental Assessments for all SE Reports. FDA issued Acknowledgment letters on February 20, 2013 for SE0005816 and on February 22, 2013 for SE0005826, SE0005828, and SE0005830. FDA issued Advice/Information (A/I) Request letters on April 10, 2013 for SE0005816 and on July 9, 2013 for SE0005826, SE0005828, and

SE0005830. On April 17, 2013, the FDA called the applicant to request additional information on the predicate products. The applicant submitted a solicited amendment (SE0008261) on April 23, 2013 to respond to this request for all SE Reports. The applicant submitted responses to the A/I letters on April 26, 2013 for SE0005816 (SE0008291) and on August 5, 2013 for SE0005826, SE0005828, and SE0005830 (SE0009468, SE0009470, and SE0009472). FDA issued a Notification letter on April 4, 2014 to inform the applicant that scientific review would begin on May 20, 2014 for these SE Reports. The applicant submitted amendments to these SE Reports on May 15, 2014 (SE0010480). FDA issued an A/I letter on February 19, 2016. The applicant submitted a response to the A/I letter on April 14, 2016 (SE0013309). FDA issued a Preliminary Finding (PFind) letter on July 14, 2016. As it was related to pending requests for supervisory review (AP0000016 and AP0000017) for other products from the applicant, on July 25, 2016, FDA granted an extension of time to respond to Deficiency 6 of the July 14, 2016 PFind letter, due 30 days after the issuance of FDA's decision on the related requests for supervisory review. The applicant submitted a response to PFind letter Deficiencies 1-5 on August 12, 2016 (SE0013579) for all SE Reports. The applicant submitted a response to PFind letter Deficiency 6 on February 8, 2017 (SE0013898) and March 29, 2017 (SE0014009) for all SE Reports, after FDA issued a decision on the request for supervisory review related to this deficiency. FDA issued a PFind letter on December 29, 2017 for information related to the National Environmental Policy Act (NEPA). The applicant submitted a response to all PFind letter deficiencies on January 25, 2018 (SE0014487) for all SE Reports. On March 16, 2018, FDA had a teleconference with the applicant to request further clarification on Table 6.1 of Deficiency 6 of the January 25, 2018, response to the PFind letter. FDA received applicant's response to the March 15, 2018 (SE0014581).

These SE Reports were received on March 10, 2011, and were initially considered provisional SE Reports based on the receipt date. However, the initial submission did not include the date the new tobacco product was first introduced or delivered for introduction into interstate commerce for commercial marketing in the United States (FCM). When the applicant provided additional information in response to FDA inquiries in April 2013 and August 2013 (see previous paragraph), the FCM dates were provided as follows: SE0005816 on July 17, 2012, SE0005826 on September 2, 2011, SE0005828 on August 30, 2011, and SE0005830 on December 12, 2011. A "provisional" SE Report is one that was submitted prior to March 22, 2011, for a new tobacco product that was first commercially marketed between February 15, 2007, and March 22, 2011. New tobacco products that are the subject of provisional SE Reports may remain on the market unless FDA finds the products not substantially equivalent (NSE) to a predicate product. As the FCM dates of the new products referenced in this review were after March 22, 2011, the applications do not meet the definition for a provisional SE Report and are, therefore, considered regular SE Reports.

However, due to specific circumstances in this case, FDA exercised enforcement discretion and did not take enforcement action against these four products without a required marketing authorization. The applicant was first notified that these were considered regular SE Reports in the April 4, 2014 Notification letter. In response to this letter, the applicant contacted FDA to verify if there was an error within the Notification letter. A teleconference was held on April 28, 2014, where FDA provided the definition of a provisional product and noted that, as these products were not introduced to the US market until after March 22, 2011, they fall outside of the definition of a provisional product. On May 15, 2014 and July 18, 2016, FDA received amendments (SE0010480 and SE0013490) from the applicant that disputed the status of the SE Reports as regular reports and stated their position that these products could be legally marketed and should be considered provisional SE Reports. To date, FDA has maintained the position that these are regular SE Reports and all correspondence have included language stating: “You may not legally market the new tobacco product described in this SE Report until FDA issues an order finding the product to be substantially equivalent to a predicate tobacco product (section 910(a)(2)(A) of the FD&C Act)”. On February 23, 2017, FDA held a teleconference to clarify to the applicant that these are regular SE Reports.

Product Name	SE Report	Amendments
J.D.'s Blend 9 oz	SE0005816	SE0004654 SE0008261 SE0008291 SE0010480 SE0013309 SE0013490 SE0013579 SE0013898 SE0014009 SE0014487 SE0014581
Longhorn Fine Cut Natural 408.24 g	SE0005826	SE0004654 SE0008261 SE0009468 SE0010480 SE0013309 SE0013490 SE0013579 SE0013898 SE0014009 SE0014487 SE0014581
Longhorn Long Cut Wintergreen 408.24 g	SE0005828	SE0004654 SE0008261 SE0009470 SE0010480 SE0013309 SE0013490 SE0013579 SE0013898 SE0014009 SE0014487 SE0014581
Longhorn Long Cut Straight 408.24 g	SE0005830	SE0004654 SE0008261 SE0009472 SE0010480 SE0013309 SE0013490 SE0013579 SE0013898 SE0014009 SE0014487 SE0014581

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 on April 10, 2013 and June 7, 2013 for SE0005816 by Stephanie Redus and Joanna Randazzo. Regulatory reviews were completed on July 9, 2013 and November 21, 2013 for SE0005826, SE0005828, and SE0005830 by Stephanie Redus.

The final reviews conclude that 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 in the United States other than exclusively in test markets as of February 15, 2007). The OCE reviews dated April 30, 2014, conclude that the evidence submitted by the applicant is adequate to demonstrate that the predicate tobacco products are eligible predicate tobacco products.

OCE also completed a review to determine whether the new tobacco 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 April 24, 2018 concludes that the new tobacco products are in compliance with the FD&C Act.

4. SCIENTIFIC REVIEW

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

4.1. CHEMISTRY

Chemistry reviews were completed by Tricia Johnson on August 11, 2014, and by Kimberly Agnew-Heard on May 31, 2016, and March 24, 2017.

The final chemistry review concludes that the new tobacco products have different characteristics related to product composition 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 related to product composition:

- Package quantity
- Tobacco blend composition (SE0005816 and SE0005826 only)

The package quantity differences are addressed by the social science reviewer. The tobacco blends for two of the new tobacco products differ from the corresponding predicate tobacco products. However, the quantities of HPHCs in the new tobacco products are not significantly different from those in the corresponding predicate tobacco products. Therefore, the differences in characteristics related to product composition between the new and corresponding predicate tobacco products do not cause the new tobacco products to raise different questions of public health.

4.2. ENGINEERING

Engineering reviews were completed by Julie Morabito on August 4, 2014, and by Aarthi Arab on June 5, 2016 and March 24, 2017.

The final engineering review concludes that the new tobacco products have the same characteristics related to product design as the corresponding predicate tobacco products.

4.3. MICROBIOLOGY

Microbiology reviews were completed by Michael Koenig on August 1, 2014 and by Prashanthi Mulinti on June 3, 2016.

The final microbiology review concludes that the new tobacco products have different characteristics related to product microbiology 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 related to product microbiology:

- Decreases in NNN, NNK, and total TSNAs over time
- Decreases in nitrite (SE0005816, SE0005826, and SE0005828 only)
- Increases in nitrate (SE0005826, SE0005828, and SE0005830 only)

Decreases in the HPHCs NNN, NNK, and total TSNAs over time indicates reduced microbial activity in the new tobacco products relative to the corresponding predicate tobacco products. Increases in nitrate and decreases in nitrite are expected to result in lower TSNAs levels, as observed. Therefore, the differences in characteristics related to microbiology between the new and corresponding predicate tobacco products do not cause the new tobacco products to raise different questions of public health.

4.4. TOXICOLOGY

Toxicology reviews were completed by Zheng Tu on January 4, 2016 and by Sang Park on June 3, 2016 and March 31, 2017.

The final toxicology review concludes that the new tobacco products have different characteristics related to product 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 related to product toxicology:

- Increase in (b) (4) [redacted] (SE0005826 only)
- Increase in (b) (4) [redacted] (SE0005826 only)

The increases in the quantities of these two ingredients are not sufficient to be of a toxicological concern. Therefore, the differences in characteristics related to toxicology between the new and corresponding predicate tobacco products do not cause the new tobacco products to raise different questions of public health.

4.5. SOCIAL SCIENCE

Social science reviews were completed by David Portnoy on July 14, 2014 and by Elisabeth Sherman on June 8, 2016.

The final social science review concludes that the characteristics which may affect consumer perception and use are different for the new and 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 related to consumer perception and use:

- Increase in package quantity from 3 oz. to 9 oz. (SE0005816 only)
- Increase in package quantity from 37.32 grams to 408.24 grams (SE0005826, SE0005828, and SE0005830 only)

The social science review states that currently FDA is not aware of any research that provides scientific evidence for the relationship between the package quantity of a smokeless tobacco product and consumer use. 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 social science perspective.

To clarify the social science review, there is no available scientific evidence on the influence differences in package quantity has on consumer perceptions of harm or use intentions to indicate that these differences could cause the new tobacco products to raise different questions of public health from a social science perspective. Moreover, the Office of Science (OS) prepared a memorandum[1] summarizing its current thinking on product quantity, which further supports OS' determination that, at this time, changes in tobacco product quantity does not cause new tobacco products to raise different questions of public

[1] See memorandum on product quantity changes dated December 7, 2017.

health. Consequently, the change in product quantity does not cause the new tobacco products to raise different questions of public health from a social science perspective.

The review also evaluated the health information summary. The applicant review originally submitted a health information summary. The first social science review concluded that the health information summary violated section 911(b)(2)(A)(i)(II) of the FD&C Act. In response to the A/I letter, the applicant rescinded the health information summary, indicating that it would provide such information upon request by any party. Therefore, the final review did not identify a deficiency related to the health information summary.

5. ENVIRONMENTAL DECISION

Environmental reviews were completed by Christine Modovsky on November 13, 2017 and April 25, 2018.

The final environmental review found the manufacturing facility where the new products will be manufactured is in violation of the Clean Water Act. Therefore, additional information is needed to determine whether to prepare an Environmental Impact Statement (EIS) or Finding Of No Significant Impact (FONSI).

6. CONCLUSION AND RECOMMENDATION

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

- Increases in package quantity
- Differences in tobacco blend composition
- Decreases in HPHCs over time: NNN, NNK, total TSNAs
- Decreases in nitrite (SE0005816, SE0005826, and SE0005828 only)
- Increases in nitrate (SE0005826, SE0005828, and SE0005830 only)
- Increase in (b) (4) [redacted] (SE0005826 only)
- Increase in (b) (4) [redacted] (SE0005826 only)

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco products to raise different questions of public health. Overall, there were minimal differences in the tobacco blends and ingredients between the new and corresponding predicate tobacco products, resulting in decreases or minimal differences in HPHCs between the new and corresponding predicate tobacco products. The social science review and the finalized memorandum[3] conclude that, based on OS's experience and the currently available evidence, the difference in product quantity do not cause the new tobacco products to raise different questions of public health. I concur with this conclusion. 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 products (i.e., were commercially marketed in the United States other than exclusively in test markets as of February 15, 2007).

All of the scientific reviews conclude that the differences between the new and corresponding predicate tobacco products are such that the new tobacco products do not raise different questions of public health. I concur with these reviews and recommend that SE order letters be issued.

However, FDA has reviewed the applicant's EA and is requesting additional information to determine whether finding these new tobacco products substantially equivalent requires preparation of an Environmental Impact Statement (EIS) or Finding of No Significant Impact (FONSI). An inadequate resolution of this issue may delay or prevent issuance of SE order letters.

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

1. All of your SE Reports lack sufficient information on the environmental effects from manufacturing the new tobacco products. In April 2018, FDA became aware that the U.S. Environmental Protection Agency's "Enforcement and Compliance History Online" (ECHO) database indicates "Noncompliance" or "Violation" status concerning the manufacturing facility of the new products and the requirements of the Clean Water Act. Evidence of compliance with relevant federal, state, and local environmental laws and regulations is in part relevant information for assessing environmental impacts due to manufacturing the new tobacco products. The significance of environmental impacts (and thus the justification for a finding of no significant impact) is in part indicated by whether the actions may violate federal, state, or local law or requirements imposed for the protection of the environment (40 CFR 1508.27(b)(10)). Thus, although our scientific review of your SE Reports may support a scientific finding of SE, FDA cannot complete its review of your applications until these new products are in compliance with these requirements.

    a. Provide updated information on the status of the violation listed in ECHO, such as documentation from the Kentucky Department for Environmental Protection (KYDEP) that the violation listed in ECHO has been resolved or that a solution satisfactory to KYDEP is in progress.

    b. Provide a statement, and support for the statement, that you comply with relevant federal, state, and local environmental laws and regulations. Otherwise, discuss potential violations (other than the Clean Water Act violation described above) of any environmental laws and regulations and, if applicable, your actions to achieve compliance with the regulations.

If the applicant adequately responds to the request and an EIS or FONSI is completed, SE order letters should be issued for the new tobacco products in SE0005816, SE0005826, SE0005828, and SE0005830, as identified on the cover page of this review.