

Technical Project Lead (TPL) Review:

SE0007837-SE0007839, SE0007842, SE0009163, and SE0009164

SE0007837: Exeter Menthol Gold 100 SP	
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	99 mm
Diameter	7.89 mm
Ventilation	28%
Characterizing Flavor	Menthol
SE0007838: Exeter Menthol Gold King SP	
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	84 mm
Diameter	7.89 mm
Ventilation	14%
Characterizing Flavor	Menthol
SE0007839: Exeter Menthol King SP	
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	84 mm
Diameter	7.89 mm
Ventilation	0%
Characterizing Flavor	Menthol
SE0007842: Exeter Red King SP	
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	84 mm
Diameter	7.89 mm
Ventilation	0%
Characterizing Flavor	None
SE0009163: Edgefield Silver 100 Box	
Package Type	Box
Package Quantity	20 cigarettes
Length	99 mm
Diameter	7.89 mm
Ventilation	40%
Characterizing Flavor	None

SE0009164: Edgefield Silver King Box	
Package Type	Box
Package Quantity	20 cigarettes
Length	84 mm
Diameter	7.89 mm
Ventilation	35%
Characterizing Flavor	None
Common Attributes of SE Reports	
Applicant	Xcaliber International Ltd., LLC
Report Type	Provisional
Product Category	Cigarette
Product Sub-Category	Combusted Filtered
Recommendation	
Issue Substantially Equivalent (SE) orders.	

Technical Project Lead (TPL):

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2018.06.06 10:22:54 -04'00'

Matthew J. Walters, Ph.D., MPH
CDR, U.S. 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: 2018.06.06 10:38:53 -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:

SE0007837: Exeter Menthol Gold 100 SP	
Product Name	Exeter Menthol Light 100 SP
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	99 mm
Diameter	7.89 mm
Ventilation	28%
Characterizing Flavor	Menthol
SE0007838: Exeter Menthol Gold King SP	
Product Name	Exeter Menthol Light King SP
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	84 mm
Diameter	7.89 mm
Ventilation	14%
Characterizing Flavor	Menthol
SE0007839: Exeter Menthol King SP	
Product Name	Exeter Menthol King SP
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	84 mm
Diameter	7.89 mm
Ventilation	0%
Characterizing Flavor	Menthol
SE0007842: Exeter Red King SP	
Product Name	Exeter Full Flavor King SP
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	84 mm
Diameter	7.89 mm
Ventilation	0%
Characterizing Flavor	None

SE0009163: Edgefield Silver 100 Box	
Product Name	Exeter Ultra Light 100 SP
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	99 mm
Diameter	7.89 mm
Ventilation	40%
Characterizing Flavor	None
SE0009164: Edgefield Silver King Box	
Product Name	Exeter Ultra Light King SP
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	84 mm
Diameter	7.89 mm
Ventilation	35%
Characterizing Flavor	None

The predicate tobacco products are combusted filtered cigarettes manufactured by the applicant.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

FDA received four Substantial Equivalence (SE) Reports, SE0007837-SE0007839 and SE0007842 from Xcaliber International Ltd., LLC (Xcaliber) on March 22, 2011. On April 8, 2013, FDA issued Acknowledgement letters for these four reports. On April 9, 2013, FDA issued Advice/Information Request (A/I) letters for these four SE Reports. On May 8, 2013, in response to information submitted verifying all products being marketed by Xcaliber, a telecon was held where the applicant informed FDA they had erroneously identified a product as (b) (4)/Edgefield (b) (4). Xcaliber should have separated the products as (b) (4) and Edgefield Silver. The applicant agreed to submit documentation showing the Edgefield product line is marketed under "Silver" designation. On May 13, 2013, FDA received responses to the April 9, 2013, A/I letters for SE0007837 (SE0008502), SE0007838 (SE0008501), SE0007839 (SE0008533), and SE0007842 (SE0008535). On May 15, 2013, in response to the May 8, 2013, telecon, FDA received proof of marketing of the Edgefield Silver product line (SE0008572). On June 13, 2013, FDA reviewed the applicant's amendment (SE0008572) and determined it was appropriate to create new SE Reports for Edgefield Silver 100 Box, SE0009163, and Edgefield Silver King Box, SE0009164. On July 18, 2013 and July 19, 2013, FDA issued Acknowledgement letter for SE0009163 and SE0009164, respectively. On August 15, 2013, FDA received responses to the A/I letters for SE0009163 and SE0009164. On June 9, 2017, FDA issued a Notification letter for all six SE Reports subject of this review indicating scientific review was expected to begin on July 24, 2017. On July 21, 2017, FDA received a response to the Notification letter introducing new predicate tobacco products for all SE Reports (SE00014209). On August 23, 2017, in response to a request from the Office of Compliance and Enforcement, FDA received evidence of commercial marketing of predicate tobacco products (SE0014253). On November 2,

2017, FDA issued an A/I letter for all SE Reports. On December 22, 2017, FDA received the applicant's response to A/I letter (SE0014451). On February 13, 2018, FDA issued a Preliminary Finding letter (Pfind) for all SE Reports. On March 14, 2018, FDA received the applicant's response to the Pfind letter (SE0014578).

Product Name	SE Report	Amendments
Exeter Menthol Gold 100 SP	SE0007837	SE0008502 SE0014209 SE0014253 SE0014451 SE0014578
Exeter Menthol Gold King SP	SE0007838	SE0008501 SE0014209 SE0014253 SE0014451 SE0014578
Exeter Menthol King SP	SE0007839	SE0008533 SE0014209 SE0014253 SE0014451 SE0014578
Exeter Red King SP	SE0007842	SE0008535 SE0014209 SE0014253 SE0014451 SE0014578
Edgefield Silver 100 Box	SE0009163	SE0008572 SE0009611 SE0014209 SE0014253 SE0014451 SE0014578
Edgefield Silver King Box	SE0009164	SE0008572 SE0009612 SE0014209 SE0014253 SE0014451 SE0014578

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 Nathan Hurley on April 9, 2013, and Anne Martin on May 27, 2013, for SE0007837-SE0007839 and SE0007842. Regulatory reviews were completed by Anne Martin on July 19, 2013, and August 28, 2013, for SE0009163 and July 19, 2013, and August 29, 2013, for SE0009164. A regulatory review for all SE Reports was completed by Kristopher Van Amburg on May 9, 2018.

The final review concludes 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 as of February 15, 2007). The OCE reviews dated August 25, 2017, 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.¹

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 Salome Bhagan, on October 23, 2017, February 2, 2018 and April 26, 2018.

The final 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:

- Addition of fire standards compliant (FSC) cigarette paper in place of non-FSC cigarette paper
- Addition of (b) (4) (b) (4) mg/cig in the cigarette paper
- Increase by 4% of (b) (4) in the cigarette paper
- Decrease by 12% of (b) (4) in the cigarette paper
- Increase in tar, nicotine and CO yields under the ISO smoking regimen (11%-24%, 8-15%, and 20%-30%, respectively) for all SE Reports
- Increase in tar and CO yields under the CI smoking regimen (5%-18% and 8%-23%, respectively) for all SE Reports
- Increase in nicotine under the CI smoking regimen (1%-8%) for SE0007837-SE0007839, SE0007842, and SE0009163

The applicant provided information to fully identify the composition of the new and predicate products by providing detailed information uniquely identifying the tobacco for the new and

¹ Addendum reviews were completed on May, 2018, to include characterizing flavor for the predicate products; the conclusions in these addendum reviews did not differ from that in the original August 2017, reviews.

corresponding predicate products including an explanation of the tobacco grading classification and a description. The most noteworthy change between the new and predicate tobacco products is the introduction of FSC cigarette paper. The introduction of FSC cigarette paper is known to increase TNCO yields as observed for these tobacco products. However, at this time, based on the information available and CTP's scientific understanding and experience with non-FSC to FSC cigarette paper modifications that are limited to changes in tobacco additives and do not result in other significant changes to the product (e.g., no changes to blend, filter, design parameters such as ventilation), the benefit of using FSC paper in cigarettes to reduce household fires is anticipated to outweigh any potential increased health risks from the small increases in HPHC exposures that may occur from the use of FSC paper. 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 related to product chemistry.

4.2. ENGINEERING

Engineering reviews were completed by Yan Sun on October 19, 2017, by Samantha Spindel, on February 2, 2018 and by Robert Meyer on May 3, 2018.

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

- Addition of fire standards compliant (FSC) cigarette paper in place of non-FSC cigarette paper
- Increased puff count (6%-14%)
- Decreased cigarette paper base paper porosity (8%)

The applicant provided the target specifications and range limits for the design parameters and the test data for the design parameters which were all within the quantitative acceptance criteria. The cigarette papers of the new products contained FSC cigarette paper whereas the predicate products contained non-FSC cigarette paper. With this change, there were minimal changes in some of the product design features such as cigarette paper base paper basis weight, cigarette paper base paper porosity, and puff count. Although these changes may affect product performance, the benefit of using FSC paper in cigarettes to reduce household fires is anticipated to outweigh any potential increased health risks from the increases in HPHC exposures that may occur from the design parameter changes. 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 related to product engineering.

4.3. TOXICOLOGY

A Toxicology review was completed by Yanling Chen on October 27, 2017.

The final 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:

- Addition of FSC cigarette paper in place of non-FSC cigarette paper

The only change in the new products from the corresponding predicate products is the change from non-FSC paper to FSC paper. This paper change causes the new products to have increased paper mass, base paper porosity, added band, added (b) (4), and increased (b) (4), as compared to the corresponding predicate products. The benefit of using FSC paper in cigarettes to reduce household fires and related human injuries is thought to outweigh any potential increased health risk associated with small HPHC increases due to using FSC paper. 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 (SE0007837 - SE0007839, SE0007842, SE0009163, and SE0009164) 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 predicate tobacco products:

- Addition of fire standards compliant (FSC) cigarette paper in place of non-FSC cigarette paper
- Addition of (b) (4) (b) (4) mg/cig) in the cigarette paper
- Increase by 4% of (b) (4) in the cigarette paper
- Decrease by 12% of (b) (4) in the cigarette paper
- Increase in tar, nicotine and CO yields under the ISO smoking regimen (11%-24%, 8-15%, and 20%-30%, respectively) for all SE Reports
- Increase in tar and CO yields under the CI smoking regimen (5%-18% and 8%-23%, respectively) for all SE Reports
- Increase in nicotine under the CI smoking regimen (1%-8%) for SE0007837-SE0007839, SE0007842, and SE0009163
- Increased puff count (6%-14%)
- Decreased cigarette paper base paper porosity (8%)

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco products to raise different questions of public health. The tobacco composition was identical between the new and corresponding predicate tobacco products. There were some minor differences in ingredients due to the change from non-FSC cigarette paper in the predicate tobacco products to FSC cigarette paper in the new tobacco products. With these changes, there was an increase in tar and carbon monoxide yields under both the ISO and CI smoking conditions. However, at this time, based on the information available and CTP's scientific understanding and experience with non-FSC to FSC cigarette paper modifications that are limited to changes in tobacco additives and do not result in other significant changes to the product (e.g., no changes to blend, filter, design parameters such as ventilation), the benefit of using FSC paper in cigarettes to reduce household fires is anticipated to outweigh any potential increased health risks from the small increases in HPHC exposures that may occur from the use of FSC paper. There were some small changes in the product design features including a decrease in cigarette paper base paper porosity (8%) and an increase in puff count (6 -14%), however, these changes are minor and are not expected to materially affect the performance of the product in the context of the health benefits to switching to FSC cigarette paper. 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).

In addition, 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.

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 SE0007837-SE0007839, SE0007842, SE0009163, and SE0009164, as identified on the cover page of this review.