

Technical Project Lead (TPL) Review:

SE0002070 - SE0002073, SE0002075, SE0002076, SE0002080 - SE0002083, SE0002085, SE0002088, and SE0007812 - SE0007814

SE0002070: Echo Blue 100 Box	
Package Type	Box
Package Quantity	20 cigarettes
Length	99 mm
Diameter	7.89 mm
Ventilation	31%
Characterizing Flavor	None
SE0002071: Echo Blue King Box	
Package Type	Box
Package Quantity	20 cigarettes
Length	84 mm
Diameter	7.89 mm
Ventilation	28%
Characterizing Flavor	None
SE0002072: Echo Gold 100 Box	
Package Type	Box
Package Quantity	20 cigarettes
Length	99 mm
Diameter	7.89 mm
Ventilation	20%
Characterizing Flavor	None
SE0002073: Echo Gold King Box	
Package Type	Box
Package Quantity	20 cigarettes
Length	84 mm
Diameter	7.89 mm
Ventilation	19%
Characterizing Flavor	None

SE0002075: Echo Menthol Gold 100 Box	
Package Type	Box
Package Quantity	20 cigarettes
Length	99 mm
Diameter	7.89 mm
Ventilation	29%
Characterizing Flavor	Menthol
SE0002076: Echo Menthol Gold King Box	
Package Type	Box
Package Quantity	20 cigarettes
Length	84 mm
Diameter	7.89 mm
Ventilation	16%
Characterizing Flavor	Menthol
SE0002080: Exeter Blue 100 Box	
Package Type	Box
Package Quantity	20 cigarettes
Length	99 mm
Diameter	7.89 mm
Ventilation	40%
Characterizing Flavor	None
SE0002081: Exeter Menthol Gold 100 Box	
Package Type	Box
Package Quantity	20 cigarettes
Length	99 mm
Diameter	7.89 mm
Ventilation	28%
Characterizing Flavor	Menthol
SE0002082: Exeter Gold King Box	
Package Type	Box
Package Quantity	20 cigarettes
Length	84 mm
Diameter	7.89 mm
Ventilation	20%
Characterizing Flavor	None

SE0002083: Exeter Gold 100 Box	
Package Type	Box
Package Quantity	20 cigarettes
Length	99 mm
Diameter	7.89 mm
Ventilation	24%
Characterizing Flavor	None
SE0002085: Exeter Blue King Box	
Package Type	Box
Package Quantity	20 cigarettes
Length	84 mm
Diameter	7.89 mm
Ventilation	35%
Characterizing Flavor	None
SE0002088: Exeter Menthol Gold King Box	
Package Type	Box
Package Quantity	20 cigarettes
Length	84 mm
Diameter	7.89 mm
Ventilation	14%
Characterizing Flavor	Menthol
SE0007812: Echo Blue 100 SP	
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	99 mm
Diameter	7.89 mm
Ventilation	31%
Characterizing Flavor	None
SE0007813: Echo Blue King SP	
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	84 mm
Diameter	7.89 mm
Ventilation	28%
Characterizing Flavor	None

SE0007814: Echo Gold 100 SP	
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	99 mm
Diameter	7.89 mm
Ventilation	20%
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):

Matthew J. Walters -S
2018.05.03 16:58:22 -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: 2018.05.04 06:55:10 -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:

SE0002070: Echo Blue 100 Box	
Product Name	Echo Ultra Light 100 Box
Package Type	Box
Package Quantity	20 cigarettes
Length	99 mm
Diameter	7.89 mm
Ventilation	31%
Characterizing Flavor	None
SE0002071: Echo Blue King Box	
Product Name	Echo Ultra Light King Box
Package Type	Box
Package Quantity	20 cigarettes
Length	84 mm
Diameter	7.89 mm
Ventilation	28%
Characterizing Flavor	None
SE0002072: Echo Gold 100 Box	
Product Name	Echo Light 100 Box
Package Type	Box
Package Quantity	20 cigarettes
Length	99 mm
Diameter	7.89 mm
Ventilation	20%
Characterizing Flavor	None
SE0002073: Echo Gold King Box	
Product Name	Echo Light King Box
Package Type	Box
Package Quantity	20 cigarettes
Length	84 mm
Diameter	7.89 mm
Ventilation	19%
Characterizing Flavor	None

SE0002075: Echo Menthol Gold 100 Box	
Product Name	Echo Menthol Light 100 Box
Package Type	Box
Package Quantity	20 cigarettes
Length	99 mm
Diameter	7.89 mm
Ventilation	29%
Characterizing Flavor	Menthol
SE0002076: Echo Menthol Gold King Box	
Product Name	Echo Menthol Light King Box
Package Type	Box
Package Quantity	20 cigarettes
Length	84 mm
Diameter	7.89 mm
Ventilation	16%
Characterizing Flavor	Menthol
SE0002080: Exeter Blue 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
SE0002081: Exeter Menthol Gold 100 Box	
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

SE0002082: Exeter Gold King Box	
Product Name	Exeter Light King SP
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	84 mm
Diameter	7.89 mm
Ventilation	20%
Characterizing Flavor	None
SE0002083: Exeter Gold 100 Box	
Product Name	Exeter Light 100 SP
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	99 mm
Diameter	7.89 mm
Ventilation	24%
Characterizing Flavor	None
SE0002085: Exeter Blue 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
SE0002088: Exeter Menthol Gold King Box	
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

SE0007812: Echo Blue 100 SP	
Product Name	Echo Ultra Light 100 SP
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	99 mm
Diameter	7.89 mm
Ventilation	31%
Characterizing Flavor	None
SE0007813: Echo Blue King SP	
Product Name	Echo Ultra Light King SP
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	84 mm
Diameter	7.89 mm
Ventilation	28%
Characterizing Flavor	None
SE0007814: Echo Gold 100 SP	
Product Name	Echo Light 100 SP
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	99 mm
Diameter	7.89 mm
Ventilation	20%
Characterizing Flavor	None

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

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On March 22, 2011, FDA received Substantial Equivalence (SE) Reports from Xcaliber International Ltd, LLC. On August 17, 2011, FDA issued Acknowledgment letters for SE0002070-SE0002073, SE0002075, SE0002076, SE0002080-SE0002083, SE0002085, and SE0002088. On March 25, 2013, FDA identified that the applicant had submitted multiple tobacco products bundled as one product and recreated separate SE Reports (SE0007812-SE0007814) for each new product. On April 8, 2013, FDA issued Acknowledgment letters for SE0007812-SE0007814. On April 8, 2013, FDA issued a Correction letter for SE0002070-SE0002073, SE0002075, SE0002076, SE0002080-SE0002083, SE0002085, and SE0002088 to correct the tobacco product names. On April 9, 2013, FDA issued Advice/Information Request letters (A/I letters) for SE0007812-SE0007814 and on April 24, 2013, for SE0002070-SE0002073, SE0002075, SE0002076, SE0002080-SE0002083, SE0002085, SE0002088. On May 13, 2013, FDA received the

applicant’s response¹ to the A/I Request letters. On January 11, 2017, FDA issued a Notification letter, indicating scientific review was expected to begin on February 25, 2017. On February 6, 2017, FDA received a solicited amendment SE0013892 correcting the predicate product information for SE0002075, SE0002076, SE0002081, and SE0002088. On February 7, 2017, FDA received amendment SE0013897 with additional corrections to the predicate product information for SE0002075, SE0002076, SE0002081, and SE0002088. On February 24, 2017, FDA received the response to the Notification letter (SE0013940). On April 11, 2017, FDA issued a Preliminary Finding letter. On May 10, 2017, FDA received the response to the Preliminary Finding letter (SE0014081). On May 18, 2017, FDA received amendment SE0014092 clarifying that the applicant’s previous response that characterizing flavors as “Not Applicable” should be “none.” On September 1, 2017, FDA issued A/I letters. On October 31, 2017, FDA received response to the A/I letter (SE0014394). On January 3, 2018, FDA issued a Preliminary Finding letter. On February 2, 2018, FDA received a response to the Preliminary Finding letter (SE0014500).

Product Name	SE Report	Amendments
Echo Blue 100 Box	SE0002070	SE0008554 SE0013940 SE0014081 SE0014092 SE0014394 SE0014500
Echo Blue King Box	SE0002071	SE0008566 SE0013940 SE0014081 SE0014092 SE0014394 SE0014500
Echo Gold 100 Box	SE0002072	SE0008536 SE0013940 SE0014081 SE0014092 SE0014394 SE0014500
Echo Gold King Box	SE0002073	SE0008515 SE0013940 SE0014081 SE0014092 SE0014394 SE0014500

¹ SE0008554, SE0008566, SE0008536, SE0008515, SE0008563, SE0008562, SE0008505, SE0008537, SE0008506, SE0008507, SE0008504, SE0008539, SE0008556, SE0008555, SE0008558

Product Name	SE Report	Amendments
Echo Menthol Gold 100 Box	SE0002075	SE0008563 SE0013889 SE0013892 SE0013897 SE0013940 SE0014081 SE0014092 SE0014394 SE0014500
Echo Menthol Gold King Box	SE0002076	SE0008562 SE0013889 SE0013892 SE0013897 SE0013940 SE0014081 SE0014092 SE0014394 SE0014500
Exeter Blue 100 Box	SE0002080	SE0008505 SE0013940 SE0014081 SE0014092 SE0014150 SE0014394 SE0014500
Exeter Menthol Gold 100 Box	SE0002081	SE0008537 SE0013889 SE0013892 SE0013897 SE0013940 SE0014081 SE0014092 SE0014150 SE0014394 SE0014500
Exeter Gold King Box	SE0002082	SE0008506 SE0013940 SE0014081 SE0014092 SE0014150 SE0014394 SE0014500

Product Name	SE Report	Amendments
Exeter Gold 100 Box	SE0002083	SE0008507 SE0013940 SE0014081 SE0014092 SE0014150 SE0014394 SE0014500
Exeter Blue King Box	SE0002085	SE0008504 SE0013940 SE0014081 SE0014092 SE0014150 SE0014394 SE0014500
Exeter Menthol Gold King Box	SE0002088	SE0008539 SE0013889 SE0013892 SE0013897 SE0013940 SE0014081 SE0014092 SE0014150 SE0014394 SE0014500
Echo Blue 100 SP	SE0007812	SE0008556 SE0013940 SE0014081 SE0014092 SE0014394 SE0014500
Echo Blue King SP	SE0007813	SE0008555 SE0013940 SE0014081 SE0014092 SE0014394 SE0014500
Echo Gold 100 SP	SE0007814	SE0008558 SE0013940 SE0014081 SE0014092 SE0014394 SE0014500

1.3. SCOPE OF REVIEW

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

2. REGULATORY REVIEW

Acceptance reviews were completed by Nathan Hurley on April 19, 2013, and Anne Martin on May 27, 2013, for SE0002070-SE0002073, SE0002075-SE0002076, SE0002080-SE0002083, and SE0002088. Acceptance reviews were completed by Nathan Hurley on April 24, 2013, and Anne Martin on May 3, 2013, for SE0002085. Acceptance reviews were completed by Nathan Hurley on April 9, 2013, and Anne Martin on May 27, 2013, for SE0007812-SE0007814. On April 11, 2017, a regulatory review was completed by Khemry Min, concluding that the SE Reports are administratively incomplete. On April 25, 2018, a regulatory review was completed by Kristopher Van Amburg. The regulatory review concluded 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 June 15, 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.²

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 Stephanie Daniels on August 11, 2017, and December 20, 2017.

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

² Addendum reviews were completed on April 25, 2018 (SE0002070-SE0002073, SE0002075-SE0002076, SE0002080-SE0002081, SE0002083, SE0002085, SE0002088, SE0007812-SE0007814), and April 27, 2018 (SE0002082), to clarify the characterizing flavor for the predicate and new tobacco products. Since the initial grandfather determination on June 15, 2017, was based on the same product characteristics apart from characterizing flavor, the addendum review does not change the conclusion of the initial determination. An Addendum review was completed on August 25, 2017, for SE0002081. The review did not change the conclusion of the original review.

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

- Addition of fire standards compliant (FSC) cigarette paper in place of non-FSC cigarette paper
- Addition of (b) (4) to the cigarette paper
- Decrease by 12% in (b) (4) in the cigarette paper
- Increase in tar and CO yields under the ISO smoking regimen (11%-24% and 16%-28%, respectively)
- Increase in tar and CO yields under the CI smoking regimen (12%-25% and 11%-18%, respectively)

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 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 composition.

4.2. ENGINEERING

Engineering reviews were completed by Karen Coyne on August 11, 2017, December 22, 2017, and March 14, 2018.

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

- Addition of FSC cigarette paper in place of non-FSC cigarette paper
- Decreased cigarette paper base paper basis weight (4%)
- Decreased cigarette paper base paper porosity (8%)
- Increased puff count (4 - 11%)

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 design.

4.3. TOXICOLOGY

A toxicology review was completed by Prince Awuah on August 10, 2017.

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 issue related to toxicology:

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

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 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 toxicology.

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 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 differences in characteristics between the new and predicate tobacco products:

- Addition of FSC cigarette paper in place of non-FSC cigarette paper
- Addition of (b) (4) to the cigarette paper
- Decrease in (b) (4) in the cigarette paper (12%)
- Increased tar and CO yields under the ISO smoking regimen (11%-24% and 16%-28%, respectively)
- Increased tar and CO yields under the CI smoking regimen (12%-25% and 11%-18%, respectively)
- Decreased cigarette paper base paper basis weight (4%)
- Decreased cigarette paper base paper porosity (8%)
- Increased puff count (4-11%)

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 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 basis weight (4%), decrease in cigarette paper base paper porosity (8%), and an increase in puff count (4 – 11%), 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 tobacco 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 these 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 SE0002070 - SE0002073, SE0002075, SE0002076, SE0002080 - SE0002083, SE0002085, SE0002088, and SE0007812 - SE0007814, as identified on the cover page of this review.