U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

May 10, 2018

SUBSTANTIALLY EQUIVALENT

Xcaliber International, LTD, LLC
Attention: Eric B. Estes, General Counsel
One Tobacco Road
Pryor, OK 74361-4002

FDA Submission Tracking Number (STN): SE0002080

Dear Mr. Estes:

The Food and Drug Administration (FDA) completed review of your Report Preceding Introduction of Certain Substantially Equivalent Products into Interstate Commerce (SE Report), submitted under section 905(j) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), for the following tobacco product:

New Tobacco Product

Date of Submission:	March 22, 2011
Date of Receipt:	March 22, 2011
Product Manufacturer:	Xcaliber International LTD, LLC
Product Name:[1]	Exeter Blue 100 Box
Product Category:	Cigarettes
Product Sub-Category:	Combusted, Filtered
Package Type:	Box
Package Quantity:	20 cigarettes
Characterizing Flavor:	None
Length:	99 mm
Diameter:[2]	7.89 mm
Ventilation:	40.0%

Based on our review of your SE Report, we find the new tobacco product specified above is substantially equivalent to the following tobacco product, which was commercially marketed in the United States as of February 15, 2007.

[1] Brand/sub-brand or other commercial name used in commercial distribution.
[2] The applicant submitted the circumference which allowed for a calculation of diameter.

Predicate Tobacco Product

Product Manufacturer:	Xcaliber International LTD, LLC
Product Name:[3]	Exeter Ultra Light 100 SP
Product Category:	Cigarettes
Product Sub-Category:	Combusted, Filtered
Package Type:	Soft Pack
Package Quantity:	20 cigarettes
Characterizing Flavor:	None
Length:	99 mm
Diameter:[4]	7.89 mm
Ventilation:	40.0%

Under the provisions of section 910 and 905(j) of the FD&C Act, you may continue to legally market the new tobacco product specified above.

To fulfill the provisions of section 910(a)(4) of the FD&C Act, you opted not to provide an adequate summary of any health information related to the new tobacco product with your application, but stated that such information will be available upon request by any person. Consistent with the requirements of Section 910(a)(4), you may wish to consider providing the following when information is requested:

A. A copy of your final SE Report upon which our order was based, redacted only to the extent necessary to exclude patient identifiers, and trade secret and confidential commercial information as defined in 21 CFR § 20.61 and 20.63 and;
B. Any research or data you have in your possession or otherwise know of specifically regarding the adverse health effects of the new tobacco product or the following statement if such statement is accurate: "[Insert manufacturer name] does not have or know of any research or data regarding any adverse health effects specifically related to [insert tobacco product name]".

Alternatively, you may provide the following when information is requested:

A. Description of the new tobacco product;
B. Description of the predicate tobacco product;
C. List of all differences in characteristics between the predicate and new tobacco products;
D. Summary of the evidence and scientific rationale concerning why the differences in characteristics do not raise different questions of public health; and
E. Any research or data you have in your possession or otherwise know of regarding the adverse health effects of the new tobacco product or the following statement if such statement is accurate: "[Insert manufacturer name] does not have or know of any research or data regarding any adverse health effects specifically related to [insert tobacco product name]".

There may be other accurate, complete and not false or misleading ways to satisfy the requirements of Section 910(a)(4) not included above. If you wish to discuss other ways to meet the requirements of 910(a)(4), submit a meeting request to FDA.

[3] Brand/sub-brand or other commercial name used in commercial distribution.
[4] The applicant submitted the circumference which allowed for a calculation of diameter.

In accordance with 40 CFR 1506.6, we will make publicly available the finding that this marketing authorization is in a class of actions categorically excluded under 21 CFR 25.35(a). No extraordinary circumstances exist for this action.

It is important to note our finding of substantial equivalence for your new tobacco product specified above to an appropriate predicate tobacco product permits marketing of your new tobacco product. Our finding does not mean FDA "approved" the new product specified above; therefore, you may not promote or in any way represent the new tobacco product specified above, or its labeling, as being "approved" by FDA. See Section 301(tt) of the FD&C Act.

The finding that your product is substantially equivalent to the predicate product is based upon the information you provided in your SE Report and the standards contained in the FD&C Act, Section 910(a)(3). This marketing order is subject to reconsideration, with notice to the manufacturer, and rescission to the extent authorized by law.

We remind you that all regulated tobacco products, including the new tobacco product specified above, are subject to the requirements of Chapter IX of the FD&C Act and its regulations. These requirements currently include, but are not limited to, annual registration, listing of products, listing of ingredients, reporting of harmful and potentially harmful constituents, and payment of user fees. There are also labeling and advertising requirements with which you must comply. It is your responsibility to ensure that the tobacco product specified above complies with all applicable statutory and regulatory requirements, including those which may be forthcoming. FDA will monitor your compliance with these applicable statutes and regulations.

For more information on your responsibilities under the FD&C Act, we encourage you to visit our website at http://www.fda.gov/TobaccoProducts. You may also obtain information by contacting FDA's Center for Tobacco Products at 1-877-CTP-1373, AskCTP@fda.hhs.gov, or SmallBiz.Tobacco@fda.hhs.gov.

We encourage you to submit all regulatory correspondence electronically via the CTP Portal (http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Manufacturing/ucm515047.htm)[5] using eSubmitter (http://www.fda.gov/ForIndustry/FDAeSubmitter). Alternatively, submissions may be mailed to:

Food and Drug Administration
Center for Tobacco Products
Document Control Center (DCC)
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

The CTP Portal and the FDA Electronic Submission Gateway (ESG) are generally available 24 hours a day, seven days a week; if the upload is successful, submissions are considered received by DCC on the day of upload. Submissions delivered to DCC by courier or physical mail will be considered timely if received during delivery hours on or before the due date (see http://www.fda.gov/tobaccoproducts/aboutctp/contactus/default.htm); if the due date falls on a weekend or holiday the delivery must be received on or before the preceding business day. We are unable to accept regulatory submissions by e-mail.

[5] The FDA's Electronic Submission Gateway (ESG) is still available as an alternative to the CTP Portal.

If you have any questions, you may contact Kristopher Van Amburg, Regulatory Health Project Manager, at (301) 348 - 3032 or kristopher.vanamburg@fda.hhs.gov.

Sincerely,

Digitally signed by Matthew R. Holman -S
Date: 2018.05.10 07:41:45 -04'00'

Matthew R. Holman, PhD
Director
Office of Science
Center for Tobacco Products