DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-127/S-013

Xttrium Laboratories, Inc.
Attention: Joe Scalise
Director of QA/RA
415 West Pershing Road
Chicago, IL 60609

Dear Mr. Scalise:

Please refer to your supplemental new drug application dated April 9, 2008, received April 10, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for chlorhexidine gluconate 4% w/w solution.

We acknowledge receipt of your submission dated March 11, 2009.

Your submission of March 11, 2009 constituted a complete response to our February 26, 2009 action letter.

This supplemental new drug application proposes the addition of two new container/closure systems with associated labeling changes: a square 32-ounce, High-Density Polyethylene bottle containing a hand pump foam dispenser closure system and a round 32-ounce, High-Density Polyethylene bottle capped with a (b) (4) screw cap.

We have completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed upon labeling text.

Please submit final printed labeling (FPL) as soon as they become available, but no more than 30 days after they are printed. The final printed labeling (FPL) must be identical to the enclosed labeling (immediate container and carton labels submitted March 11, 2009). The labeling must be formatted in accordance with the requirements of 21 CFR 201.66, where applicable.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 19-127/S-013**." Approval of this submission by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Larry Bauer, Regulatory Project Manager, at (301) 796-4842.

Sincerely,

{See appended electronic signature page}

Joel Schiffenbauer, M.D.
Deputy Director
Division of Nonprescription Clinical Evaluation
Office of Nonprescription Products
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Joel Schiffenbauer

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