DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-422/S-036

Xttrium Laboratories, Inc.
Attention: Joe Scalise
Director of Quality Assurance/Regulatory Affairs
415 West Pershing Road
Chicago, Il 60609-2731

Dear Mr. Scalise:

Please refer to your supplemental new drug application dated September 28, 2007, received October 2, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for chlorhexidine gluconate solution, 2% w/w.

We acknowledge receipt of your submissions dated March 11 and November 17, 2008. Your November 17, 2008 submission constituted a complete response to our July 29, 2008 action letter.

This supplemental new drug application, submitted as "Changes Being Effected in 30 days," provides for the addition of a 1200-mL, **(b) (4)** Bottle and a pump with associated revised labeling. However, as we notified you in our October 17, 2007 letter to this application, an approved supplement is required for these proposed changes before distributing the drug product made with these changes. Therefore, this supplement was reviewed as a prior approval supplement.

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 and with the minor editorial revisions listed below.

1. Remove the bullets before the indicated use "surgical hand scrub" and "healthcare personnel handwash" under the header Purposes.

2. To increase readability of the ***Purpose*** statements we recommend that you revise the statement "surgical hand scrub/healthcare personnel handwash" so that surgical hand scrub and healthcare personnel handwash are on separate lines. This format provides a valuable visual cue for indicating the purpose of the drug product, without unnecessarily distracting or confusing the reader (see below).

Active ingredient	***Purposes***
chlorhexidine gluconate 4% solution…….……	surgical hand scrub healthcare personnel handwash

The final printed labeling (FPL) must include the revisions listed and be otherwise identical to the enclosed 1200-mL bottle label and must be formatted in accordance with the requirements of 21 CFR 201.66. These revisions are terms of the approval of this application.

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 19-422/S-036**." 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
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20857

Please submit one market package of the drug product when it is available.

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 Mary Vienna, Regulatory Project Manager, at (301) 796-4150.

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

Enclosure

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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