DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-125/S-034

Xttrium Laboratories, Inc.
Attention: Ram Chakroborty, Ph.D.
Senior Vice President
415 West Pershing Road
Chicago, IL 60609

Dear Dr. Chakroborty:

Please refer to your supplemental new drug application dated September 29, 2004, received October 4. 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Exidine (4% chlorhexidine gluconate solution).

We acknowledge receipt of your submission dated April 19, 2005.

Your submission of April 19, 2005 constituted a complete response to our April 4, 2005 action letter.

This supplemental new drug application provides for revised labeling for this product.

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.

The final printed labeling (FPL) must be identical to the submitted labeling (4 and 8-ounce immediate container labels submitted April 19, 2005; 16, 30 and 32-ounce and 1-gallon immediate container labels submitted on September 29, 2004), and must be formatted in accordance with the requirements of 21 CFR 201.66.

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/these submission(s) "**FPL for approved supplement NDA 19-125/S-034**." 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, HFD-410
FDA
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 Tia Frazier, Regulatory Project Manager, at (301) 827-2271.

Sincerely,

{See appended electronic signature page}

Curtis Rosebraugh, M.D., M.P.H.
Deputy Director
Division of Over-the-Counter Drug Products
Office of Drug Evaluation V
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/

Curtis Rosebraugh
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