DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-422/S-033

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

Dear Dr. Chakroborty:

Please refer to your supplemental new drug application dated August 23, 2004, received August 26, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Bactoshield® CHG 2% (2% chorhexidine gluconate) solution.

This supplemental new drug application proposes an alternate container closure system and revised labeling for this new packaging configuration.

We have completed our review of this application. 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 (immediate container labels submitted August 23, 2004), and must be formatted in accordance with the requirements of 21 CFR 201.66.

Please submit the FPL electronically 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, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 19-422/S-033." 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).

We request that you make the following labeling revisions at the time of next printing.

1. Reposition the net quantity of contents statement so that it is positioned in the lower 30 percent of the PDP, as required by 21 CFR 201.62(e). We consider the entire printed area of the label to be the PDP, therefore, this statement must be moved to the lower 30 percent of the printed area on the label.

2. The statement of weight of the net contents must be expressed in terms of avoirdupois measurements as described in 21 CFR 201.62(b). Therefore, the order of the net quantity of contents statements should be switched so that the avoirdupois measurements precede the metric measurements as follows:
"Net Contents: 1.05 qt (33.8 fl oz) (1 liter)"

3. Clarify the meaning of "SDS" in the net contents on the PDP.

4. Clarify where the expiration date is located. The expiration date must be printed on the immediate container as well as the outer carton, as described in 21 CFR 201.17.

5. Add the phrase "Peel here for more ***Drug Facts*** ►**"** to the bottom right-hand corner of the label (where the label should be opened) to direct the user to the rest of the labeling under the PDP.

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

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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