



NDA 019125/S040

## SUPPLEMENT APPROVAL

Xttrium Laboratories  
Attention: Joe Scalise  
Director of Quality Assurance/  
Regulatory Affairs  
1200 East Business Center Drive  
Mount Prospect, Illinois 60056

Dear Mr. Scalise:

Please refer to your Supplemental New Drug Application (sNDA) dated May 17, 2012, received May 18, 2012, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for chlorhexidine gluconate 4% solution.

We acknowledge receipt of your amendments dated June 13, August 1 and 21, and October 7 2012.

This "Changes Being Effected" supplemental new drug application provides for changes in the Drug Facts labeling to add directions for use in infants.

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

### **LABELING**

Submit final printed labeling, as soon as they are available, but no more than 30 days after they are printed. The final printed labeling (FPL) must be identical to the enclosed DYNA-HEX 4 4, 8, 16, 30, and 32 oz immediate container labels, and 1 gallon immediate container label submitted on October 7, 2012.

This FPL must be in the "Drug Facts" format (21 CFR 201.66), where applicable. The final printed labeling should be submitted electronically according to the guidance for industry titled "Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008)." Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 19125/040.**" Approval of this submission by FDA is not required before the labeling is used.

## **DRUG REGISTRATION AND LISTING**

All drug establishment registration and drug listing information is to be submitted to FDA electronically, via the FDA automated system for processing structured product labeling (SPL) files (eLIST). At the time that you submit your final printed labeling (FPL), the content of labeling (Drug Facts) should be submitted in SPL format as described at

<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

In addition, representative container or carton labeling, whichever includes Drug Facts, (where differences exist only in the quantity of contents statement) should be submitted as a JPG file.

## **REPORTING REQUIREMENTS**

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 Celia Peacock, Regulatory Project Manager at (301) 796-4154.

Sincerely,

*{See appended electronic signature page}*

Joel Schiffenbauer, M.D.

Deputy Director

Division of Nonprescription Clinical Evaluation

Office of Drug Evaluation IV

Center for Drug Evaluation and Research

ENCLOSURES

Immediate Container Labeling

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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JOEL SCHIFFENBAUER  
11/09/2012