



NDA 019125/S-044

SUPPLEMENT APPROVAL

Xttrium Laboratories, Inc.
Attention: Lori Miller
Quality Assurance/Regulatory Affairs Supervisor
1200 E. Business Center Dr.
Mount Prospect, IL 60056

Dear Ms. Miller:

Please refer to your supplemental new drug application (sNDA) dated and received March 16, 2017, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for chlorhexidine gluconate solution, 4%.

This “Prior Approval” supplemental new drug application provides for the following changes:

- Adds an “Allergy alert” warning to all DYNA-HEX 4[®] labeling in accordance with the Agency’s “Changes Being Effected” (CBE-0) Request Letter dated February 2, 2017
- Modifies labeling to incorporate various other revisions in accordance with Agency requests dated May 3, June 12, August 9, and August 21, 2017

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 and with the minor editorial revisions listed below:

DYNA-HEX 4[®] 15 mL packet

Revise the declaration of net quantity of contents statement: “15 mL” by inserting the fluid volume in ounces, to read: “0.5 fl oz (15 mL)”, in accordance with 21 CFR 201.62.

DYNA-HEX 4[®] 15 mL carton full view and enlargement of principal display panel

Revise the declaration of net quantity of contents statement: “50 Single-Use 0.5 fl oz (15-mL) Packettes” to read: “50 Single-Use 0.5 fl oz (15 mL) Packettes”, by removing the hyphen between “15” and “mL”.

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 labeling listed in the following table, must incorporate the changes specified above, and must be in the “Drug Facts” format (21 CFR 201.66), where applicable.

Submitted Labeling	Date of Submission
DYNA-HEX 4 [®] 4 ounce immediate container	September 6, 2017
DYNA-HEX 4 [®] 8 ounce immediate container	September 6, 2017
DYNA-HEX 4 [®] 16 ounce immediate container	September 6, 2017
DYNA-HEX 4 [®] 30 ounce immediate container	September 6, 2017
DYNA-HEX 4 [®] 32 ounce immediate container	September 6, 2017
DYNA-HEX 4 [®] 128 ounce immediate container	September 6, 2017
DYNA-HEX 4 [®] 15 mL carton	September 6, 2017
DYNA-HEX 4 [®] 15 mL immediate container (packet)	September 6, 2017

The final printed labeling should be submitted electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (May 2015, Revision 3)*. For administrative purposes, designate this submission “**Final Printed Labeling for approved NDA 019125/S-044.**” 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 Laurie Buonaccorsi, Regulatory Project Manager, at (240) 402-6297.

Sincerely,

{See appended electronic signature page}

Theresa Michele, MD
Director
Division of Nonprescription Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURES:

Carton and Container Labeling

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

/s/

THERESA M MICHELE
09/14/2017