NDA 019127/S-027

SUPPLEMENT APPROVAL

Xttrium Laboratories, Inc.
Attention: Lori Miller
Director of Regulatory Affairs
1200 East Business Center Drive
Mount Prospect, IL 60056

Dear Lori Miller:

Please refer to your supplemental new drug application (sNDA) dated and received February 27, 2025, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Dyna-Hex 4 (chlorhexidine gluconate) solution, 4%.

This "Prior Approval" supplemental new drug application provides for revised labeling for the 32 fl oz round and square high-density polyethylene (HDPE) container closures as requested in our Prior Approval Supplement Request letter dated January 29, 2025.

APPROVAL & LABELING

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 enclosed agreed-upon labeling, with the minor editorial revision listed below:

> For the 32 fl oz immediate container, round, under the "***Directions***", "**Surgical hand scrub**" subheading, vertically align the bulleted statement: "■ rinse thoroughly" in accordance with 21 CFR 201.66(d)(4).

LABELING

Submit final printed labeling (FPL), with the revisions listed above, as soon as they are available, but no more than 30 days after they are printed. The FPL must be identical to the enclosed labeling (except for the minor revision), described in the table below and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

Submitted Draft Labeling	Date of Submission
32 fl oz immediate container, round	April 4, 2025
32 fl oz immediate container, square	April 4, 2025

The FPL should be submitted electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*.[1] For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 019127/S-027**." 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 FDA.gov.[2] Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*. 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).

[1] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

[2] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm

U.S. Food and Drug Administration
Silver Spring, MD 20993
www.fda.gov

If you have any questions, contact Xiaoxue Nehrbass, Senior Regulatory Project Manager, at Xiaoxue.Nehrbass@fda.hhs.gov or at 301-796-1486.

Sincerely,

{See appended electronic signature page}

Melanie Blank, M.D., M.S.
Deputy Director
Division of Nonprescription Drugs II
Office of Nonprescription Drugs
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURES:

- Immediate Container Label – 32 fl oz, Round
- Immediate Container Label – 32 fl oz, Square

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

MELANIE J BLANK
05/27/2025 12:34:20 PM