NDA 019422/S-056

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 June 11th, 2026, received submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Dyna-Hex 2 (chlorhexidine gluconate 2%) solution.

This Prior Approval supplemental new drug application provides for the following changes for the 4 fl oz Dyna-Hex 2 container size:

- Removal of the "surgical handscrub" indication and associated portion of the "Uses" and Directions" section
- Removal of the "Questions or comments?" section
- Removal of the laundering/cleaning statement

This supplemental application also provides the following changes for the 32 fl oz Dyna-Hex 2 container size:

- Removal of the "patient preoperative skin preparation or skin wound/general skin cleansing" indication, and associated portions of the labeling under the "When using this product" and "Directions" sections.

APPROVAL & LABELING

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

LABELING

Submit final printed labeling (FPL), 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 (container labels submitted on June 11, 2026), and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

The FPL should be submitted electronically according to 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 019422/S-056**." 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 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 Chara Gunawardhana, Regulatory Project Manager, at 301-348-1585 or chara.gunawardhana@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Martha Lenhart, M.D., Ph.D.
Acting Division Director
Division of Nonprescription Drugs II
Office of Nonprescription Drugs
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURE:

- Container Labeling

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/

MARTHA K LENHART
07/25/2026 10:36:42 AM