NDA 019125/S-050

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 May 11, 2026, received, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Dyna-Hex 4 (chlorhexidine gluconate 4%) solution.

This Prior Approval supplemental new drug application proposes removal of the header "Questions or comments?" and the removal of the laundering/cleaning instructions from the 4 fl oz Dyna-Hex container label (NDC 0116-1061-04).

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.

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 label submitted May 11, 2026) and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

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 019125/S-050**." Approval of this submission by FDA is not required before the labeling is used.

[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.

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).

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

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

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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
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