NDA 019422/S-055

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 October 10, 2025, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Dyna-Hex 2 (chlorhexidine gluconate) solution, 2%.

This "Prior Approval" supplemental new drug application provides for an 18-fl oz SKU that excludes the "skin wound and general skin cleansing" indication.

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 submitted labeling (18-fl oz immediate container label submitted October 10, 2025) 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 019422/S-055**." 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 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).

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

ENCLOSURE:

- Immediate Container Labeling

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

---

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
02/03/2026 06:11:37 PM