NDA 019125/S-045

SUPPLEMENT APPROVAL

Xttrium Laboratories, Inc.
Attention: Lori Miller
Quality Assurance and Regulatory Affairs Supervisor
1200 East Business Center Drive
Mount Prospect, IL 60056

Dear Ms. Miller:

Please refer to your supplemental new drug application (sNDA) dated and received June 3, 2022, 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%.

We also refer to our Prior Approval Supplement Request letter dated May 5, 2022.

This “Prior Approval” supplemental new drug application provides for the addition of an 18 fl. oz. HDPE container closure system.

We acknowledge your clarification in the June 3, 2022, sNDA, that an incorrect label for the 4 fl. oz. product was submitted in the most recent annual report, and that the label approved in 2017 is still the current label for the 4 fl. oz. product. As the labeling for the 4 fl. oz. product has remained unchanged from the labeling approved in 2017 for the 4 fl. oz. product, FDA does not need to re-approve in this supplement.

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, described in the table below and must be in the “Drug Facts” format (21 CFR 201.66), where applicable.

Submitted Draft Labeling	Date Submitted
Dyna-Hex 4 18 fl. oz. immediate container	September 14, 2022

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-045**." 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

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

Sincerely,

{See appended electronic signature page}

Karen Minerve Murry, MD, FACE
Deputy Director, Office of Nonprescription Drugs
Acting Director, Division of Nonprescription Drugs II
Center for Drug Evaluation and Research

ENCLOSURE(S):

- 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/

KAREN M MURRY
09/29/2022 07:37:40 AM