



NDA 019422/S-049

SUPPLEMENT APPROVAL

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

Dear Ms. Miller:

Please refer to your Supplemental New Drug Application (sNDA) dated and received September 27, 2018, and your amendment, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for chlorhexidine gluconate solution, 2%.

This “Prior Approval” supplemental new drug application provides for the addition of a 1200 mL polyethylene terephthalate (PET) container closure system, with associated 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 agreed-upon labeling text with the minor editorial revision: delete the word SOAP wherever it appears in labeling.

LABELING

Submit final printed labeling, with the revision listed above, as soon as they are available, but no more than 30 days after they are printed. The final printed labeling must be identical to labeling submitted on January 17, 2019 and with the noted required change above, for the 1200 mL immediate container closure system, and must be in the “Drug Facts” format (21 CFR 201.66), where applicable.

The final printed labeling should be submitted electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (April 2017, Revision 4). For administrative purposes, designate this submission “**Final Printed Labeling for approved NDA 019422/S-049.**” 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 <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Information on submitting SPL files using eLIST may be found in the guidance for industry titled “SPL Standard for Content of Labeling Technical Qs and As” at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>. 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, call Celia Peacock, Senior Regulatory Project Manager at (301) 796-4154.

Sincerely,

{See appended electronic signature page}

Theresa Michele, MD
Director
Division of Nonprescription Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURES:

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/

THERESA M MICHELE
01/25/2019 10:54:28 AM