NDA 210872/S-001

SUPPLEMENT APPROVAL

Zurex Pharma, Inc.
Attention: Andrew Morgan, RPh
Executive Vice President
Regulatory Affairs and Clinical
2113 Eagle Drive
Middleton, WI 53562

Dear Mr. Morgan:

Please refer to your supplemental new drug application (sNDA) dated and received August 24, 2020, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for ZuraGard (isopropyl alcohol) solution, 70% v/v.

This "Prior Approval" supplemental new drug application provides for the addition of a blue (tint/color) and clear 26-mL applicator and a clear 10.5-mL applicator.

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 in the "Drug Facts" format (21 CFR 201.66), where applicable and identical to the following:

Labeling submitted on April 28, 2021:

- 10.5-mL clear applicator secondary container (applicator lidding)
- 26-mL blue applicator secondary container (applicator lidding)
- 26-mL clear applicator secondary container (applicator lidding)
- 26-mL clear applicator immediate container (applicator label)
- 26-mL blue applicator immediate container (applicator label)
- 10.5-mL clear applicator immediate container (applicator label)

Labeling submitted on May 14, 2021:

- Package insert for 10.5-mL clear applicator
- Package insert for 26-mL clear applicator
- Package insert for 26-mL blue applicator
- 25-count outer container (outer carton for 10.5-mL clear applicator)

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 210872/S-001**." 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.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

[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

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 Kris Leazer, Regulatory Project Manager, at 240-402-1418.

Sincerely,

{See appended electronic signature page}

Karen A. Hicks, MD
Acting Deputy Director
Division of Nonprescription Drugs II
Office of Nonprescription Drugs
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Carton and Container Labeling
- Package Insert

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 A HICKS
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