



NDA 18-374/S-026

SUPPLEMENT APPROVAL

Sun Pharmaceuticals Industries, Inc.
Attention: Likhitha Konatham, PharmD
Regulatory Affairs Associate
2 Independence way
Princeton, NJ 08540

Dear Dr. Konatham:

Please refer to your Supplemental New Drug Application (sNDA) dated January 26, 2018, received January 26, 2018, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for BACTRIM (sulfamethoxazole and trimethoprim) injection, 80 mg/mL and 16 mg/mL.

This Prior Approval supplemental new drug application, submitted in response to our December 19, 2017, supplement request letter, provides for revisions to add propylene glycol toxicity and metabolic acidosis to the **HIGHLIGHTS OF PRESCRIBING INFORMATION**, **WARNINGS AND PRECAUTIONS (5)** and **ADVERSE REACTIONS (6)** sections, and the **ADVERSE REACTIONS, Postmarketing Experience (6.2)** subsection of the prescribing information.

APPROVAL & LABELING

We have completed our review of this supplemental application and it is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at:

<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>.

Content of labeling must be identical to the enclosed labeling (text for the package insert), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

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/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

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 J. Christopher Davi, MS, Regulatory Project Manager, at (301) 796-0702.

Sincerely,

{See appended electronic signature page}

Joseph Toerner, MD, MPH
Deputy Director for Safety
Division of Anti-Infective Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURE: Content of Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

JOSEPH G TOERNER
02/09/2018