NDA 17377/S-080 **SUPPLEMENT APPROVAL**

Sun Pharmaceuticals, Inc
Attention: Meera Patel
Senior Associate. Regulatory and Business Continuity
2 Independence Way
Princeton, NJ 08540

Dear Ms. Patel:

Please refer to your supplemental new drug application (sNDA) dated June 16, 2020, received June 16,2020, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Bactrim and Bactrim DS Tablets (sulfamethoxazole and trimethoprim), 400mg/80mg and 800mg/160mg.

This "Changes Being Effected" supplemental new drug application was submitted in response to the Agency supplement request dated May 12, 2020, requiring the Applicant under Section 409I of the Public Service Act, also known as the Best Pharmaceutical for Children Act which mandates the critical need for pediatric labeling, to update the label with pediatric information. This supplemental application provides for pharmacokinetic information on trimethoprim and sulfamethoxazole in pediatric patients. In addition, the **Microbiology** subsection (**12.4**) has been updated, and minor editorial changes have been made throughout the labeling.

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 with minor editorial revisions listed below and reflected in the enclosed labeling.

P. jiroveci has been corrected to *P. jirovecii (i.e., to double "i" ending)*

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(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at FDA.gov.[1] Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information, with the addition of any labeling changes in pending "Changes

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

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 *SPL Standard for Content of Labeling Technical Qs and As*.[2]

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 Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), 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, Senior Regulatory Project Manager, at 301-796-0702.

Sincerely,

{See appended electronic signature page}

Dmirti Iarikov, MD, PhD
Deputy Director
Division of Anti-Infectives
Office of Infectious Diseases
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Content of Labeling
    - Prescribing Information

[2] 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.

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/

DMITRI IARIKOV
07/28/2020 01:18:32 PM