NDA 17-376/S-063
NDA 17-376/S-064

SUPPLEMENT APPROVAL

Monarch Pharmaceuticals, LLC
c/o Pfizer Inc.
Attention: Mikhail Abarshalin
Senior Manager, Pfizer Global Regulatory Affairs
235 East 42nd Street
New York, NY 10017

Dear Mr. Abarshalin:

Please refer to your supplemental new drug applications (sNDAs) dated January 9, 2020, received January 10, 2020 (S-063), and dated and received February 12, 2020 (S-064), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for SEPTRA (trimethoprim and sulfamethoxazole) Tablets, 80 mg/400 mg and SEPTRA DS (Double Strength) (trimethoprim and sulfamethoxazole) Tablets, 160 mg/800 mg.

These Prior Approval supplemental new drug applications provide for revisions to the **WARNINGS** and the **ADVERSE REACTIONS** sections of the prescribing information to include the adverse reactions of Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS), Acute Generalized Exanthematous Pustulosis (AGEP), S-063, and Acute Febrile Neutrophilic Dermatosis (AFND), S-064. In addition, the **CONTRAINDICATIONS** section has been updated to include dofetilide, several headings in the **WARNINGS** section have been revised for clarity, and the **PRECAUTIONS**, **Drug Interactions with SEPTRA** subsection has been updated to tabular format. Updates have also been made to the **REFERENCES** section and minor editorial revisions have been made throughout the PI.

APPROVAL & LABELING

We have completed our review of these applications and they are approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

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]

[1] 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 *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 these supplemental applications, 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, MS, Senior Regulatory Project Manager, at (301) 796-0702.

Sincerely,

{See appended electronic signature page}

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

ENCLOSURE: Content of Labeling

[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
08/10/2020 05:52:27 PM
Thank you