



NDA 018615/S-080

SUPPLEMENT APPROVAL

PAI Holdings, LLC dba Pharmaceutical Associates, Inc.
Tom Bolton
Director of Regulatory Affairs and Compliance
1700 Perimeter Rd
Greenville, SC 29605

Dear Mr. Bolton:

Please refer to your supplemental new drug application (sNDA) dated and received September 23, 2021, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Sulfatrim Oral Suspension (sulfamethoxazole and trimethoprim oral suspension, USP), 200 mg/40 mg per 5mL.

This “Changes Being Effectuated” sNDA provides for updates to the prescribing information (PI) to add a new subsection entitled “**Hypersensitivity and Other Serious or Fatal Reactions**” to the **WARNINGS** section and additional information to the **ADVERSE REACTIONS** section concerning acute respiratory failure, severe cutaneous adverse reactions, and circulatory shock.

Additionally, a new subsection entitled “**Cardiovascular**” was added to the **ADVERSE REACTIONS** section to include the following: Circulatory shock (see **WARNINGS**), QT prolongation resulting in ventricular tachycardia and *torsades de pointes*.

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.

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 Being Effectuated” (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

¹ <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

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, 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
 - 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
10/15/2021 05:23:33 PM