NDA 007073-S130
NDA 020465

SUPPLEMENT APPROVAL

Pharmacia & Upjohn Company LLC
Attention: Nestor Duci
Senior Manager
445 Eastern Point Road
Groton, CT 06340

Dear Mr. Duci:

Please refer to your supplemental new drug application (sNDA) dated August 27, 2021, received and submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Azulfidine (sulfasalazine) and Azulfidine (sulfasalazine) EN tablets.

We also refer to our letter dated August 3, 2021 notifying you, under Section 505(o)(4) of the FDCA, of new safety information that we believe should be included in the labeling for aminosalicylic acid and similar agents. This information pertains to the risk of severe cutaneous adverse reactions (SCARs), which includes Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN), drug reaction with eosinophilia and systemic symptoms (DRESS), and acute generalized exanthematous pustulosis (AGEP), reported in FAERS.

This supplemental new drug application provides for revisions to the labeling for Azulfidine and Azulfidine EN, consistent with our August 3, 2021 letter.

APPROVAL & LABELING

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

We note that your August 27, 2021, submission includes final printed labeling (FPL) for your Prescribing Informations. We have not reviewed these FPL. You are responsible for assuring that the wording in these FPL is identical to that of the approved content of labeling in the structured product labeling (SPL) format.

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 (Prescribing Information), 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. If the content of labeling in SPL format initially submitted with this CBE-0 labeling supplement is identical to the attached approved labeling, an additional submission of content of labeling in SPL format is not required.

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).

All promotional materials that include representations about your drug product must be promptly revised to be consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 314.70(a)(4)]. The revisions in your promotional materials should include prominent disclosure of the important new safety information that appears in the revised labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4).

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

We have now administratively closed the NDA 20465. Therefore, all 15-day alert reports, periodic (including quarterly) adverse drug experience reports, field alerts,

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

annual reports, supplements, and other submissions should be addressed to the original NDA 007073 for this drug product, not to this NDA 20465. In the future, do not make submissions to the NDA 20465 except for the final printed labeling requested above.

If you have any questions, call Kelly Richards, Regulatory Project Manager, at (240) 402-4276.

Sincerely,

{See appended electronic signature page}

Joyce Korvick, M.D., M.P.H.
Deputy Director for Safety
Division of Gastroenterology (DG)
Office of Immunology and Inflammation (OII)
Center for Drug Evaluation and Research

ENCLOSURES:

- Content of Labeling
  - Prescribing Information for Azulfidine
  - Prescribing Information for Azulfidine EN

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/

JOYCE A KORVICK
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