NDA 022000/S-022

GENERAL ADVICE

Takeda Pharmaceuticals USA, Inc
Attention: Valerie Tews
Sr. Manager, Regulatory Strategy
95 Hayden Avenue
Lexington, MA 02421

Dear Ms. Tews:

Please refer to your supplemental new drug application (sNDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lialda (mesalamine) tablets.

We also refer to our approval letter dated May 25, 2021, which contained the following error in the Prescribing Information (PI):

- The term “hepatotoxicity” was omitted from the listing of “Hepatic” adverse reactions in Section 6.2 Postmarketing Experience of the Prescribing Information (PI).

This General Advice letter acknowledges the error described above and incorporates the correction of the error. The effective approval date will remain May 25, 2021, the date of the original letter.

If you have any questions, call Andrew Dodson, PharmD, Regulatory Project Manager, at 301-796-8760.

Sincerely,

{See appended electronic signature page}

Joyce Korvick, MD, MPH
Deputy Director for Safety
Division of Gastroenterology
Office of Immunology and Inflammation
Center for Drug Evaluation and Research

Enclosure: Prescribing Information

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
07/08/2021 05:30:39 PM

NDA 022000/S-022

SUPPLEMENT APPROVAL

Takeda Pharmaceuticals U.S.A., Inc.
Attention: Valerie Tews
Sr. Manager, Regulatory Strategy
95 Hayden Avenue
Lexington, MA 02421

Dear Ms. Tews:

Please refer to your supplemental new drug application (sNDA) dated November 18, 2020, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Lialda (mesalamine) tablets.

This Prior Approval sNDA provides for the addition of the terms toxic epidermal necrolysis (TEN) and pleurisy/pleuritis to the Prescribing Information (PI).

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.

- Updated the revision date at the end of the Highlights and at the end of the document in the Prescribing Information to the approval date.

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 Effected" (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 Andrew Dodson, PharmD, Regulatory Project Manager, at 301-796-8760.

Sincerely,

{See appended electronic signature page}

Joyce Korvick, MD, MPH
Deputy Director for Safety
Division of Gastroenterology
Office of Immunology and Inflammation
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/

JOYCE A KORVICK
05/25/2021 04:16:31 PM