NDA 021153/S-056
NDA 021957/S-023
NDA 022101/S-020

SUPPLEMENT APPROVAL

AstraZeneca Pharmaceuticals LP
Attention: Emery Gigger
Regulatory Affairs Director
One MedImmune Way
Gaithersburg, MD 20878

Mr. Gigger:

Please refer to your supplemental new drug applications (sNDA) dated February 18, 2020, received February 18, 2020, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Nexium (esomeprazole magnesium) delayed-release capsules and Nexium (esomeprazole magnesium) for delayed-release oral suspension.

These Prior Approval sNDAs provide for updates throughout the Prescribing Information to align with similar updates made to the Prescribing Information for Nexium I.V. (NDA 021689/S-034).

APPROVAL & LABELING

We have completed our review of these applications, as amended. These are 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.

- Update the revision date at the end of the Medication Guide and the Instructions for Use to the approval date.

We note that your August 13, 2021 submissions include final printed labeling (FPL) for your Prescribing Information, Medication Guide, and Instructions for Use. We have not reviewed this FPL. You are responsible for assuring that the wording in this 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 (text for the Prescribing Information, Medication Guide, and Instructions for Use), 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 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).

CARTON AND CONTAINER LABELING

We acknowledge your February 18, 2020 and September 10, 2020 submissions containing final printed carton and container labeling for Nexium (esomeprazole magnesium) delayed-release capsules and Nexium (esomeprazole magnesium) for delayed-release oral suspension, respectively.

REPORTING REQUIREMENTS

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

[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.

If you have any questions, contact Jay Fajiculay, PharmD, Regulatory Project Manager, at (301) 796-9007 or email Jay.Fajiculay@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

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

ENCLOSURE(S):

- Content of Labeling
  - Prescribing Information
  - Medication Guide
  - Instructions for Use

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
08/25/2021 01:58:48 PM