NDA 021957

NOTIFICATION OF
NON-COMPLIANCE WITH PREA

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

Dear Mr. Gigger:

Please refer to your New Drug Application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (the Act) for Nexium (esomeprazole magnesium) for delayed release oral suspension), which was approved on October 20, 2006.

The Agency has determined that you have failed to meet the postmarketing requirement (PMR) of the Pediatric Research Equity Act (PREA) for this application because you have not yet submitted your pediatric assessment for PMR 59-1, which was deferred until June 30, 2008.

Under the provisions of section 505B(d)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) [21 U.S.C. 355c(d)(1)], you must respond in writing within 45 calendar days of the date of this letter. Your response should include the reason(s) for the delayed pediatric assessment and a date by which you expect to submit the assessment. You may also include a request for a deferral extension, if applicable, which should be identified as a "**DEFERRAL EXTENSION REQUESTED**" in your response. We note that you requested a deferral extension on June 19, 2019; however, we have determined that your request did not qualify for an extension.

In accordance with the FD&C Act, FDA will post this letter and your response to the website at http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/ucm343203.htm with redactions for any trade secrets and confidential commercial information 60 calendar days from the date of this letter.

Please identify your response to this letter as a "**RESPONSE TO PREA NON-COMPLIANCE LETTER.**" To facilitate our review, submit this information to your NDA with a cross-reference letter to the relevant Investigational New Drug Application (IND), e.g., the IND to which your protocol may have been submitted.

If you have any questions, contact Mimi Phan, Regulatory Project Manager, at (301) 796-5408 or mimi.phan@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Dragos Roman, MD
Director (Acting)
Division of Gastroenterology and Inborn Errors Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

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/

DRAGOS G ROMAN
08/21/2019 04:40:45 PM