



NDA 22307/S-006

**SUPPLEMENT APPROVAL  
RELEASE REMS REQUIREMENT**

Eli Lilly and Company  
Attention: Peter Morrow, MS  
Director, Global Regulatory Affairs - US  
Lilly Corporate Center  
Indianapolis, IN 46285

Dear Mr. Morrow:

Please refer to your Supplemental New Drug Application (sNDA) dated February 3, 2012, received February 2, 2012, submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Effient (prasugrel) 5 and 10 mg Tablets.

We also acknowledge receipt of your risk evaluation and mitigation strategy (REMS) assessment dated January 31, 2011.

This supplemental new drug application proposes to eliminate the Medication Guide as an element of the approved Effient (prasugrel) REMS.

We have completed our review of this supplemental application. It is approved, effective on the date of this letter.

**RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS**

The REMS for Effient (prasugrel) was originally approved on July 10, 2009. The REMS consists of a Medication Guide, a communication plan, and a timetable for submission of assessments of the REMS.

We have determined that maintaining the Medication Guide as part of the approved labeling is adequate to address the serious and significant public health concern and meets the standard in 21 CFR 208.1. Therefore, it is no longer necessary to include the Medication Guide as an element of the approved REMS to ensure that the benefits of Effient (prasugrel) outweigh its risks.

Because the assessment demonstrates that the communication plan has been completed and has met its goals, we have determined that it is no longer necessary to include it as an element of the approved REMS to ensure that the benefits of the drug outweigh the risks.

Therefore, a REMS is no longer required for Effient (prasugrel).

We remind you that the Medication Guide will continue to be part of the approved labeling in accordance with 21 CFR 208.

**POSTMARKETING REQUIREMENTS UNDER 505(o)**

We remind you of the following post-marketing requirement listed in our action letter dated July 10, 2009 that is still open:

2. You will gather baseline cancer history and cancer adverse event data from the ongoing trial TRILOGY, a 10,300-subject trial being conducted in patients with acute coronary syndrome who are being managed medically (without coronary revascularization). The final report on cancers in this trial is to be submitted to IND 63,449.

The timetable you submitted on July 8, 2009 states that you will conduct this trial according to the following timetable:

Protocol Submission: Received 06/20/2008  
Trial Completion Date: 12/2012  
Final Report Submission: 01/2013

**POSTMARKETING COMMITMENTS SUBJECT TO REPORTING REQUIREMENTS UNDER SECTION 506B**

We also remind you of the following post-marketing commitment listed in our action letter dated July 10, 2009 that is still open:

6. You commit to the collection of samples at baseline for genotyping CYP450 enzymes in TRILOGY subjects, to allow a comparison of effectiveness and bleeding in prasugrel and clopidogrel subgroups by metabolizer status. These data will be submitted with the final study report of TRILOGY. The periodic reports will include the fraction of subjects who consented to genetic testing.

We acknowledge that the protocol for this trial has been submitted.

Final Protocol Submission: Received 06/20/2008  
Trial Completion Date: 12/2012  
Final Report Submission: 01/2013

**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, please contact:

Alison Blaus  
Regulatory Health Project Manager  
(301) 796-1138

Sincerely,

*{See appended electronic signature page}*

Mary Ross Southworth, Pharm.D.  
Deputy Director of Safety  
Division of Cardiovascular and Renal Products  
Office of New Drugs  
Center for Drug Evaluation and Research

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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MARY R SOUTHWORTH  
03/23/2012