DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022433/S-009

SUPPLEMENT APPROVAL
RELEASE REMS REQUIREMENT

AstraZeneca LP
Attention: Patricia Patterson
Director, Regulatory Affairs
1800 Concord Pike
P.O. Box 8355
Wilmington, DE 19803-8355

Dear Ms. Patterson:

Please refer to your Supplemental New Drug Application (sNDA) dated and received April 5, 2013, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Brilinta (ticagrelor) 90 mg Tablets.

We acknowledge receipt of your amendment dated September 16, 2013 and your risk evaluation and mitigation strategy (REMS) assessment dated January 17, 2013.

This supplemental new drug application proposes to eliminate the requirement for the Brilinta (ticagrelor) REMS.

We have completed our review of this supplemental application, as amended, and it is approved, effective on the date of this letter.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for Brilinta (ticagrelor) was originally approved on July 20, 2011, and the most recent REMS modification was approved on January 24, 2013. The REMS consists of a Medication Guide, communication plan, and a timetable for submission of assessments of the REMS.

You propose that FDA eliminate the requirement for a REMS for Brilinta (ticagrelor).

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 Brilinta (ticagrelor) outweigh its risks.

Because the assessment demonstrates that the communication plan has been completed and has met its goals, we have also 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, we agree with your proposal, and a REMS for Brilinta (ticagrelor) is no longer required.

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

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 call:

Lori Anne Wachter, RN, BSN, RAC
Regulatory Project Manager for Safety
(301) 796-3975

Sincerely,

{See appended electronic signature page}

Mary Ross Southworth, PharmD.
Deputy Director for Safety
Office of Drug Evaluation I
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

MARY R SOUTHWORTH
10/30/2013