DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20839 / S-053

SUPPLEMENT APPROVAL
RELEASE REMS REQUIREMENT

sanofi-aventis U.S. LLC
Attention: Nancy Barone Kribbs, Ph.D.
Senior Director, Global Regulatory Affairs
9 Great Valley Parkway
PO Box 3026
Malvern, PA 19355

Dear Dr. Kribbs:

Please refer to your Supplemental New Drug Application (sNDA) dated April 25, 2011, received April 25, 2011, submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Plavix (clopidogrel bisulfate) 75 mg Tablets.

We also acknowledge receipt of your risk evaluation and mitigation strategy (REMS) assessment included in the April 25, 2011 submission.

This supplemental new drug application proposes to eliminate the requirement for the approved REMS.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for Plavix (clopidogrel bisulfate) was originally approved on February 1, 2011. The REMS consists of a Medication Guide and a timetable for submission of assessments of the REMS.

You propose that FDA no longer require a REMS for Plavix (clopidogrel bisulfate).

We have determined that it is no longer necessary to include the Medication Guide as an element of the approved REMS, and that a REMS is no longer necessary to ensure that the benefits of Plavix (clopidogrel bisulfate) outweigh its risks. Therefore, we agree with your proposal and a REMS for Plavix (clopidogrel bisulfate) 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 contact:

Alison Blaus
Regulatory Project Manager
(301) 796-1138

Sincerely,

{See appended electronic signature page}

Mary Ross Southworth, Pharm.D.
Deputy Director for Safety
Division of Cardiovascular and Renal Products
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/

ALISON L BLAUS
05/03/2011

MARY R SOUTHWORTH
05/03/2011