NDA 020839/S-075

**SUPPLEMENT APPROVAL**

Sanofi Aventis US LLC
Attention: Gargi Lakhwani
Manager, Regulatory Affairs
55 Corporate Drive
Bridgewater, NJ 08807

Dear Ms. Lakhwani:

Please refer to your Supplemental New Drug Application (sNDA) dated and received April 17, 2020, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for PLAVIX (clopidogrel tablets).

This "Changes Being Effected" supplemental new drug application provides for:

> Updates to all labeling to replace "clopidogrel bisulfate" established name with "Clopidogrel Tablets" to align with the current USP monograph.

## APPROVAL & LABELING

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

## CARTON AND CONTAINER LABELS

Submit final printed carton and container labels that are identical to enclosed carton and container labels, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format – Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission "**Product Correspondence – Final Printed Carton and Container Labels for approved NDA 020839/S-075.**" Approval of this submission by FDA is not required before the labeling is used.

## REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, contact Megan Nguyen, Regulatory Business Process Manager, at Megan.Nguyen@fda.hhs.gov or (301) 796 - 7826.

Sincerely,

*{See appended electronic signature page}*

Ramesh Raghavachari, Ph.D.
Chief, Branch I
Division of Post-Marketing Activities I
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosure(s):

Carton and Container Labeling

Ramesh Raghavachari

Digitally signed by Ramesh Raghavachari
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