NDA 20-839/S-018

Sanofi-Synthelabo Inc.
Attention: Mr. Kenneth Palmer
90 Park Avenue
New York, NY 10016

Dear Mr. Palmer:

Please refer to your July 2, 2001 supplemental new drug application, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Plavix (clopidogrel bisulfate) Tablets.

This "Changes Being Effected" supplemental new drug application provides final printed labeling revised by adding “fever” to the **ADVERSE REACTIONS/Postmarketing Experience** subsection. Additionally, the manufacturer information has been removed from the package insert.

We have completed the review of this supplemental application and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the July 2, 2001 submitted submitted final printed package insert. Accordingly, the supplemental application is approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

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

If you have any questions, please call:

Ms. Colleen LoCicero
Regulatory Health Project Manager
(301) 594-5332

Sincerely,

{See appended electronic signature page}

Raymond J. Lipicky, M.D.
Director
Division of Cardio-Renal Drug 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/

Raymond Lipicky
1/28/02 09:41:42 AM