020839_ S-020

CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER(S)

NDA 20-839/S-020

Trade Name: Plavix Tablets

Generic Name(s): (clopidogrel bisulfate)

Sponsor: Sanofi-Synthelabo, Inc.
Agent:

Approval Date: September 10, 2002

Indication: Provides for CBE/expiry

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-839/ S-020

9-10-02

Sanofi-Synthelabo Inc.
Attention: John Purpura
90 Park Avenue
New York, NY 10016

Dear Mr. Purpura:

Please refer to your supplemental new drug application dated March 11, 2002, received March 12, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Plavix (clopidogrel bisulfate) 75 mg Tablets.

We acknowledge receipt of your submission dated August 14, 2002.

This "Changes Being Effected" supplemental new drug application provides for ——— · expiry dating for the Plavix blister configuration.

We have completed our review of this supplemental new drug application, and it is approved.

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 question, call Colleen LoCicero, RPh, Regulatory Health Project Manager, at (301) 594-5332.

Sincerely,

{See appended electronic signature page}

Kasturi Srinivasachar, Ph. D.
Chemistry Team Leader, DNDC I for the
Division of Cardio-Renal Drug Products, (HFD-110)
DNDC I, Office of New Drug Chemistry
Center for Drug Evaluation and Research

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/s/

Kasturi Srinivasachar
9/10/02 10:51:08 AM

CHEMIST'S REVIEW	1. ORGANIZATION HFD-110	2. NDA Number 20-839
3. Name and Address of Applicant (City & State) Sanofi-Synthelabo Inc. 90 Park Avenue New York, NY 10016		4. Supplement(s) Number(s) Date(s) SCE-020 03/11/02
4. Drug Name Plavix	5. Nonproprietary Name Clopidogrel bisulfate	7. Amendments & Other (reports, etc) Dates SCE-020(BC) 08/14/02
8. Supplement Provides For CBE SUPPLEMENT the approval of —— expiry dating of the Plavix blister configuration.		
8. Pharmacological Category	9. How Dispensed Oral	11. Related IND(s)/ NDA(s)/DMF(s)
12. Dosage Form(s) Tablets	13.Potency(ies) 75 mg	
14. Chemical Name Methyl (+)-(S)-alpha-(2-chlorophenyl)-6,7-dihydrothienol[3,2-c]pyridine-5,(4H)-acetate sulfate(1:1)		15.Records/Reports Current Yes___No ___. Reviewed Yes__No ___.

16.Comments

A CBE supplement and applicant amended the supplement with real time —— stability data.

17.Conclusions and Recommendations

The real time stability data at —— time point and storage condition of 25°C/60%RH condition has remained within the regulatory specifications. An expiration date of —— for the —— blister configuration is approved.

18. REVIEWER

Name Ramsharan D. Mittal	Date Completed 09/06/02

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page(s) of trade secret and/or confidential commercial information (b4)

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/s/

Ramsharan Mittal
9/6/02 06:52:41 PM
CHEMIST

Kasturi Srinivasachar
9/9/02 12:12:08 PM
CHEMIST

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-839/S-020

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

Dear Mr. Purpura:

We have received your supplemental drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product: Plavix (clopidogrel bisulfate) Tablets

NDA Number: 20-839

Supplement number: S-020

Date of supplement: March 11, 2002

Date of receipt: March 12, 2002

Unless we notify you within 60 days of the receipt date that the application is not sufficiently complete to permit a substantive review, this application will be filed under section 505(b) of the Act on May 11, 2002 in accordance with 21 CFR 314.101(a).

All communications concerning this supplement should be addressed as follows:

U.S. Postal Service:
Center for Drug Evaluation and Research
Division of Cardio-Renal Drug Products, HFD-110
Attention: Division Document Room
5600 Fishers Lane
Rockville, Maryland 20857

Courier/Overnight Mail:
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Cardio-Renal Drug Products, HFD-110
Attention: Division Document Room
1451 Rockville Pike
Rockville, Maryland 20852

If you have any questions, please call:

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

Sincerely yours,

/S/

Kasturi Srinivasachar, Ph.D.
Chemistry, Team Leader
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research