020839___ S-004

CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER(S)

NDA 20-839/S-004

Trade Name: Plavix Tablets

Generic Name(s): (clopidogrel bisulfate)

Sponsor: Sanofi-Synthelabo, Inc.
Agent:

Approval Date: January 27, 2000

Indication: Provides for manufacturing/controls

JAN 27 2000

NDA 20-839/S-004

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

Dear Mr. Purpura:

Please refer to your supplemental new drug application (NDA) dated August 10, 1999, received August 11, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Plavix (clopidogrel bisulfate) Tablets, 75 mg.

We acknowledge receipt of your submission dated December 2, 1999.

The supplemental application provides for manufacture and control of Plavix Tablets by Bristol-Myers Squibb at their plant in Humacao, PR.

We have completed the review of this supplemental application and it is approved.

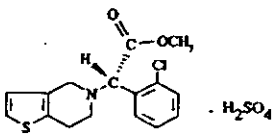
We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

Sincerely yours,

/S/ 1-27-00

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

JAN 27 2000

CHEMIST'S REVIEW	1. ORGANIZATION HFD-110	2. NDA Number 20-839
3. Name and Address of Applicant (City & State) Sanofi Pharmaceuticals, Inc. New York, NY		4. Supplement(s) Number(s) SCS-004 Date(s) 10 Aug 99
5. Drug Name Plavix	6. Nonproprietary Name Clopidogrel bisulfate	7. Amendments & Other (reports, etc) - Dates Amendment 2 Dec 99
8. Supplement Provides For: Manufacture and control of Plavix tablets by Bristol-Myers Squibb at their plant in Humacao, PR.		
9. Pharmacological Category Prevention of vascular ischemia	10. How Dispensed ☒Rx ☐OTC	11. Related IND(s)/ NDA(s)/DMF(s)
12. Dosage Form(s) TCM	13. Potency(ies) 75 mg	
14. Chemical Name and Structure  Methyl (S)-(+)-α-(2-Chlorophenyl)-6,7-dihydro-thieno-[3,2-c]pyridine-5(4*H*)-acetate hydrogen sulfate		15. Records/Reports Current ☒Yes ☐No Reviewed ☒Yes ☐No

16. Comments

This is a Special Supplement - Changes Being Effected. SUBMITTED UNDER SUPAC-IR LEVEL 3 SITE CHANGE

(continued)

17. Conclusions and Recommendations

APPROVAL is recommended.

18. REVIEWER

Name James H. Short /S/ Date Completed 17 Dec 99

Distribution: ☐ Original Jacket ☐ Reviewer ☐ Division File ☐ CSO

jhs/10/21/99/N20-839.S04

/S/
1-27-00

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