020839— S-003

CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER(S)

NDA 20-839/S-003

Trade Name: Plavix Tablets

Generic Name(s): (clopidogrel bisulfate)

Sponsor: Sanofi-Synthelabo, Inc.
Agent:

Approval Date: August 20, 1999

Indication: Provides for revisions to drug substance specifications

NDA 20-839/S-003

AUG 20 1999

Sanofi Pharmaceuticals, Inc.
Attention: John Purpura
90 Park Avenue
New York, N.Y. 10016

Dear Mr. Purpura:

Please refer to your May 28, 1999 supplemental new drug application, received June 1, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Plavix (clopidogrel bisulfate) Tablets, 75 mg.

This supplemental application provides for revisions to the drug substance specifications to include the addition of [ ] test method for determination of [ ].

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/ 8-20-99

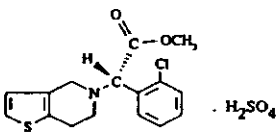
Kasturi Srinivasachar, Ph.D.
Chemistry Team Leader, DNDC I for the
Division of Cardio-Renal Drug Products (HFD-110)
Office of New Drug Chemistry
Center for Drug Evaluation and Research

CC:
Original NDA
HFD-110/Division File
HFD-110/CSO
HFD-110/J.Short, 7-23-99
HFD-810/J.Simmons
HFD-80
HFD-232
District Office
Draft: tjm, 8/18; Final 8/18/99 /S/

Approval Date: November 17, 1997

APPROVAL

AUG 2 0 199

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-003 Date(s) 28 May 99
5. Drug Name Plavix	6. Nonproprietary Name Clopidogrel bisulfate	7. Amendments & Other (reports, etc) - Dates SNC 19 Oct 98 SNC 12 Apr 99
8. Supplement Provides For: An [determination of] of the drug substance as an additional specification for the drug substance.		
9. Pharmacological Category Prevention of vascular ischemia	10. How Dispensed [X] 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  · H_2SO_4 Methyl (S)-(+)-α-(2-Chlorophenyl)-6,7-dihydrothieno-[3,2-c]pyridine-5(4*H*)-acetate hydrogen sulfate		15. Records/Reports Current [X] Yes [ ] No Reviewed [X] Yes [ ] No

16. Comments

This is a Special Supplement - Changes Being Effected.

At the time of the original submission, the applicant believed clopidogrel bisulfate [ ] The purpose of the correspondence of 19 Oct 98 is to notify the Agency that [ ] has been identified and

Evidence for the [ ] has been substantiated using [ ]

(continued)

17. Conclusions and Recommendations

APPROVAL is recommended.

18. REVIEWER

Name James H. Short — Date Completed 23 Jul 99

Distribution: [ ] Original Jacket [ ] Reviewer [ ] Division File [ ] CSO

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8-12-99

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