020839__S-002

CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER(S)

NDA 20-839/S-002

Trade Name: Plavix Tablets

Generic Name(s): (clopidogrel bisulfate)

Sponsor: Sanofi-Synthelabo, Inc.
Agent:

Approval Date: May 21, 1998

Indication: Provides for a new packaging configuration

NDA 20-839/ S-002

MAY 21 1998

5-7

Sanofi Pharmaceuticals, Inc.
Attention: Gregory M. Torre, Ph.D., J.D.
90 Park Avenue
New York, NY 10016

Dear Dr. Torre:

Please refer to your December 19, 1997 supplemental new drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Plavix (clopidogrel bisulfate) Tablets, 75 mg.

The user fee goal date is June 23, 1998.

The supplemental application provides for a new packaging configuration, 30 tablets in a — bottle.

We have completed the review of this supplemental application and it is approved with the understanding that you will place the first three production lots of 30 count bottles into your stability program.

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/ 5-21-98

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

cc: NDA 20-839/ S-002
HFD-110/ DIV FILE
HFD-110/ JShort 5/11/98
HFD-110/ Project Manager/ DRoeder
HFD-92
DISTRICT OFFICE
HFD-810, CHoiberg
cg 05/18/98

Approval Date: November 17, 1997

APPROVAL

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) Date(s) SCM-002 19 Dec 97
5. Drug Name Plavix	6. Nonproprietary Name Clopidogrel bisulfate	7. Amendments & Other (reports, etc) - Dates SNC 7 Jan 98
8. Supplement Provides For: Packaging 30 tablets in a — bottle.		
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		15. Records/Reports Current [X] Yes [ ] No Reviewed [X] Yes [ ] No

16. Comments

The SNC, which does not relate to this supplement, deals with the Agency's uniqueness concerns for this tablet. The firm makes a best-effort commitment to achieve additional debossing of "1171" on the other side of the Plavix tablet which is already debossed with "75." Commercial implementation of this commitment is expected to take [redacted].

This supplement provides for packaging Plavix Tablets in a 30 count — bottle, in addition to the approved 90 and 500 tablet packages. The 30 count bottle configuration will be supported by establishing a 7 tablet count — bottle to be placed on stability as a new lower configuration to bracket the 30 count bottle.

The container for the proposed 30 count configuration is a [redacted] white, — bottle. The closure is a [redacted] cap lined with a [redacted] inner seal. The container and closure are the same as were approved for the 90 count configuration.

(continued)

17. Conclusions and Recommendations

APPROVAL is recommended with the following statement added " ... with the understanding that you will place the first — production lots of 30 count bottles into your stability program for this product."

18. **REVIEWER**

Name James H. Short /S/ **Date Completed** 13 Apr 98

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

jhs/4/10/98/N20-839.S02 /S/ 5.4.98

Redacted 1

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