CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

20-636 / S-012

Trade Name: Viramune

Generic Name: (nevirapine)

Sponsor: Boehringer Ingelheim Pharmaceuticals, Inc.

Approval Date: August 5, 1999

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-636 / S-012

CONTENTS

Reviews / Information Included in this NDA Review.

Approval Letter	X
Approvable Letter	
Final Printed Labeling	
Medical Review(s)	
Chemistry Review(s)	X
EA/FONSI	
Pharmacology Review(s)	
Statistical Review(s)	
Microbiology Review(s)	
Clinical Pharmacology/ Biopharmaceutics Review(s)	
Administrative and Correspondence Document(s)	

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-636 / S-012

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-636/S-012

AUG 5 1999

Boehringer Ingelheim Pharmaceuticals, Inc.
Attention: Kevin Dransfield
Manager, Drug Regulatory Affairs
900 Ridgebury Road
P. O. Box 368
Ridgefield, Connecticut 06877

Dear Mr. Dransfield:

Please refer to your supplemental new drug application dated April 29, 1999, received June 14, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Viramune® (nevirapine) Tablets, 200 mg.

We note that this supplement was submitted as a 'Special Supplement - Changes Being Effected' under 21 CFR 314.70(c).

This supplemental new drug application provides for reduced testing for nevirapine anhydrous (drug substance) by drug product manufacturer, ← Your submission stated within 30 days of the date of your submission as the implementation date for the change.

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.

If you have any questions, contact Sean J. Belouin, Regulatory Project Manager, at 301-827-2335.

Sincerely,

Stephen P. Miller

Stephen P. Miller, Ph.D.
Chemistry Team Leader for the
Division of Antiviral Drug Products (HFD-530)
DNDC III, Office of New Drug Chemistry
Center for Drug Evaluation and Research

cc:
Archival NDA 20-636
HFD-530/Div. Files
HFD-530/CSO/SJBelouin SJB 8/3/99
HFD-530/Chem/ZGu ZG 8/3/99
HFD-530/ChemTmLdr/SMiller
HFD-95/DDMS
HFD-830/DNDC Division Director
DISTRICT OFFICE

Drafted by: cn/July 20, 1999
Initialed by:
final:
filename: 20636s12

APPROVAL (AP)

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-636 / S-012

CHEMISTRY REVIEW(S)

JUL 19 1999

SUPPLEMENTAL NDA CHEMIST'S REVIEW	1. ORGANIZATION HFD-530	2. NDA NUMBER 20,636

3. NAME AND ADDRESS OF APPLICANT *(City and State)*
Boehringer Ingelheim Pharmaceuticals, Inc.
900 Ridgebury Road, P. O. Box 368
Ridgefield, CT 06877-0368

4. AF NUMBER

5. DOCUMENT(S)

NUMBER(S)	DATE(S)
SCM-012	4/29/99

6. NAME OF DRUG
VIRAMUNE®

7. NONPROPRIETARY NAME
Nevirapine

8. SUPPLEMENT(S) PROVIDES FOR:
Reduced testing for Nevirapine anhydrous by drug product manufacturer.

9. AMENDMENTS AND OTHER

DATES

10. PHARMACOLOGICAL CATEGORY	11. HOW DISPENSED	12. RELATED IND/NDA/DMF(S)
Anti-viral	|X| Rx | | OTC	

13. DOSAGE FORM(S) tablets

14. POTENCY(IES): 200 mg

15. CHEMICAL NAME AND STRUCTURE
11-cyclopropyl-5,11-dihydro-4-methyl-6H-dipyrido[3,2-b:2'3'-e][1,4]-diazepin-6-one

16. MEMORANDA

17. COMMENTS

This special supplement, change being effected, provides reduced testing for nevirapine anhydrous (drug substance) by drug product manufacturer, ———.

The active ingredient (nevirapine anhydrus) in VIRAMUNE® Tablets is manufactured by Boehringer Ingelham Chemicals, Inc. (BIC) in Petersburg, Virginia. BIC performs complete analytical testing of this drug substance according to the current testing procedures and specifications. In addition to the testing at BIC, the drug product manufacturer, ——— has been performing full testing of each batch of nevirapine anhydrous prior to release for use in the manufacture of VIRAMUNE® Tablets. BIC and ——— are members of the Boehringer Ingelham family of companies.

The sponsor states that data have been obtained to demonstrate the equivalence of results from testing at BIC and ——— Therefore, ——— will discontinue duplicate testing and will release nevirapine through acceptance of BIC's certificate of analysis and perform an identity test on all batches of nevirapine anhydrous received from BIC.

18. CONCLUSIONS AND RECOMMENDATIONS

Under the provision of CFR211.84(d)(2), this supplement is recommended for approval.

19. REVIEWER

NAME	SIGNATURE	DATE COMPLETED
Zi-Qiang Gu, Ph.D.	Zi-Qiang Gu	July 9, 1999

20. CONCURRENCE: HFD-530/SMiller D/Bowing for Steve Miller 7/19/99

DISTRIBUTION	X	Orig. NDA	X	Div File	X	HFD-830/CChen
	X	HFD-530/SMiller	X	HFD-530	X	HFD-530/
	X	HFD-530/ZGu	X		X	