

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

20-636 / S-005

Trade Name: Viramune

Generic Name: (nevirapine)

Sponsor: Boehringer Ingelheim Pharmaceuticals, Inc.

Approval Date: September 19, 1997

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APPLICATION NUMBER:

20-636 / S-005

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APPROVAL LETTER

211

NDA 20-636/S-005

SEP 19 1997

Dawn R. E. Watson, R.Ph.
Manager, Drug Regulatory Affairs
Boehringer Ingelheim Pharmaceuticals, Inc.
900 Ridgebury Road.
P.O. Box 368
Ridgefield CT 06877

Dear Dr. Watson

Please refer to your supplemental New Drug Application dated August 6, 1997 submitted pursuant to Section 505(b) of the Federal Food, Drug and Cosmetic Act for VIRAMUNE® (nevirapine) Tablets, 200 mg.

The User Fee goal date for this application is February 7, 1998.

The supplemental application provides for an additional packaging configuration of 60 tablets in a 120 cc HDPE bottles with child resistant closures.

We have completed the review of this supplemental application and it is approved, effective on the date of this letter.

We request that you submit a labeling supplement when the 60-count configuration is added to the How Supplied section of the package insert.

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

Sincerely yours,



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

APPROVED

Distribution:

NDA 20-636 Original
HFD-530 Division File
HFD-530/ TCrescenzi

HFD-530/ GLunn
HFD-530/SMiller
HFD-830/CChen

HFD-530/JMartin
Boston District Office
HFD-92/DDM-RMT

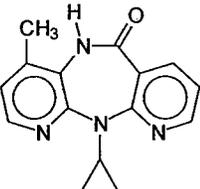
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APPLICATION NUMBER:

20-636 / S-005

CHEMISTRY REVIEW(S)

SEP 17 1997

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			4. AF NUMBER			
			5. SUPPLEMENT(S)			
			NUMBER(S) SCP-005	DATE(S) 8/6/97		
6. NAME OF DRUG VIRAMUNE [®] Tablets		7. NONPROPRIETARY NAME nevirapine tablets				
8. SUPPLEMENT(S) PROVIDES FOR: An additional packaging configuration of 60 tablets in 120 cc HDPE containers with child resistant closures.			9. AMENDMENTS / REPORTS			
10. PHARMACOLOGICAL CATEGORY Anti-HIV		11. HOW DISPENSED <input checked="" type="checkbox"/> Rx <input type="checkbox"/> OTC		12. RELATED IND/NDA/DMF(S)		
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 see p. 2						
18. CONCLUSIONS AND RECOMMENDATIONS The sponsor proposes to package Viramune 200 mg tablets in lots of 60 tablets in 120 cc HDPE bottles. Only the container is new; the closure, liner, and filler are the same as those used in the original NDA. A letter of authorization is provided to refer to a DMF for the bottle. Stability testing has been conducted for 3 batches at: _____ RH for up to 9 months and at _____ RH for up to 4 months. All of the specifications were met for each batch at each time point. The stability study will continue. The previously approved expiration date of 30 months will be used. Moisture permeation testing was conducted and the permeation rate was found to be _____ for tight containers. Copies of the label and the change in the package insert are submitted. These reflect the availability of Viramune tablets on bottles of 60. It is, therefore, recommended that this supplement be approved.						
19. REVIEWER						
NAME George Lunn, Ph.D.		SIGNATURE 		DATE COMPLETED 9/16/97		
20. CONCURRENCE: HFD-530/SMiller <i>Smiller 9/17/97</i>						
DISTRIBUTION	<input checked="" type="checkbox"/>	Original Jacket	<input checked="" type="checkbox"/>	GLunn	<input checked="" type="checkbox"/>	TCrescenzi
	<input checked="" type="checkbox"/>	Division File	<input checked="" type="checkbox"/>	SMiller	<input checked="" type="checkbox"/>	JMartin
	<input checked="" type="checkbox"/>	HFD-830/CChen				

WITHHOLD 2 PAGE(S)

Chemistry Review