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APPLICATION NUMBER:
201152Orig1s000

PHARMACOLOGY REVIEW(S)

PHARMACOLOGIST'S REVIEW

NDA: 201152

Date Submitted: June 3, 2010

Date Assigned: June 3, 2010

Date Completed: September 1, 2010

Assigned Reviewer: Pritam Verma, Ph.D.

DAVP

HFD-530

SPONSOR: Boehringer Ingelheim Pharmaceuticals, Inc.

900 Ridgebury Road

PO Box 368

Ridgefield, Connecticut 06877-0368

DRUG: Nevirapine Tablets, Extended Release have been developed (b) (4) : a
400 mg adult strength (b) (4)

FORMULATION: The tablet formulations contain nevirapine anhydrous, lactose monohydrate, hypromellose (hydroxypropyl methylcellulose), iron oxide (b) (4) magnesium stearate (b) (4)

RELATED INDs and NDAs: 74,744; 36,026; 20-636; and 20-933

INDICATION: Nevirapine XR is indicated for combination antiretroviral treatment of HIV-1 infection.

INTRODUCTION

Nevirapine tablets (immediate release [IR]) were approved and received first marketing authorization in the US in June 1996 (marketed as VIRAMUNE). An oral suspension formulation was approved in 1998. The nevirapine XR tablet is investigated to support the same indication as the nevirapine IR tablet. An extended release formulation of nevirapine may offer a meaningful therapeutic benefit, relative to marketed VIRAMUNE® (nevirapine). The recommended dose for marketed VIRAMUNE® (nevirapine) is one 200 mg tablet daily for the first 14 days, followed by one 200 mg tablet twice daily. In contrast, nevirapine XR would be prescribed for once daily dosing. Nevirapine extended-release tablets are proposed to be marketed under the trade name VIRAMUNE XR.

TOXICOLOGY

The toxicology and safety profile of nevirapine has been previously established and no additional toxicology studies were conducted in support of the nevirapine development program. For detail description of nonclinical studies, please refer to the review of NDAs 20-636; and 20-933.

CONCLUSIONS

There are no nonclinical pharmacology and toxicology issues which would preclude the approval of this NDA.

Reviewer signature: _____

Supervisor signature: _____

Application
Type/Number

Submission
Type/Number

Submitter Name

Product Name

NDA-201152

ORIG-1

BOEHRINGER
INGELHEIM
PHARMACEUTICA
LS INC

Nevirapine Extended Release
Tablets

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/s/

PRITAM S VERMA
09/01/2010

HANAN N GHANTOUS
09/01/2010