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APPLICATION NUMBER: NDA 29665/S004

ADMINISTRATIVE DOCUMENTS

NOV 27 1998

RHPM Review of Labeling

NDA: 20-665/SLR-004 Diovan (valsartan) Capsules

Date of submission: October 16, 1998

Date of receipt: October 21, 1998

Applicant: Novartis Pharmaceuticals Corporation

Background: In response to our supplement request letter dated May 8, 1998, that asked for a revision of the ADVERSE REACTIONS section of the package insert for Diovan (valsartan) Tablets to include a Post-Marketing Experience subsection, listing angioedema, elevated liver enzymes and rare clinical liver disease, and any other adverse reactions reported in post-marketing experience, Novartis has submitted final printed labeling.

Review: The submitted final printed labeling has been revised as follows:

"Novartis" and "Rx only" have been added to the top of the package insert. "Diovan" now has "®" instead of "™" next to it.

ADVERSE REACTIONS: a new subsection has been added:

"Post-Marketing Experience"

The following additional adverse reactions have been reported in post-marketing experience:

Hypersensitivity: There are rare reports of angioedema;

Digestive: Elevated liver enzymes and very rare reports of hepatitis."

At the end of the package insert,
"NOVARTIS
Distributed by
Novartis Pharmaceuticals Corporation
East Hanover, New Jersey 07936"

replaces the information on Ciba.

I found no other changes to the text of the package insert.

Recommendation: I will prepare an approval letter for Dr. Lipicky's signature.

JS!
Kathleen F. Bongiovanni

11-18-98

cc: NDA 20-665/S-004
HF-2/MedWatch
HFD-110
HFD-110/KBongiovanni
HFD-110/SBenton

kb/11/18/98.

RHPM Review of Labeling

MAR 6 1998

NDA: 20-818 Diovan HCT (valsartan/hydrochlorothiazide)
80/12.5 and 160/12.5 Tablets

Date of submission: February 24, 1998

Date of receipt: February 25, 1998

Applicant: Novartis

Background: On February 20, 1998, Dr. Lipicky signed an approvable letter for NDA 20-818, requesting final printed labeling identical to the enclosed marked-up draft labeling.

Review: I have reviewed the submitted final printed labeling. The language is identical to the language in the draft labeling included with the approvable letter. In the marked-up draft labeling, we requested that the firm delete from the labeling. The labeling still includes in a header on the top of the reverse side. In a telephone conversation with Ms. Nancy Price on February 25, 1998, they agreed to delete this at the time of their next printing.

Recommendation: I will prepare an approval letter for this NDA for Dr. Lipicky's signature.

/S/

----- 3-4-98
Kathleen F. Bongiovanni

cc: NDA 20-818
HFD-110
HFD-111/KBongiovanni
HFD-111/SBenton
kb/3/3/98.