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APPROVAL PACKAGE FOR:

APPLICATION NUMBER

20-668/S-003

Administrative Documents

APR 22 1999

RHPM Review of Final Printed Labeling

Application: NDA 20-668/S-003
Lexxel (enalapril maleate/felodipine) Tablets, 5/5 mg

Sponsor: Astra Pharmaceuticals, L.P.

Supplement Date: December 19, 1997

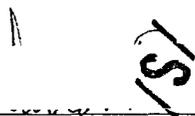
Approval Letter: October 28, 1998

Review

NDA 20-668/S-003 provides for a new strength combination tablet, 5 mg enalapril maleate and 2.5 mg felodipine. An approval letter (on draft labeling) was issued on October 28, 1998. The sponsor submitted final printed labeling in a submission dated January 15, 1999, received January 19, 1999. I reviewed this final printed labeling and found it to be identical in content to the approved draft.

Conclusion

An "acknowledge and retain" letter will be drafted for Dr. Lipicky's signature.



David Roeder
Regulatory Health Project Manager

dr/10-9-98

cc: NDA 20-668
HFD-110
HFD-110/DRoeder/SBenton

DF
OCT 28 1998

RHPM Review of Draft Labeling

Application: NDA 20-668/S-003
Lexxel (enalapril maleate/felodipine) Tablets, 5/5 mg

Sponsor: Astra Pharmaceuticals, L.P.

Supplement Date: December 19, 1997

Draft Labeling : October 2, 1998

Review

NDA 20-668/S-003 provides for a new strength combination tablet, 5 mg enalapril maleate and 2.5 mg felodipine. A not-approvable letter was issued for this supplement on June 19, 1998, because of a failed facility inspection. We also made labeling recommendations (see fax dated August 19, 1998). Subsequent to the fax, the sponsor asked if Dr. Lipicky would reconsider the sponsor's proposal to revise the first sentence of the **DOSAGE AND ADMINISTRATION: Therapy Guided by Clinical Effect** subsection. After discussing the issue, the following revisions of this subsection were agreed to:

In addition to these revisions, the sponsor has revised the **DESCRIPTION** section to include the new tablet strength as well as the addition of synthetic red iron oxide and simethicone as ingredients to the 5-2.5 mg tablet. They also revised the **HOW SUPPLIED** section to include the new strength.

The firm submitted draft labeling with all of the above changes plus some minor editorial changes in a submission dated October 2, 1998.

Conclusion

The chemist has recommended approval of the supplement, and Dr. Lipicky has agreed to the labeling changes. I recommend that the supplement be approved on draft labeling.


David Roeder
Regulatory Health Project Manager

dr/10-9-98

cc: NDA 20-668
HFD-110
HFD-110/DRoeder/SBenton