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APPROVAL PACKAGE FOR:

APPLICATION NUMBER
20-364/S-008

Administrative Documents

JUN 16 1999

RHPM Review of Final Printed Labeling

Application: NDA 20-364/S-008
Lotrel (amlodipine besylate/belazepril hydrochloride) Capsules

Applicant: Novartis Pharmaceuticals Corporation

Date of Supplement: April 29, 1998

Receipt Date: May 4, 1999

The Agency issued a supplement request letter to Novartis on September 19, 1997 asking that they revise the Lotrel labeling to include eosinophilic pneumonitis. In addition, Norvartis was asked to revise the format of the ADVERSE REACTIONS section to separate the adverse reactions seen in other ACE Inhibitors into a separate subsection or paragraph.

The applicant submitted a supplement with final printed labeling dated April 29, 1998. This supplement provides for the following changes to the **ADVERSE REACTIONS** section of the package insert:

> "Alopecia" was added to the list of adverse reactions seen infrequently in clinical trial or postmarketing experience.
>
> "Pancreatitis," "hemolytic anemia" and "pemphigus" were moved to a paragraph where they were included in a list of adverse reactions that occurred in postmarketing experience with benazepril.
>
> "Gynecomastia" was moved to the list of adverse reactions that have occurred in other calcium channel blockers, and eosinophilic pneumonitis was added as an adverse reaction attributed to other ACE Inhibitors.

In addition, the corporate name and address were changed to the following:

> Novartis
>
> Distributed by
> Novartis Pharmaceuticals Corporation
> East Hanover, New Jersey 07936

The reorganization of the **ADVERSE REACTIONS** section is in keeping with our request of September 19, 1999.

Conclusion

An approval letter will be drafted for Dr. Lipicky's signature. This supplemental NDA was submitted in accordance with 21 CFD 314.70(c).

David Roeder
Regulatory Health Project Manager