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APPLICATION NUMBER: NDA 19787/S002

ADMINISTRATIVE DOCUMENTS

CSO Review of Final Printed Labeling

JAN 12 1995

Application: NDA 19-787/S-002
Norvasc (amlodipine besylate) Tablets

Sponsor: Pfizer Inc.

Supplement Date: October 5, 1993

Receipt Date: October 12, 1993

Type of Supplement: Special Supplement: Changes Being Effected

Review

The sponsor submitted a "Special Supplement: Changes Being Effected" that provided for the following labeling changes under **ADVERSE REACTIONS**:

"Cardiovascular: arrhythmia" was expanded to read **"Cardiovascular: arrhythmia (including ventricular tachycardia and atrial fibrillation), . . ."**

Gingival hyperplasia was added under **Gastrointestinal**.

The third from the last paragraph in this section was revised to read as follows:

Other reactions occurred sporadically and cannot be distinguished from concurrent medications or disease states such as myocardial infarction an angina.

The original submission contained no data to support these changes. I requested this information; the sponsor complied with this request with a correspondence dated September 7, 1994.

Pending review by the Medical Officer, I recommend that the supplement be approved.



David Roeder
Consumer Safety Officer

dr/12-12-94

cc: Original NDA
HFD-110
HFD-111/DRoeder
HFD-111/SBenton