# CENTER FOR DRUG EVALUATION AND RESEARCH

# APPROVAL PACKAGE FOR:

# APPLICATION NUMBER

# NDA 19-787/S30

# Medical Review(s)

# DIVISION OF CARDIO-RENAL DRUG PRODUCTS

*Clinical Review*

**NDA:** 19-787 (amlodipine)

**Sponsor:** Pfizer Pharmaceuticals

**Submission:** SE5-030 (14 September 2001): response to a pediatric Written Request of 2 November 1999.

**Review date:** 6 November 2001

**Reviewer:** N. Stockbridge, M.D., Ph.D., HFD-110

**Summary:** The sponsor submitted results of two studies, parallel dose ranging and population pharmacokinetics. Exclusivity was granted. Labeling suggestions are made.

**Distribution:** NDA 19-787

HFD-110/Project Manager

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# 1 Background

This supplement was received 17 September 2001. The user-fee goal date (10-month) is 17 July 2002.

The sponsor presents the results of two studies, a placebo withdrawal from two doses and a population pharmacokinetic study. In addition, the sponsor provides summaries of reports of clinical experience with amlodipine in children.

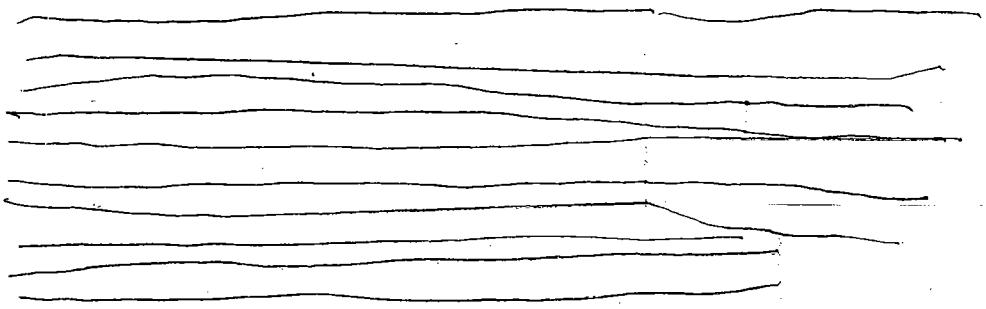
The studies used the commercially available tablet formulation for amlodipine. There are no chemistry issues.

The sponsor has provided a financial disclosure statement, denying inappropriate financial arrangements as defined under 21 CFR 54.2(a), (b), or (f).

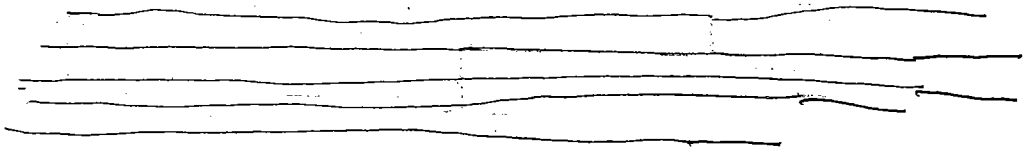
## 2 Labeling

The sponsor proposes inclusion of a description of the study results in the label for Norvasc (amlodipine besylate).

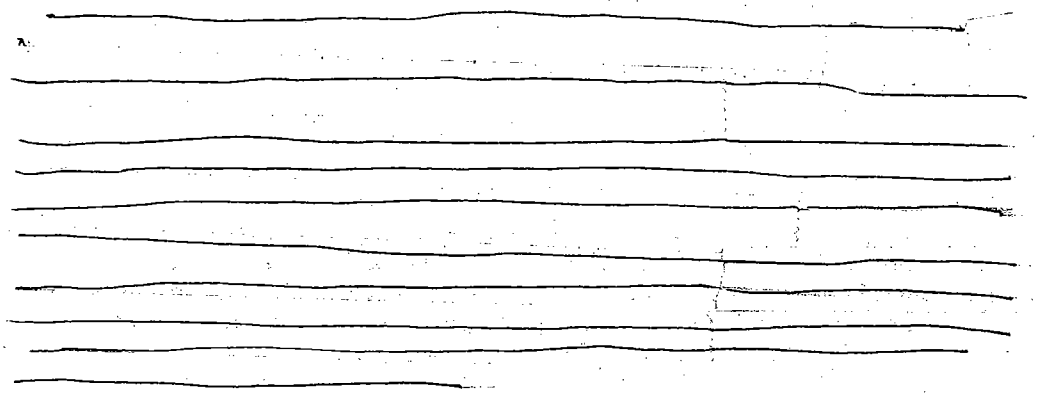
Under Pharmacokinetics, there is a new section, as follows:



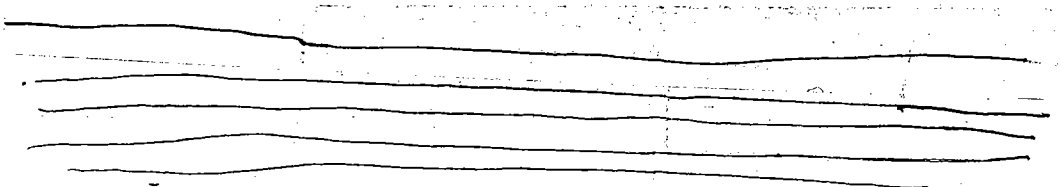
This section should be rewritten as follows:



Following the section on effects in hypertension, the sponsor proposes to add the following:



This section should rewritten as follows:



[redacted]

The sponsor proposes a specific new indication in hypertensive children. This change should be denied, since the only distinguishing characteristic of the new indication is the age group.

The sponsor proposes new language for Pediatric Use:

[redacted]

These data are not "unavailable"; they do not exist:

[redacted]

The sponsor proposes a new section of DOSAGE AND ADMINISTRATION:

***Children***

[redacted]

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