CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 19787/S004

CORRESPONDENCE

ORIGINAL

Regulatory Affairs Division
Pfizer Pharmaceuticals Group
Pfizer Inc
235 East 42nd Street
New York, NY 10017-5755
Tel 212 573 5999 Fax 212 733 6609

Pfizer Pharmaceuticals

May 27, 1999

Jean Lyons, MS
Director
Regulatory Affairs

SUPPL FOR CORRESP
(SNC)
B-004

Mr. David Roeder
Regulatory Health Project Manager
Division of Cardio-Renal Drug Products (HFD-110)
Center for Drug Evaluation and Research
Office of Drug Evaluation I
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

CENTER FOR DRUG EVALUATION AND RESEARCH
RECD
JUN 1 - 1999
HFD-110

RE: Norvasc (amlodipine besylate) tablets
NDA # 19-787
Stability of Amlodipine Besylate in Two Liquid Dosage Forms

Dear Dave,

In follow up to our telephone conversation today, attached please find the above referenced publication. This article details the stability program conducted on samples of two extemporaneously prepared suspensions of amlodipine which were stored at room temperature or refrigerated. It was just published in the May/June 1999 issue of the Journal of the American Pharmaceutical Association. As I mentioned in our conversation, Pfizer is seeking approval from the Agency to use either of these suspensions for the pop PK studies in children between the ages of 2-6 without having to perform bioequivalence studies on these liquids. In our previous discussions with the Agency, agreement was reached that it would be acceptable to dose small children with a tablet which had been ground and mixed with applesause. We believe that use of the referenced liquids would provide a simpler dosing regimen. We would appreciate the Agency's comments.

Thank you very much for your assistance. We look forward to hearing from you.

Sincerely,

Jean Lyons, M.S.
Director, Regulatory Affairs

ORIGINAL

Please review the attached supplement and let me know if I may be of any further assistance.

Sincerely,

I. Kissen

Inna Kissen, Ph.D.

IK:amw
ENCLOSURE
norvasc2/14

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