

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 19787/S006

CORRESPONDENCE

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NDA NO. 19787 SUPP. NO. S-006
NDA SUPPLEMENT FOR SCS

Inna Kissen, PhD
Associate Director—Drug Regulatory Affairs

March 31, 1995

Raymond Lipicky, M.D., Director
Division of Cardio-Renal
Drug Products (HFD-110)
Office of Drug Evaluation I
Center for Drug Evaluation and Research
Food and Drug Administration
1451 Rockville Pike
Rockville, Maryland 20852



RE: Norvasc (amlodipine besylate) Tablets
NDA #19-787
Special Supplement - Changes Being Effectuated

Dear Dr. Lipicky:

Pursuant CFR 314.70(c), we are submitting herein a Special Supplement to Norvasc (amlodipine besylate) Tablets, NDA #19-787.

The Special Supplement provides for the replacement of particle size methodology with
for amlodipine besylate, the drug substance for manufacture of Norvasc Tablets. The
present methodology uses

The replacement methodology,

Additional minor improvements of the procedure are also made in the way in which the sample suspension is maintained and added to the cell and in utilizing a more representative sample size.

The supplement contains the following:

ORIGINAL

If you have any questions, please call my office.

Sincerely,



Inna Kissen, Ph.D.

IK:amw
ENCLOSURE
norvasc2/7

CONFIDENTIAL/TRADE SECRET INFORMATION
SUBJECT TO 18-USE-1905 AND TO WHICH ALL
CLAIMS OF PRIVILEGE AND CONFIDENTIALITY
ARE ASSERTED IN BOTH STATUTORY AND
COMMON LAW.