

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 19787/S016

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Inna Kissen, PhD
Associate Director—Drug Regulatory Affairs

January 20, 1998

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 Pile
Rockville, MD 20852

NDA NO. 19-787 REF. NO. 016
NDA SUPPL FOR. SCS

RE: Norvasc (amlodipine besylate) tablets
NDA # 19-787



Dear Dr. Lipicky;

This supplement requests the approval of an alternate purification process
amlodipine besylate drug substance synthesis. The
currently approved process includes a purification in . It has been
demonstrated that the proposed intermediate and finish drug
substance with quality comparable to that of the approved process. Approval is requested for
implementation of the process.
remain unchanged.

The synthetic route employed with the proposed process change remains unchanged from the
current process. The finish drug substance specification remains the same.

If you have any questions regarding this supplement, please do not hesitate to call my office at
212-573-2503.

Sincerely,

Inna Kissen, Ph.D.

/jr

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