CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 19787/S011

CORRESPONDENCE

Regulatory Affairs Division
Pfizer Inc
235 East 42nd Street
New York, NY 10017-5755
Tel 212 573 2503 Fax 212 573 1563

NDA NO. 19-787 REF. NO. S-011

NDA SUPPL FOR SCM

Inna Kissen, PhD
Associate Director—Drug Regulatory Affairs

January 22, 1996

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
Supplemental Application: Alternate Packaging Site

Dear Dr. Lipicky:

This supplement requests approval of packaging site change for . We are requesting the approval of a new packaging site for as an additional packaging site for Norvasc Tablets (amlodipine besylate) NDA #19-787. As per the requirements, please refer to the attached stability commitment from Pfizer. At this time we are also submitting a similar supplement to the Division of Neuropharmacological Drug Products for Zoloft (sertraline HCl) Oral Antidepressant, NDA #19-839.

This letter also serves to request that Drug Master File dated May 19, 1995 submitted by be cross-referenced to NDA #19-787. Please refer to the attached authorization letter from regarding their support of this request.

A copy of this submission has been sent to the FDA Brooklyn District Office. Please add this information to the appropriate subject file.

Sincerely,

I. Kissen

Inna Kissen, Ph.D.

IK:amw
Enclosure
NORVASC2.DOC/12

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

ORIGINAL