CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number: NDA 20145/S007

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

DF

APR 14 1995

NDA 20-145/S-006

Schering Corporation
Attention: Richard N. Spivey, Pharm.D., Ph.D.
Galloping Hill Road
Kenilworth, NJ 07033

Dear Dr. Spivey:

Please refer to your March 6, 1995 supplemental new drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Nitro-Dur (nitroglycerin) Transdermal Systems.

The supplemental application provides for the following changes in the carton labels:

1. Deletion of the picture instructions on the back of each individual carton and addition of a blank space intended for the prescription label in its place.

2. Addition of the graphic "Nitro-Dur" patch on the front of the cartons.

We have completed the review of this supplemental application and it is approved.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please contact:

Mr. Gary Buehler
Consumer Safety Officer
(301) 594-5300

Sincerely yours,

Raymond J. Lipicky, M.D.
Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

cc:
Original NDA
HF-2/MedWatch (with labeling)
HFC-130/JAllen
HFD-80 (with labeling)
HFD-110
HFD-110/CSO
HFD-240 (with labeling)
HFD-613 (with labeling)
HFD-735/DBarash (with labeling)
HFD-110/GBuehler/3/30/95;4/3/95
sb/3/31/95;4/4/95
R/D: RWolters/4/3/95
EBarry
ADeFelice
MGordon
NMorgenstern/4/3/95

Approval Date: April 4, 1995

APPROVAL