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Application Number: NDA 20145/S007

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-145/S-007

MAY 23 1995

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

Dear Dr. Spivey:

Please refer to your April 20, 1995 supplemental new drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Nitro-Dur (nitroglycerin) Transdermal System.

The supplemental application provides for final printed labeling revised by adding the following as the second paragraph under **ADVERSE REACTIONS:**

> Allergic reactions to nitroglycerin are also uncommon, and the great majority of those reported have been cases of contact dermatitis or fixed drug eruption in patient receiving nitroglycerin in ointments or patches. There have been a few reports of genuine anaphylactoid reactions, and these reactions can probably occur in patients receiving nitroglycerin by any route.

We have completed the review of this supplemental application and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the final printed labeling included in the April 20, 1995 submission. Accordingly, the supplemental application is approved effective on the date of this letter.

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

At your next printing, please remove the following sentence from the **PRECAUTIONS, Carcinogenesis, Mutagenesis, Impairment of Fertility** subsection of the labeling:

Although we had asked for this wording in the past, on reflection we believe it could suggest more evidence of a clinical benefit than seems warranted.

This change should be submitted as a supplemental application.

If you have any questions, please contact:

Mr. Gary Buehler
Regulatory Health Project Manager
(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;5/10/95
sb/5/9/95;5/22/95;5/22/95
R/D: RWolters/5/10/95
SChen/5/11/95
EBarry
ADeFelice/5/11/95
NMorgenstern/5/12/95;5/22/95
RTemple

Approval Date: April 4, 1995

APPROVAL