DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-145/S-021

Schering Corporation
Attention: Ms. Yvette Henderson
2000 Galloping Hill Road
Kenilworth, New Jersey 07033

Dear Ms. Henderson:

Please refer to your supplemental new drug application dated December 3, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for NITRO-DUR (nitroglycerin) 0.1, 0.2, 0.3, 0.4, 0.6 and 0.8 mg/hr Transdermal Infusion System.

We acknowledge receipt of your submissions dated December 3, 2004 and January 5, 2005.

This "Changes Being Effected" supplemental new drug application provides for revisions of the package insert to reflect updates to the **WARNINGS** and **HOW SUPPLIED** sections. A supplemental amendment dated January 5, 2005 was submitted containing the final labeling to replace the draft labeling submitted December 3, 2004, which contained previously deleted product presentations "Hospital Unit 100 doses" in the **HOW SUPPLIED** section of the labeling.

You submitted electronic final printed labeling revised as follows:

1. Under **WARNINGS**, the first sentence has been revised from:

   Amplification of the vasodilatory effects of the NITRO-DUR patch by sildenafil can result in severe hypotension.

   To:

   Amplification of the vasodilatory effects of the NITRO-DUR patch by phosphodiesterase inhibitors, e.g., sildenafil can result in severe hypotension.

2. Under **HOW SUPPLIED**, the following revision from:

   Store between 15-30°C (59 - 86°F). Do not refrigerate.

   To:

   Store at 25° (77° F); excursions permitted to 15-30°C (59 - 86°F) [see USP Controlled Room Temperature]. Do not refrigerate.

We have completed our review of this supplemental new drug application and it is approved, effective on the date of this letter, for use as recommended in the amended final printed labeling (FPL) submitted on January 5, 2005.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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 call:

Mr. John David
Regulatory Project Manager
(301) 594-5309

Sincerely,

{See appended electronic signature page}

Norman Stockbridge, M.D., Ph.D.
Acting Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Norman Stockbridge

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