DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-145 / S-016

Schering Corporation
Attention: Nicholas J. Pelliccione, Ph.D.
2000 Galloping Hill Road
Kenilworth, NJ 07033

Dear Dr. Pelliccione:

Please refer to your supplemental new drug application dated June 26, 2002, received June 27, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Nitro-Dur (nitroglycerin) Transdermal Infusion System, 0.1 mg/hr, 0.2 mg/ hr, 0.3 mg/hr, 0.4 mg/hr, 0.6 mg/hr and 0.8 mg/ hr.

We acknowledge receipt of your submission dated September 17, 2002.

This supplemental new drug application provides for analytical methods and revised release specifications for Polymers A, B, C, and D.

We have completed the review of this supplemental application, as amended, 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, call Edward Fromm, Regulatory Health Project Manager, at (301) 594-5313.

Sincerely,

{See appended electronic signature page}

Kasturi Srinivasachar, Ph.D.
Chemistry Team Leader, DNDC I for the
Division of Cardio-Renal Drug Products, (HFD-110)
DNDC I, Office of New Drug Chemistry
Center for Drug Evaluation and Research

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/s/

Kasturi Srinivasachar

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