DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-705 S-016

Sciele™ Pharma Inc.
Attention: Allison Lowry
Five Concourse Parkway, Suite 1800
Atlanta, GA 30328

Dear Ms. Lowry:

Please refer to your supplemental new drug application dated March 27, 2006, received March 28, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Nitrolingual® Pumpspray (glyceryl trinitrate) 0.4 mg per spray.

We acknowledge receipt of your submissions dated June 21, July 24 and September 6, 2006.

This "Changes Being Effected" supplemental new drug application provides information to strengthen priming instructions on the secondary carton and container labels, which is intended to increase the safe use of the product. The carton components were also updated to reflect your new company name and address.

We have completed our review of this supplemental new drug application as amended and it is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on September 6, 2006.

Please submit the final printed labeling (FPL) electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA.

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, at (301) 796-1059.

Sincerely,

{See appended electronic signature page}

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

Cc: G. Pohl Boskamp
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Germany

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/s/

Norman Stockbridge

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