DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 9-175/S-033

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 July 26, 2007, received July 27, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Furadantin® (nitrofurantoin) Oral Suspension, 25mg/5mL.

This "Changes Being Effected" supplemental new drug application provides for revisions to the package insert to include information relative to recent epidemiologic and scientific data regarding *Clostridium difficile* associated disease (CDAD).

We completed our review of this application. It is approved, effective on the date of this letter, for use as recommended in the content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format submitted on July 26, 2007.

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
Food and Drug Administration
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call J. Christopher Davi, MS, Regulatory Project Manager, at (301) 796-0702.

Sincerely,

{See appended electronic signature page}

Katherine A. Laessig, MD
Deputy Director
Division of Anti-Infective and Ophthalmology Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosure: Labeling Submitted on July 26, 2007

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

/s/

Kathrine Laessig
5/30/2008 09:56:05 AM