DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 9-175/S-037

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

Dear Ms. Lowry:

Please refer to your supplemental new drug application dated January 8, 2009, received January 9, 2009, 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 changes to the Furadantin® package insert to more adequately characterize and communicate the risk for nitrofurantoin–associated hepatotoxicity.

We completed our review of this application and it is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text. As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed label submitted January 8, 2009. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, designate this submissions "SPL for approved supplement NDA 9-175/S-037."

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, Senior Regulatory Project Manager, at (301) 796-0702.

Sincerely,

{See appended electronic signature page}

Sumathi Nambiar, MD, MPH
Deputy Director for Safety
Division of Anti-Infective and Ophthalmology Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosure: Labeling submitted on January 8, 2009

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

/s/

Sumathi Nambiar

2/6/2009 02:42:55 PM