DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 15-034/S-040

Sciele Pharma, Inc.
Five Concourse Parkway
Suite 1800
Atlanta, GA 30328

Attention: Allison Lowry, RAC
Sr. Manager, Regulatory Affairs

Dear Ms. Lowry:

Please refer to your supplemental new drug application dated July 27, 2007, received August 2, 2007, submitted under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Ponstel™ (mefenamic acid) 250 mg capsules.

We acknowledge receipt of your submissions dated January 25 and February 26, 2008.

This "Changes Being Effected" supplemental new drug application provides for changes to the NSAID Medication Guide as requested in our January 5, 2007 letter.

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 enclosed content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format submitted on February 26, 2008 and with the following editorial revision to the package insert as agreed upon in an email exchange with Allison Lowry of Sciele Pharma on February 4, 2008.

Information for Patients

7. In late pregnancy, as with other NSAIDs, PONSTEL should be avoided because it <u>may</u> cause premature closure of the ductus arteriosus.

We will transmit the content of labeling in SPL format, as amended, to the National Library of Medicine for public dissemination.

We note that your July 27, 2007 submission includes final printed labeling (FPL) for your package insert and Medication Guide. We have not reviewed this FPL. You are responsible for assuring that the wording in this printed labeling is identical to that of the approved content of labeling in the SPL format.

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
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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 Kathleen Davies, Regulatory Project Manager, at (301) 796-2205.

Sincerely,

{See appended electronic signature page}

Bob Rappaport, MD
Director
Division of Anesthesia, Analgesia
And Rheumatology Products
Office of Drug Evaluation II
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/

Sharon Hertz
3/6/2008 04:20:47 PM
Signing for Bob Rappaport, M.D.