DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-118/S-001

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

Dear Ms. Lowry:

Please refer to your supplemental new drug application dated October 23, 2007, received October 24, 2007, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Fenoglide (fenofibrate) Tablets, 40 mg and 120 mg.

We acknowledge receipt of your submissions dated January 14 and 31, 2008

This supplemental new drug application provides for a revision to the package insert with regard to taking with food and to add a tradename, Fenoglide.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use recommended in the content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format submitted on January 31, 2008.

CARTON AND IMMEDIATE CONTAINER LABELS

We acknowledge your January 31, 2008 submission containing final printed carton and container labels.

PROMOTIONAL MATERIALS

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

LETTERS TO HEALTH CARE PROFESSIONALS

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 Kati Johnson, Regulatory Project Manager, at (301) 301-796-1234.

Sincerely,

{See appended electronic signature page}

Mary H. Parks, MD
Director
Division of Metabolism & Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure: Package Insert
90-count bottle label, 40 mg
7-count sample bottle label, 120 mg
90-count bottle label, 120 mg
Sample bottle display tray, 120 mg

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

/s/

Eric Colman
2/29/2008 07:00:21 PM
Eric Colman for Mary Parks