DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-350/S-005

Sciele Pharma, Inc.
US Agent for SkyePharma AG
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 July 26, 2007, received July 30, 2007, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Triglide (fenofibrate) Tablets, 50 mg, 160 mg.

We acknowledge receipt of your submissions dated August 22, 2007.

This "Changes Being Effected" supplemental new drug application provides for revised package insert and bottle labels and cartons to state that the tablets should only be stored in the moisture protective containers. This labeling was submitted in response to our letter dated June 27, 2007 which was issued following receipt of a June 6, 2007 periodic report describing six adverse events in four patients related to difficulty with pill swallowing.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text for the package insert and with the minor editorial revisions listed below:

1. In Table 2 (Effects of Fenofibrate** in Patients with Fredrickson Type IV/V Hyperlipidemia), add the header "Fenofibrate**" for Study 2. In addition, revise the footnote text to state "**Equivalent to 200 mg fenofibrate capsules, micronized. Dosage comparable to 160 mg TRIGLIDE" (emphasis added)
2. Make the titles of all tables consistent with regard to **bolding**.
3. In the definitions under the table "Fredrickson Classification of Hyperlipoproteinemias", the abbreviation for triglycerides is "Tg". It should be corrected to "TG" to match the contents of the table.
4. In the WARNINGS section, Liver Function subsection, the following sentence should be revised to correct the spelling of "doseranging": "The incidence of increases in transaminase related to fenofibrate therapy appears to be dose-related. In an 8-week **doseranging** study, the incidence of ALT or AST elevations…" (emphasis added)
5. In the PRECAUTIONS section, Pancreatitis subsection, the following sentence should be revised to correct the spelling of "severe": "This occurrence may represent a failure of efficacy in patients with **sever** hypertriglyceridemia…" (emphasis added)
6. The ADVERSE REACTION header should be corrected to read ADVERSE REACTIONS (emphasis added)
7. In the ADVERSE REACTIONS section, HEMIC AND LYMPHATICSYSTEM subsection, "LYMPHATICSYSTEM" should be corrected to read "LYMPHATIC SYSTEM"

CONTENT OF LABELING

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(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling (text for the package insert) except for including the revisions listed above. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved NDA 21-350/S-005."

CARTON AND IMMEDIATE CONTAINER LABELS

We acknowledge your July 26, 2007 submission containing final printed carton and container labels.

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 reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Kati Johnson, Regulatory Project Manager, at (301) 796-1234.

Sincerely,

{See appended electronic signature page}

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

Enclosure:

Package Insert
50 mg bottle label (30-count)-FF-L30-2, Rev. 10.06
50 mg carton (30-count)-FF-TC5-2, Rev. 10/06

160 mg bottle label (7-count sample)-FF-SL16-05, Rev 10.06
160 count carton label (7-count sample)-TG-SC16-2, Rev 10/06
160 mg sample tray (7-count)-TRI-SST-03, Rev 10/06

160 mg bottle label (30-count)-TG-L30-3 Rev. 10/06
160 mg carton label (30-count)-TG-TC16-2 Rev. 10/06

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
1/15/2008 11:24:36 AM
Eric Colman for Mary Parks