



NDA 21-350/S-008

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 September 23, 2008, received September 24, 2008, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Triglide (fenofibrate) Tablets, 50 mg and 160 mg.

This "Changes Being Effected" supplemental new drug application provides for revisions to the package insert (WARNINGS and PRECAUTIONS sections) to include information on the FIELD study requested in our September 6, 2007 and March 6, 2008 letters.

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the attached final printed labeling (FPL) submitted on September 23, 2008.

As requested in the January 15, 2008 approval letter for supplement -005, at the next printing revise the header ADVERSE REACTION to ADVERSE REACTIONS in the package insert. In addition, **bold** the header "Venothromboembolic Disease" in the PRECAUTIONS section to be consistent with the other headers.

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) 796-1234.

Sincerely,

*{See appended electronic signature page}*

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

Enclosure: Package Insert

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**This is a representation of an electronic record that was signed electronically and  
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/s/

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Eric Colman  
11/17/2008 02:28:48 PM  
Eric Colman for Mary Parks