



NDA 21-350/S-002

First Horizon Pharmaceutical Corp.
Agent for SkyePharma
Attention: Stephanie Cook, Manager, Regulatory Affairs
6195 Shiloh Road
Alpharetta, GA 3005

Dear Ms. Cook:

Please refer to your supplemental new drug application dated February 17, 2006, received February 21, 2006 submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Triglide (fenofibrate) Tablets, 50 and 160 mg..

We acknowledge receipt of your submission dated March 15, 2006.

This "Changes Being Effectuated" supplemental new drug application provides for the following:

1. Addition of an "Information for Patients" subsections to the PRECAUTIONS section of the package insert to instruct patients to store tablets in the original bottle and not to consume chipped or broken tablets.
2. Addition of a 30-count bottle size for the 160 mg strength tablet.

We completed our review of this supplemental new drug application, as amended. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on March 15, 2006.

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
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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, Chief, Project Management Staff, at (301) 796-1234.

Sincerely,

{See appended electronic signature page}

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

Enclosure: package insert (submitted February 17, 2006)
30-count bottle label (160 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
7/3/2006 03:28:39 PM
Eric Colman for Mary Parks