DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, MD 20857

NDA 21-350

Skye Pharma Inc.
Attention: Gordon L. Schooley, Ph.D.
Chief Scientific Officer
10450 Science Center Drive
San Diego, CA 92121

Dear Dr. Schooley:

Please refer to your new drug application (NDA) dated June 22, 2001, received June 25, 2001, pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Triglide (fenofibrate) Tablets, 50 mg and 160 mg.

We acknowledge receipt of your submission dates December 15 and 17, 2004, and January 28, March 4, and April 15 and 27, 2005.

The March 4, 2005, submission constituted a complete response to our December 14, 2004, action letter.

This new drug application provides for the use of Triglide (fenofibrate) Tablets, 50 mg and 160 mg, as an adjunctive therapy to diet for the reduction of LDL-C, Total-C, Triglycerides and Apo B in adult patients with primary hypercholesterolemia or mixed dyslipidemia (Fredrickson Types IIa and IIb) and as adjunctive therapy to diet for treatment of adult patients with hypertriglyceridemia (Fredrickson Types IV and V hyperlipidemia).

We completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the submitted final printed labeling (package insert and container labels submitted March 4, 2005).

However, the storage statement should be revised to say "excursions permitted between 15 - 30ºC (59 - 86ºF)" at the next printing. The electronic final printed labeling (FPL) may be submitted in the next annual report.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirement for this application.

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:

Division of Drug Marketing, Advertising
and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

The expiry date for 90-count bottles of 50 mg tablets is 12 months. For the 90-count bottles of 160 mg tablets, it is 18 months.

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 Valerie Jimenez, Regulatory Project Manager, at (301) 827-9090.

Sincerely,

{See appended electronic signature page}

David Orloff, M.D.
Director
Division of Endocrine and Metabolic Drug Products, HFD-510
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosures
- Package Insert
- 50 mg tablet container label
- 160 mg tablet container label

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

/s/

Mary Parks
5/7/05 05:22:09 PM
for Dr. Orloff