DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21350/S-014

SUPPLEMENT APPROVAL

Shionogi Inc.
US Agent for SkyePharma AG
Attention: Denise Flanagan, PhD
Senior Director Regulatory Affairs, CMC
300 Campus Drive
Florham Park, NJ 07932

Dear Dr. Flanagan:

Please refer to your Supplemental New Drug Application (sNDA) dated April 30, 2014, received May 1, 2014, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Triglide (fenofibrate) Tablets, 50 mg and160 mg.

We acknowledge receipt of your amendment dated November 7, 2014, containing revised labeling.

This "Prior Approval" supplemental new drug application provides for revisions to the PATIENT COUNSELING INFORMATION section (17) of the package insert to add the following information under "Patients should be advised":

- that Triglide must be kept in the original bottle to protect from moisture. The bottle contains a desiccant in the cap to protect tablets from moisture.
- that tablets should not be stored or placed in any other container, such as pill boxes or pill organizers.
- not to take chipped or broken tablets.

The supplement initially proposed instructions in the PATIENT COUNSELING INFORMATION section for the pharmacist to dispense the medication in the original manufacturer bottle with the dessicant cap. These instructions will be accomplished via revisions to the container labeling in a subsequent supplemental application.

This revision was submitted in response to our letter dated August 28, 2013, which issued following submissions of safety reports of patients experiencing difficulty in swallowing the tablets.

During the review, we were also informed that the 50 mg strength tablet is no longer marketed. Therefore, the package insert has been revised to reflect that the only available strength is 160 mg.

APPROVAL & LABELING

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that includes labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

REPORTING REQUIREMENTS

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

Sincerely,

{See appended electronic signature page}

James P. Smith, MD, MS
Deputy Director
Division of Metabolism and Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

ENCLOSURE: Content of Labeling

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

/s/

JAMES P SMITH
04/15/2015