DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21612/S-014, S-015

SUPPLEMENT APPROVAL

Galephar Pharmaceutical Research Inc.
US Agent for Cipher Pharmaceuticals, Inc.
Attention: Arthur Deboeck
Road 198 Km 14.7 #100 Juncos Industrial Park,
Juncos, PR 00777-3873

Dear Mr. Deboeck:

Please refer to your Supplemental New Drug Applications (sNDAs) dated January 27, 2012 (S-014) and January 15, 2013 (S-015), received January 30, 2012 (S-014) and January 16, 2013 (S-015), submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Lipofen (fenofibrate) Capsules, 50 mg and 150 mg.

We acknowledge receipt of your amendments dated September 20, 2012 and January 15, 2013 to Supplement -014. The September 20, 2012, submission constituted a complete response to our May 30, 2012, action letter.

Supplement -014, submitted as a Prior Approval supplemental new drug application, provides for the following:
−addition of Galephar Pharmaceutical Research, Inc (Humacao, PR) as an alternate drug product manufacturing site
(b) (4)

Supplement -015 was submitted as a "Prior Approval" supplemental new drug application in response to our letter dated October 15, 2012, issued to sponsors of marketed fenofibrate products. The primary revisions were made to the following sections of the PI:

- Modification of the WARNINGS AND PRECAUTIONS section to include results from the ACCORD Lipid trial;
- Revision of the WARNINGS AND PRECAUTIONS and ADVERSE REACTIONS sections to include information on paradoxical decreases in HDL in patients taking fenofibrates;
- Revisions of the WARNINGS AND PRECAUTIONS and DRUG INTERACTIONS section to state that cases of myopathy, including rhabdomyolysis, have been reported in patients taking fenofibrates co-administered with colchicine.

In addition, some additional revisions were made to correct some formatting errors and to further harmonize with other approved fenofibrate products.

We have completed our review of these supplemental applications, as amended. They are 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).

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and container labels that are identical to the enclosed immediate container labels as soon as they are available, but no more than 30 days after they are printed.

Please submit these labels electronically according to the guidance for industry titled "Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008)." Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Product Correspondence – Final Printed Carton and Container Labels for approved NDA 21612/S-014**." Approval of this submission by FDA is not required before the labeling is used.

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

Sincerely,

{See appended electronic signature page}

Eric Colman, MD
Deputy Director
Division of Metabolism and Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

ENCLOSURES:
- Content of Labeling
- Container Labeling
  - 50 mg (90-count bottle)
  - 150 mg (5-count sample bottle)
  - 150 mg (90-count bottle)

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

/s/

ERIC C COLMAN
01/18/2013