DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-612/S-002, S-004

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 dated July 4, 2007 (S-002) and August 26, 2008 (S-004), submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Lipofen Capsules, 50 mg, 100 mg and 150 mg.

These "Changes Being Effected" supplemental new drug applications provide for the following:

Supplement -002 proposes to add a 5-count sample bottle for the 150 mg strength product, and associated labeling revisions.

Supplement -004 proposes revisions to the PRECAUTIONS and WARNINGS sections of the package insert in response to our letters dated September 6, 2007 and March 6, 2008. The supplement also included the final printed labeling for the 90-count package for the 150 mg products that was approved with the initial NDA on January 11, 2006.

We completed our review of these supplemental new drug applications. They are approved, effective on the date of this letter, for use as recommended in the following final printed labeling (FPL):

1. Supplement -002: 5-count bottle label, 150 mg strength product submitted July 4, 2007. This labeling was subsequently updated with the final printed labeling contained in your submission dated August 15, 2007. The acknowledgement of this updated labeling will be conveyed under separate cover.

2. Supplement -004: Package Insert (Revised 062008) and 90-count bottle labels (150 mg) contained in the August 26, 2008 submission.

At the next printing of the bottle labels (commercial and sample packages), revise the storage statement to state, "Store at Controlled Room Temperature, 15° C - 30° C (59° F - 86° F)" and implement this across all labeling.

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

Attachments: Package Insert
5-count 150 mg bottle label
90-count 150 mg bottle label

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

12/12/2008 12:58:19 PM

Eric Colman for Mary Parks