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RESEARCH**

*APPLICATION NUMBER:*

**21-612**

**APPROVAL LETTER**



NDA 21-612

Cipher Pharmaceuticals Ltd.  
Galephar PR Inc., Agent for Cipher Pharmaceuticals Ltd.  
Road 198 No. 100 km 14.7  
Juncos Industrial Park  
Juncos, Puerto Rico 00777-3873

Attention: Arthur Deboeck  
Vice President and General Manager

Dear Mr. Deboeck:

Please refer to your new drug application (NDA) dated December 24, 2002, received February 26, 2003, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Lipofen (fenofibrate capsules) 50, 100, and 150 mg.

We acknowledge receipt of your submissions dated July 4, September 9, October 19, and December 15, 2005, and January 10 and 11 (email), 2006.

The July 4, 2005, submission constituted a complete response to our July 15, 2004, action letter.

This new drug application provides for the use of Lipofen (fenofibrate capsules) as adjunctive therapy to diet to reduce elevated LDL-C, Total-C, Triglycerides, Apo B, and to increase HDL-C in adult patients with primary hypercholesterolemia or mixed dyslipidemia (Frederickson Type IIa, IIb) in addition to the treatment of adult patients with hypertriglyceridemia (Frederickson 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 agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert submitted January 11, 2006, immediate container labels submitted December 15, 2005). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved NDA 21-612.**" Approval of this submission by FDA is not required before the labeling is used.

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:

Food and Drug Administration  
Center for Drug Evaluation and Research  
Division of Drug Marketing, Advertising, and Communications  
Food and Drug Administration  
5901-B Ammendale Road  
Beltsville, MD 20705-1266

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 Margaret Simoneau, M.S., R.Ph., Regulatory Project Manager, at (301) 796-1295.

Sincerely,

*{See appended electronic signature page}*

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

Enclosure

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/s/

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Mary Parks

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