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RESEARCH**

*APPLICATION NUMBER:*

**21-612**

**APPROVABLE LETTER**

6/2/04



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration  
Rockville, MD 20857

NDA 21-612

Galephar PR Inc.  
Attention: Authur M. Deboeck  
U.S. Agent for Cipher Pharmaceuticals Inc.  
Road 198 No. 100 km 14.7  
Juncos Industrial Park  
Juncos, PR 00777-3873

Dear Mr. Deboeck:

Please refer to your new drug application (NDA) dated December 24, 2002, February 26, 2003, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Luxacor (fenofibrate capsules) 50 mg, 100 mg, 150 mg, 160 mg.

We acknowledge receipt of your submissions dated January 7, 18, and 25, February 3, 9, and 16, March 30, and May 5, 14, and 21, 2004.

Your March 30, 2004, submission constituted a complete response to our December 18, 2003, action letter.

We completed our review of this application, as amended, and it is approvable. Before the application may be approved, however, it will be necessary for you to:

REGULATORY

1. Submit a patent certification for patent 6,589,552.
2. Submit proof of receipt by the patent holder and applicant for the listed drug of your Paragraph 4 Patent Certification notification for patent 6,589,552 and patent 6,652,881.
3. Submit a statement whether the patent holder or applicant (for the listed drug) has filed any suit against your firm with respect to patent 6,652,881.
4. Submit a statement regarding the status or final disposition of each patent infringement suit filed against Cipher Pharmaceuticals with respect to this application.

LABELING

5. In addition, it will be necessary for you to submit draft labeling with the following revisions to the labeling you submitted March 30, 2004:

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benzhydrol metabolite which is, in turn, conjugated with glucuronic acid and excreted in urine.

In vivo metabolism data indicate that neither fenofibrate nor fenofibric acid undergo oxidative metabolism (e.g., cytochrome P450) to a significant extent.

6. Revise the mock-ups of the bottle labels submitted March 30, 2004, to comply with 21 CFR 201.10(g)(2). In your March 30, 2004, submission, the size of the established name is too small with respect to the proprietary name. The established name must be no less than one-half the height of the proprietary name.

The electronic labeling rule published December 11, 2003, (68 FR 69009) requires submission of labeling content in electronic format effective June 8, 2004. For additional information, consult the following guidances for industry regarding electronic submissions: *Providing Regulatory Submissions in Electronic Format - NDAs* (January 1999) and the draft guidance *Providing Regulatory Submissions in Electronic Format - Content of Labeling* (February 2004). The labeling may also be submitted in paper, but it is not required.

Within 10 days after the date of this letter, you are required to amend this application, notify us of your intent to file an amendment, or follow one of your other options under 21 CFR 314.110. If you do not follow one of these options, we will consider your lack of response a request to withdraw the application under 21 CFR 314.65. Any amendment should respond to all the deficiencies listed. We will not process a partial reply as a major amendment nor will the review clock be reactivated until all deficiencies have been addressed.

The drug product may not be legally marketed until you have been notified in writing that the application is approved.

If you have any questions, call Valerie Jimenez, Regulatory Project Manager, at (301) 827-9090.

Sincerely,

*{See appended electronic signature page}*

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

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/s/

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David Orloff  
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