CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

Application Number: NDA 19922

Trade Name: CORLOPAM

Generic Name: FENOLDOPAM MESYLATE

Sponsor: NEUREX CORPORATION

Approval Date: SEPTEMBER 23, 1997

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION: NDA 19922

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	Included	Pending Completion	Not Prepared	Not Required
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Medical Review(s)	X			
Chemistry Review(s)	X			
EA/FONSI	X			
Pharmacology Review(s)	X			
Statistical Review(s)	X			
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Application Number: NDA 19922

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 19-922

SEP 23 1997

Neurex Corporation
Attention: Ms. Bonnie Horner
3760 Haven Avenue
Menlo Park, CA 94025-1012

Dear Ms. Horner:

Please refer to your December 12, 1988 new drug application (NDA) resubmitted on June 21, 1996 under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Corlopam (fenoldopam mesylate) 10 mg/ml Injection.

We acknowledge receipt of your amendments and correspondence dated May 3, July 15, August 6, 12, 13, 14, 20 and 23, September 9, October 8, 17, and 21, November 12, 19 (two), 21, 22 (two) and 26, and December 5 (two), 6, 11, and 20 (two), 1996; January 7, 13 and 27, February 4, 6 (two) and 11, March 13, 27 and 28, April 8, 15, 25, and 28, May 2, 7, and 20, June 6, 9, 12, 17 and 27, August 11 and September 18, 1997.

This new drug application provides for the in-hospital, short-term (up to 48 hours) use of Corlopam in the management of severe hypertension when rapid, but quickly reversible, emergency reduction of blood pressure is clinically indicated, including malignant hypertension with deteriorating end-organ function.

We have completed the review of this application, including the submitted draft labeling, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the enclosed marked-up draft. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed marked-up draft labeling. Marketing the product with FPL that is not identical to this draft labeling may render the product misbranded and an unapproved new drug.

Please submit sixteen copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy weight paper or similar material. For administrative purposes this submission should be designated "FINAL PRINTED LABELING" for approved NDA 19-922. Approval of this submission by FDA is not required before the labeling is used.

Should additional information relating to the safety and effectiveness of the drug become available, revision of that labeling may be required.

In addition, please submit three copies of the introductory promotional material that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to the Division of Cardio-Renal Drug Products and two copies of both the promotional material and the package insert directly to:

Food and Drug Administration
Division of Drug Marketing, Advertising and Communications, HFD-40
5600 Fishers Lane
Rockville, Maryland 20857

We remind you of your phase 4 commitment specified in your submission dated August 8, 1997, i.e.,

We suggest that you contact the Division of Cardio-Renal Drug Products to schedule a meeting to discuss the objectives and design of the trial.

Protocols, data, and final reports should be submitted to your IND for this product and a copy of the cover letter sent to this NDA. Should an IND not be required to meet your Phase 4 commitments, please submit protocols, data and final reports to this NDA as correspondence. For administrative purposes, all submissions, including labeling supplements, relating to these Phase 4 commitments must be clearly designated "Phase 4 Commitments."

Please submit one market package of the drug when it is available.

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, please contact:

Ms. Zelda McDonald
Regulatory Health Project Manager
(301) 594-5333

Sincerely yours,

Robert Temple, M.D.
Director
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 19-922

OCT 1 - 1997

Neurex Corporation
Attention: Helen P. Shu, Ph.D.
3760 Haven Avenue
Menlo Park, CA 94025-1012

Dear Dr. Shu:

Please refer to your new drug application (NDA) submitted pursuant to section 505 (b) of the Federal Food, Drug, and Cosmetic Act for Corlopam (fenoldopam mesylate) 10 mg/ml Injection.

As you requested, this is written confirmation that you can disregard the following paragraph that was inadvertently included in our letter of September 23, 1997:

> Within 10 days after the date of this letter, you are required to amend the application, notify us of your intent to file an amendment, or follow one of your other options under 21 CFR 314.110. In the absence of such action, FDA may take action to withdraw the application.

We have instructed our Freedom of Information staff to redact that paragraph from the letter that will be available to the general public. We are sorry for any inconvenience it may have caused.

If you have any questions, please contact:

Ms. Zelda McDonald
Regulatory Health Project Manager
Telephone: (301) 594-5333

Sincerely yours,

Ray Lipicky

Raymond J. Lipicky, M.D.
Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research