

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**ADVISORY COMMITTEE: CARDIOVASCULAR AND RENAL DRUGS**  
**ADVISORY COMMITTEE**

**DATE OF MEETING: 06/26/97**

**AGENDA**

## AGENDA

**FOOD AND DRUG ADMINISTRATION  
Center for Drug Evaluation and Research  
Division of Cardioresenal Drug Products  
81st Meeting, June 26,  
Cardiovascular and Renal Drugs Advisory Committee  
National Institutes of Health  
Clinical Center - Building 10  
Jack Masur Auditorium  
9000 Rockville Pike  
Bethesda, Maryland**

Parking in the Clinical Center visitor area is reserved for Clinical Center patients and their visitors. If you must drive please use an outlying lot such as Lot 41B. Free shuttle bus service is provided from Lot 41B to the Clinical Center every eight minutes. Free shuttle bus service from the subway is also available.

### JUNE 26, 1997

- 9:00 a.m.      OPEN PUBLIC HEARING  
One hour allocated unless public participation does not last that long.  
  
NDA 19-922, Corlopam (fenoldopam mesylate) Neurex Inc., for the short term treatment of hypertension when oral therapy is not feasible or possible and for use in hypertensive crisis.  
  
Sponsor's Presentation (Agenda attached)
- 10:30 a.m.      Break
- 10:45 a.m.      FDA Review  
Medical Reviewers: Abraham Karkowsky, M.D., Ph.D., Steve Rodin, M.D.  
Statistical Reviewer: Kun Jin, Ph.D.  
Pharmacokinetic Reviewers: Ahmed Al-Tahtawy, Ph.D., Ameeta Parekh, Ph.D.
- 11:15 a.m.      Committee Review  
Committee Reviewer: Michael Weber, M.D.  
  
Committee Discussion and Recommendations
- 12:30 p.m.      Lunch Break
- 1:15 p.m.      NDA 20-164, Lovenox injection (enoxaparin sodium) Rhône-Poulenc Rorer, to be indicated for the treatment of unstable angina and non-Q-wave myocardial infarction, concurrently administered with aspirin.  
  
Sponsor's presentation (Agenda attached)
- 3:00 p.m.      Break
- 3:15 p.m.      FDA Review  
Medical Reviewer: Kurt Sizer, M.D.  
Biostatistical Reviewer: Mohammed Huque, Ph.D.  
Biopharmaceutical Reviewer: Lydia Kaus, Ph.D.  
  
Committee Review  
Committee Reviewer: Marvin Konstam, M.D.  
  
Committee Discussion and Recommendations  
  
Adjourn  
  
Committee will meet in closed session on June 27th, to review pending NDA's.

**NEUREX CORPORATION**  
**CORLOPAM® (fenoldopam mesylate) Solution for Intravenous**  
**Infusion - NDA 19-922**  
**Cardiorenal Advisory Committee Presentation**  
**June 26, 1997**

|                       |                    |
|-----------------------|--------------------|
| Introduction          | Dr. Robert Luther  |
| Clinical Pharmacology | Dr. Addison Taylor |
| Efficacy              | Dr. David Ellis    |
| Renal Function        | Dr. Vandana Mathur |
| Safety                | Dr. David Ellis    |
| Conclusion            | Dr. Robert Luther  |

**CARDIOVASCULAR AND RENAL DRUGS  
ADVISORY COMMITTEE MEETING  
JUNE 26, 1997**

|   |                               |
|---|-------------------------------|
| <b>Introduction</b>                       | <b>Max Talbott, Ph.D.</b> —   |
| <b>Overview of Lovenox</b>                | <b>Janet Rush, M.D.</b>       |
| <b>Efficacy Data (ESSENCE)</b>            | <b>Marc Cohen, M.D.</b>       |
| <b>Safety Data (ESSENCE)</b>              | <b>Gregg Fromell, M.D.</b>    |
| <b>Clinical Impact of ESSENCE</b>         | <b>Eugene Braunwald, M.D.</b> |
| <b>Consistency with Guidance Document</b> | <b>Janet Rush, M.D.</b>       |

**CARDIOVASCULAR AND RENAL DRUGS ADVISORY COMMITTEE  
CENTER FOR DRUG EVALUATION AND RESEARCH**

**CHAIRPERSON**

Massie, Barry, M.D. 06/30/97  
Director, Coronary Care Unit  
Department of Medicine (111C)  
Veterans Administration Hospital  
4150 Clement Street  
San Francisco, California 94121

**ACTING EXECUTIVE SECRETARY**

Standaert, Joan C.  
Center for Drug Evaluation and Research  
Food and Drug Administration  
234 Summit Street, Room 117  
Toledo, Ohio 43604  
419/259-6211 FAX 419/259-6353

**MEMBERS**

**Consumer Representative**

Raehl, Cynthia, Pharm.D. 06/30/97  
Chair, Pharmacy Department  
School of Pharmacy, Texas Technical University  
Health Science Center  
1300 South Coulter Drive  
Amarillo, Texas 79106-9711

Weber, Michael, M.D. 06/30/97  
Chairman, Department of Medicine  
Brookdale University Hospital Medical Center  
1 Brookdale Plaza  
Brooklyn, New York 11212

Grines, Cindy, M.D. 06/30/99  
Director, Cardiac Catheterization  
Division of Cardiovascular Diseases  
William Beaumont Hospital  
3601 West Thirteen Mile Road  
Royal Oak, Michigan 48073-6769

Lindenfeld, JoAnn, M.D. 06/30/99  
Professor of Medicine, Division of Cardiology  
University of Colorado Health Science Center  
4200 East Ninth Avenue, B-130  
Denver, Colorado 80262

Moye, Lemuel, M.D., Ph.D. 06/30/99  
Associate Professor of Biometry  
University of Texas Health Science Center at Houston  
Coordinating Center for Clinical Trials  
1200 Herman Pressler Street, Suite 801  
Houston, Texas 77030

Thadani, Udho, M.D. FRCP 06/30/99  
Professor of Medicine  
Division of Cardiology  
Oklahoma University Health Sciences Center  
920 S.L. Young Boulevard, 5-SP-300  
Oklahoma City, Oklahoma 73104

Califf, Robert, M.D. 06/30/00  
Professor of Medicine/Director, Duke Clinical  
Research Center  
Duke University Medical Center  
2024 West Main Street, Box 31123  
Durham, North Carolina 27707

DiMarco, John, M.D. 06/30/00  
Professor of Medicine  
Cardiovascular Division  
University of Virginia Hospital, Box 3608  
Hospital Drive, 5th Floor  
Private Clinic, Room 3608  
Charlottesville, Virginia 22908

Konstam, Marvin, M.D. 06/30/00  
Professor of Medicine  
New England Medical Center  
750 Washington Street, Box 108  
Boston, Massachusetts 02111

Roden, Dan, M.D.C.M. 06/30/00  
Vanderbilt University  
Division of Clinical Pharmacology  
532C Medical Research Building 1  
23rd and Pierce Avenue  
Nashville, Tennessee 37232-6602