

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

National Institutes of Health
9000 Rockville Pike
Building 10, Clinical Center
Jack Masur Auditorium
Bethesda, MD.

CARDIOVASCULAR AND RENAL DRUGS ADVISORY COMMITTEE

AGENDA
93rd Meeting

Thursday, August 9, 2001

8:30 a.m. Meeting open for public comment: Chairman Presiding: Jeffrey Borer, M.D.

Remodulin (NDA 21-272)

Pulmonary Hypertension Association: Linda Carr, President (5 minutes)

JoAnne Schmidt, Huntington, N.Y. (5 minutes)

Beth DeSerano, Marion, Iowa. (5 minutes)

Oral and written comments entered into the record by Joan C. Standaert: (10 minutes)

Laboni Mahfuz, Garland TX

Shelly Shapiro, M.D., (trial investigator), University of Southern California

Extraneal (NDA 21-321)

Dante Germanotta, MA

8:55 a.m. Conflict of Interest Statement entered into the Record: Joan C. Standaert, Executive Secretary

Members Cardiovascular and Renal Drugs Advisory Committee:

Paul Armstrong, M.D., University of Alberta, Edmonton Alberta, Canada

Michael Artman, M.D., New York University Medical Center, NY

Jeffrey Borer, M.D., Weill Medical College at Cornell University, NY

Thomas Fleming, Ph.D., University of Washington, WA

Alan Hirsch, M.D., University of Minnesota Medical School, Minneapolis, MN

JoAnn Lindenfeld, M.D., University of Colorado Health Science Center CO

Steven Nissen, M.D., The Cleveland Clinic Foundation, Cleveland, OH

Temporary Member:

Gloria Anderson, M.D. (Consumer Representative), Morris Brown College, Atlanta GA

Invited Guests

Andrew Brem, M.D., Rhode Island Hospital, Providence, RI

Jeffrey Kopp, M.D., NIH, Bethesda, MD

PRESENTATIONS:

9:00 a.m.: NDA 21-272, Remodulin (treprostinil sodium injection), for treatment of pulmonary hypertension, United Therapeutics Corporation.

Sponsor's Presentation:

Introduction:

Roger Jeffs, Ph.D., United Therapeutics Corp.

Treprostinil Efficacy:

S. Rich, M.D., Rush Presbyterian-St. Lukes Medical Center

Treprostinil Safety:

R. Barst, M.D., Columbia Presbyterian Medical Center

11:00 a.m.: Regulatory Considerations: Robert Temple, M.D., Director, ODE-1

11:15 a.m.: Break

11:30 a.m.: Committee Discussion and Review:

Committee Reviewer: Thomas Fleming, Ph.D.

1; 00 p.m. Lunch

1:45 p.m.: NDA 21-321, Extraneal (7.5% icodextrin) Peritoneal Dialysis solution, for treatment of chronic renal failure, Baxter Healthcare Corporation.

Sponsor's Presentation:

Introduction and Role of Extraneal:

Salim Mujais, M.D., Vice President of Global Medical Affairs, Baxter (15 minutes)

Clinical Trial Experience with Extraneal: (25 minutes)

Marsha Wolfson, M.D., Vice President of Global Clinical Affairs, Baxter

Frank Ogrinc, Ph.D., Clinical Statistician, Baxter

Conclusions:

Salim Mujais M.D., Baxter (5 minutes)

3:00 p.m.: Break

3:15 p.m.: Committee Discussion and Review:

Committee Reviewer: Andrew Brem, M.D.

5:30 p.m. Adjourn

August 10, 2001

8:30 a.m.: Public comment: Pulmonary Hypertension Association, Linda Carr (5 minutes)

9:00 a.m.: NDA 21-290, Tracleer (bosentan tablets) for treatment of primary pulmonary hypertension, Actelion, Ltd.

Sponsor's Presentation:

Overview of Efficacy and Safety:

Isaac Korbin, M.D.

Drug-induced liver injury:

Willis Maddrey, M.D., UT Southwestern Medical Center

Benefit-Risk Assessment:

Lewis Rubin, M.D., UCSD

11:00 a.m.: Committee Discussion and Recommendations:

Committee Reviewer: JoAnn Lindenfeld, M.D.

