

CENTER FOR DRUG EVALUATION AND RESEARCH

**ADVISORY COMMITTEE: ADVISORY COMMITTEE FOR
REPRODUCTIVE HEALTH DRUGS**

DATE OF MEETING: 04/20/98

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AGENDA

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Advisory Committee for Reproductive Health Drugs
Monday, 20 April 1998
Food and Drug Administration
Holiday Inn Gaithersburg, MD

- | | | |
|-------|---|------------------------------------|
| 8:30 | Chairman's Introduction | Diana Petitti, M.D. |
| | Opening Remarks | Lisa Rarick, M.D. |
| | Conflict of Interest Statement | Kimberly L. Topper, M.S. |
| | <i>ISSUE - NDA 20-797 Antocin, (Atosiban injection) for use in the management of premature labor</i> | |
| 9:00 | The R. W. Johnson Pharmaceutical Research Institute Presentation | |
| | Introduction | Alan Dunton, M.D. |
| | Pre-term Labor | Steve Caritis, M.D., F.A.C.O.G. |
| | Preclinical Safety/Pharmacokinetics | Robert Wills, Ph.D. |
| | Clinical Review U. S. Program | George Creasy, M.D., F.A.C.O.G. |
| | Ex - U.S. Program | Per Bengtsson, M.D. |
| | Neonatologist Perspective | Robert Ward, M.D., F.A.A.P., F.C.P |
| | Perinatologist Perspective | Roberto Romero, M.D., F.A.C.O.G. |
| 10:15 | Break | |
| 10:35 | Committee Discussion | |
| 11:05 | FDA Division of Reproductive and Urologic Drugs Presentation | |
| | Introduction and Regulatory Background | Sandra Kweder, M.D. |
| | Pharmacology/Toxicology | Mary Ellen McNerney, Ph.D. |
| 11:45 | Committee Discussion | |
| 12:00 | Lunch | |
| 1:00 | Open Public Hearing | |
| 2:00 | FDA Statistical Presentation | Joy Mele, M.S. |
| 2:55 | Committee Discussion | |
| 3:25 | Break | |
| 3:40 | Summary of Issues for Discussion | Sandra Kweder, M.D. |
| 3:50 | Committee Discussion | |
| 5:00 | Adjourn | |

ADVISORY COMMITTEE FOR REPRODUCTIVE HEALTH DRUGS
CENTER FOR DRUG EVALUATION AND RESEARCH

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Consumer Representative:

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President
National Black Women's Health Project
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February 10, 1998

Wingo, Phyllis A., Ph.D. 6/30/00
Director of Surveillance
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Advisory Committee for Reproductive Health Drugs Meeting
April 20, 1998

Statistician:

Ralph D'Agostino, Ph.D.
Boston University
111 Cummington Street
Boston, MA 02215
(Chairman of the Nonprescription Drugs Advisory Committee)

Guests:

Linda Van Mater, M.D.
Newborn Medicine Hunnewell 438
Children's Hospital
300 Longwood Avenue
Boston, MA 02115

Michael Greene, M.D.
Department of Obstetrics and Gynecology
Massachusetts General Hospital
Founder's Room 430
Boston, MA 02114

William Oh, M.D.
Hasbro Children Hospital
593 Eddy Street
Providence, RI 02903

Charles Lockwood, M.D.
New York University Medical Center
550 First Avenue
New York, NY 10016

FDA Reviewers

Lisa Rarick, M.D.
Director
Division of Reproductive and Urologic Drug Products

Phill Price, M.D.
Medical Officer
Division of Reproductive and Urologic Drug Products

Sandra Kweder, M.D.
Medical Officer
Division of Reproductive and Urologic Drug Products

Mary Ellen McNerney, Ph.D.
Pharmacologist
Division of Reproductive and Urologic Drug Products

Joy Mele, Ph.D.
Mathematical Statistician
Division of Biometrics II

Jack Fitzsimmons, M.D.
Medical Officer
Office of Women's Health

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The R. W. Johnson Pharmaceutical Research Institute Presenters

Alan Dunton, M.D.
Vice President
Global Clinical Research & Development
R. W. Johnson Pharmaceutical Research Institute

Steve Caritis, M.D., F.A.C.O.G.
University of Pittsburgh School of Medicine

Robert Wills, Ph.D.
Vice President
Preclinical Development
R. W. Johnson Pharmaceutical Research Institute

George Creasy, M.D., F.A.C.O.G.
Director, Gynecology & Reproductive Medicine
Global Clinical Research & Development
R. W. Johnson Pharmaceutical Research Institute

Per Bengtsson, M.D.
Director Obstetrics
Ferring Pharmaceuticals

Robert Ward, M.D., F.A.A.P., F.C.P.
University of Utah School of Medicine

Roberto Romero, M.D., F.A.C.O.G.
Wayne State University School of Medicine

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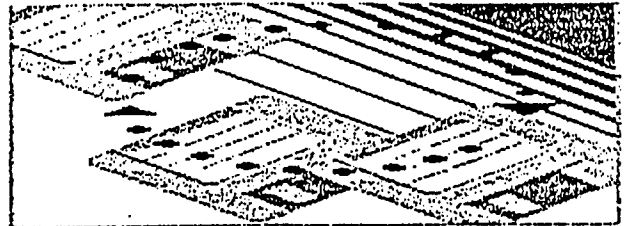
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QUESTIONS

Questions to the Committee

1. Do the data presented today support the effectiveness of atosiban for preterm labor?
2. Do the data presented today support the safety of atosiban as a treatment for preterm labor?
3. Taking into consideration the overall benefits and risks of atosiban, do you recommend that this drug be approved as a treatment for preterm labor?
4. Should additional studies of atosiban be conducted? If so, what specific type(s) and in what population?
5. What are reasonable and appropriate endpoints (to require for approval) for studies of new tocolytic agents?

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