

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

PERIPHERAL AND CENTRAL NERVOUS SYSTEM DRUGS  
ADVISORY COMMITTEE

Wednesday, June 6, 2001

8:15 a.m.

Holiday Inn  
Bethesda, Maryland

## PARTICIPANTS

Claudia H. Kawas, M.D., Consultant and Acting  
Chairman  
Sandra Titus, Ph.D., Executive Secretary

## MEMBERS:

Ella P. Lacey, Ph.D., Consumer Representative,  
LaRoy P. Penix, M.D.  
Richard D. Penn, M.D.  
Gerald Van Belle, Ph.D.

## CONSULTANTS:

Gustavo C. Roman, M.D.  
Jerry S. Wolinsky M.D.

## XYREM CONSULTANTS:

## VOTING:

Pippa Simpson, Ph.D.  
Carol Falkowski, Ph.D.

## NON-VOTING:

Christine A. Sannerud, Ph.D.  
Jerry Frankenheim, Ph.D.  
Jo-Ellen Dyer, Ph.D.

## ON PONE-LINK - NON-VOTING:

Ronald Chervin, M.D.  
Christian Guilleminault, M.D.

## FDA:

Robert Temple, M.D.  
Russell Katz, M.D.  
Ranjit Mani, M.D.  
John Feeney, M.D.  
Deborah B. Leiderman, M.D.

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## 1 P R O C E E D I N G S

## 2 Call to Order and Introductions

3 DR. KAWAS: Good morning, everyone, and  
4 welcome to the Wednesday, June 6, 2001 meeting of  
5 the Peripheral and Central Nervous System Advisory  
6 Committee. My name is Claudia Kawas, and I think  
7 we can begin with introductions, please, perhaps  
8 over by Dr. Temple's side.

9 DR. TEMPLE: Bob Temple, I am the Office  
10 Director.

11 DR. KATZ: Russ Katz, Division of  
12 Neuropharmacological Drug Products, FDA.

13 DR. FEENEY: John Feeney, neurology team  
14 leader, FDA.

15 DR. MANI: Ranjit Mani, medical reviewer,  
16 Neuropharm., FDA.

17 DR. LEIDERMAN: Deborah Leiderman,  
18 Director, Controlled Substance Staff, FDA.

19 DR. SIMPSON: Pippa Simpson, University of  
20 Arkansas Medical Sciences, biostatistician.

21 DR. FALKOWSKI: Carol Falkowski, drug  
22 abuse researcher, Hazelden Foundation.

23 DR. ROMAN: Gustavo Roman, Professor of  
24 Neurology at the University of Texas, San Antonio.

25 DR. WOLINSKY: Jerry Wolinsky, Professor

1 of Neurology, University of Texas, Houston.

2 DR. TITUS: Sandy Titus, FDA, the  
3 administrator of the Peripheral and Central Nervous  
4 System Committee.

5 DR. PENN: Richard Penn, neurosurgeon at  
6 the University of Chicago.

7 DR. LACEY: Ella Lacey, professor emerita,  
8 Illinois University, Carbondale, Illinois.

9 DR. VAN BELLE: Gerald Van Belle,  
10 Department of Biostatistics, from the University of  
11 Washington.

12 DR. PENIX: LaRoy Penix, Associate  
13 Professor of Neurology at Moorehouse School of  
14 Medicine.

15 DR. SANNERUD: Christina Sannerud, Drug  
16 and Chemical Evaluation Section, Drug Enforcement  
17 Administration.

18 DR. DYER: I am Jo Dyer, with the  
19 University of California, San Francisco and the San  
20 Francisco Poison Control System, California.

21 DR. FRANKENHEIM: Jerry Frankenheim,  
22 pharmacologist, National Institute on Drug Abuse.

23 DR. KAWAS: Today we have met to discuss  
24 the consideration of Xyrem, proposed to reduce the  
25 incidence of cataplexy and to improve the symptom

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