

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

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Richard D. Penn, M.D.
Gerald Van Belle, Ph.D.

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Jerry S. Wolinsky M.D.

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Carol Falkowski, Ph.D.

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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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