Minutes for April 29, 1999
Peripheral and Central Nervous System Advisory Committee

Issue: Safety and Efficacy of Freedox® (tirilazad mesylate) Injection [NDA 20-399]

The meeting was held at the Holiday Inn in Gaithersburg, Maryland. Prior to the meeting, the members and consultants had reviewed background material from the FDA and from Pharmacia and Upjohn. There were approximately 125 persons in attendance.

Attendance:
PCNS Members Present: Sid Gilman, M.D. (chair), David Drachman, M.D., Claudia Kawas, M.D., Michael Brooks, M.D., James Grotta, MD

PCNS Neurology SGE Consultants: Ella Lacey, Ph.D., Richard Penn, M.D., Gerald Van Belle, Ph.D.

PCNS Members Absent: Harold Adams, M.D., Zaven Khachaturian, Ph.D.

FDA Participants: Robert Temple, M.D., Russell Katz, M.D., Gregory Burkhart M.D., Armando Oliva, M.D., Judith A. Racoosin, M.D., MPH, Lu Cui, Ph.D.

FDA Presentations: Russell Katz, M.D., Acting Director, Neuropharmacological Drug Products gave an historical overview of the NDA. Armando Oliva, M.D., Medical Officer, presented **Efficacy Data** and Judith A. Racoosin, M.D., MPH, Medical Officer, presented **Safety Data.**

Pharmacia and Upjohn Presentations: Mark Corrigan, M.D., VP, Global Clinical Development, Pharmacia and Upjohn introduced and concluded with **SAH Development Program: Past and Present Issues.** Lawrence Marshall, M.D., Professor & Chief Division of Neurological Surgery,University of California San Diego presented **Risk Benefit Assessment: SAH: Response to Specific FDA Comments.**

The committee asked the sponsor and FDA questions and also had a lengthy discussion before they addressed the charge to the committee:

Questions to PCNS on Freedox®:

1. Has the sponsor submitted substantial evidence of effectiveness for the proposed indication sought: for the treatment of aneurysmal subarachnoid hemorrhage (SAH) to improve survival and functional outcome in patients with poor neurological function following the initial hemorrhage?

   Yes 0 **No 8**

2. Has the sponsor submitted sufficient safety data to support approval of application?

   Yes 8 **No 0**

A verbatim transcript of this meeting will be available on the FDA's Dockets Management Branch Website approximately 30 days after the meeting. The address is: Http://www.fda.gov/ohrms/dockets/ac/acmenu.htm

I certify that I attended the April 29, 1999 meeting of the Peripheral and Central Nervous System Drugs Advisory Committee and that these minutes accurately reflect what transpired.

/S/

Sandra Titus, Ph.D.
Executive Secretary, PCNS

Date

/S/

Sid Gilman, M.D.
Chair, PCNS

Date

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