Minutes for April 28, 1999
Peripheral and Central Nervous System Advisory Committee

Issue: Safety and Efficacy of Aggrenox™ (Dipyridamole/aspirin)capsule [NDA 20-884]

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 Boehringer. 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, M.D.

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

Cardiology SGE Consultants: Robert Califf, M.D., Marvin Konstam, M.D.

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

FDA Participants: Robert Temple, M.D, Florence Houn, M.D, MPH,, Russell Katz, M.D., Lilia Talarico, M.D., Kathy Robie-Suh, M.D., Ph.D., Ann Farrell, M.D, Mushfiqur Rashid, Ph.D., John Feeney, M.D.

Overview of Boehringer's Presentation:
Manfred Haehl, M.D., Senior Vice President, Medical & Drug Regulatory Affairs, BIPI made Boehringer's introduction. This was followed by a presentation by Gregory Albers, M.D. (Associate Professor Neurology, Director of Stanford Stroke Center, Stanford University) on **Stroke Management.** Thomas Mueller, M.D., Ph.D. (Head, Haemostasis Laboratory, Blood Transfusion Center, Oldenburg, Germany) presented the **Rationale for the Development** of the NDA. James Street, Ph.D., Senior Biostatistician, BIPI presented **Clinical Findings**. Kenneth J. Rakowski, M.D., Head, Drug Surveillance and Information, BIPI presented **Safety**.

Overview of FDA's Presentations:
Kathy Robie-Suh, M.D., Ph.D., Medical Team Leader, GI and Coagulation Drug Products provided an **Overview of the NDA.** Ann Farrell, M.D., Medical Officer, GI and Coagulation Drug Products discussed **Efficacy Issues.** Mushfiqur Rashid, Ph.D., Mathematical Statistician, Division of Biometrics II presented the **Statistical Review.**

The committee asked the sponsor and FDA questions and also had a lengthy discussion before they addressed the charge to the committee. **The Committee altered the questions that were posed and answered the following questions:**

1. Based on this single study has the sponsor provided substantial evidence of effectiveness of AGGRENOX™ for stroke reduction? **Yes 10 No 0**

2. Based on this single study has the sponsor provided substantial evidence of effectiveness of AGGRENOX™ for reduction of death? **Yes 3 No 7**

3. Are there any particular safety concerns with use of AGGRENOX™? **Yes 0 No 10**

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 28, 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

3510 m1