FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)

Peripheral and Central Nervous System Drugs Advisory Committee
Hilton Washington DC North/Gaithersburg
Gaithersburg Maryland
May 17, 2006

The committee will discuss new drug application [NDA] 20823, SE1-016, EXELON®, (rivastigmine tartrate) Capsules (1.5 milligrams mg, 3.0 mg, 4.5 mg, and 6.0 mg), Novartis Pharmaceuticals Corporation, for the proposed indication of the treatment of mild to moderate dementia associated with Parkinson's disease.

AGENDA

8:00	Call to Order	**Karl Kieburtz, MD, MPH** Chair, Peripheral & Central Nervous System Drugs Advisory Committee, PCNS
	Conflict of Interest Statement	**LT Darrell Lyons, BSN** Executive Secretary, PCNS
8:30	Welcome and Introductory Comments	**Russell Katz, MD** Director Division of Neurology Products, FDA

Sponsor Presentations:

8:40	Exelon® (rivastigmine) Introduction and Regulatory Overview	**Martina Stuck, PhD** Senior Associate Director, Drug Regulatory Affairs Novartis Pharmaceuticals Corporation
8:45	The Neuropathology of Parkinson's Disease with Dementia	**James B. Leverenz, MD** Neurology and Psychiatry and Behavioral Sciences University of Washington School of Medicine UW Alzheimer's Disease Research Center VA NW Network Mental Illness & Parkinson's Disease Research, Education, and Clinical Centers
9:00	Parkinson's disease Dementia (PDD): A Clinical Perspective	**Howard Feldman, MMCM, FRCP (C)** Professor and Head Division of Neurology University of British Columbia, Canada
9:15	Clinical Summary	**Clive Ballard, MD**

Professor of Age Related Diseases
King's College, London
University of London
Strand, London, England, United Kingdom

9:20 Committee discussion

10:00 Break

Sponsor Presentations Continued:

10:15	Rationale for Indication of Parkinson's Disease Dementia (PDD) & Study Design	**Roger Lane, MD, MPH** Disease Area Section Head for Dementia Neuroscience Clinical Development & Medical Affairs, Novartis Pharmaceuticals Corporation
10:30	Express Results	**Sibel Tekin, MD** Clinical Program Leader Neuroscience Clinical Development and Medical Affairs, Novartis Pharmaceuticals Corporation
10:50	Benefits-Risk Assessment	**Murat Emre, MD** Director, Behavioral Neurology and Movement Disorders Unit Professor of Neurology Department of Neurology Istanbul University Istanbul, Turkey
11:05	Exelon® (rivastigmine) PDD Indication Regulatory Considerations	**Martina Stuck, PhD** Senior Associate Director Drug Regulatory Affairs Novartis Pharmaceuticals Corporation

11:10 Committee Discussion

12:00 Lunch

1:00 Open Public Hearing

2:00 Questions for the Committee

3:00 Break

5:00 Adjourn

MEETING ROSTER

Committee Members:

Karl Kieburtz, MD, MPH

Michael D. Hughes, MD

Sandra F. Olson, MD

Ralph L. Sacco, MD, M.S.

Temporary Voting Members:

Eric Ahlskog, MD, Ph.D.

Irene Litvan, MD

Marshall Loeb (PR)

Carol L. Koski, MD

Non-Voting Member

Roger Porter, MD (IR)

FDA Participants (Non-Voting):

Robert Temple, MD

Russell Katz, MD

Marc K. Walton, MD

Ranjit B. Mani, MD

Participants List

Eric Ahlskog, MD, Ph.D.
Professor
Mayo Clinic
200 First Street SW, Gonda-8
Rochester, MN 55905

Irene Litvan, MD
Director,
Movement Disorder Program
University of Louisville
School of Medicine
500 S. Preston
Louisville, KY 40202

Carol L. Koski, MD
Department of Neurology
Santa Fe, NM 87501
University of Maryland Medical Systems
22 S. Greene Street
Baltimore, MD 21201

Marshall Loeb
(Patient Representative)
31 Montrose Road
Scarsdale, NY 10583