

**FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)
Meeting of the Peripheral and Central Nervous System Drugs Advisory
Committee
May 17, 2006**

*[NDA] 20823, SE1-016, EXELON®; for the treatment of mild to
Moderate dementia associated with Parkinson's disease.*

AGENDA

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|------|-----------------------------------|---|
| 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, B.S.N
Executive Secretary, PCNS |
| 8:30 | Welcome and Introductory Comments | FDA
Acting Director, Division of Nonprescription
Clinical Evaluation |
| 8:40 | Presentation | FDA
Medical Team Leader, Division of Metabolism and
Endocrinology Products |
| 9:10 | Presentation | FDA
Senior Regulatory Review Scientist, Division of
Nonprescription Regulation Development |

Sponsor Presentations:

- | | | |
|-------|---|---|
| 9:20 | Presentation | Sponsor
NOVARTIS |
| 9:30 | Presentation | Sponsor
NOVARTIS |
| 9:40 | Presentation | Sponsor
NOVARTIS |
| 10:05 | Consumer Understanding and Use
in OTC Setting | Saul Shiffman, Ph.D.
Research Professor of Health Psychology and
Pharmaceutical Sciences
University of Pittsburgh |
| 10:30 | Orlistat's Consumer Education and
Behavioral Support Program | Steve Burton
Vice-President of Weight Control
GlaxoSmithKline |

10:40 Summary and Commitments

John Dent, Ph.D.

Senior Vice-President, Research & Development
GlaxoSmithKline

10:45 Break

11:00 **Question and Answer Period**

FDA Presentations:

11:15 Safety and Efficacy Review

Julie Golden, M.D.

Medical Officer, Division of Metabolism and
Endocrinology Products

11:40 Label Comprehension Review

Susanna Weiss, Ph.D., J.D.

Social Science Analyst, Division of Nonprescription
Clinical Evaluation

11:55 Actual Use Study Review

Karen Feibus, M.D.

Medical Officer, Division of Nonprescription
Clinical Evaluation

12:15 **Lunch**

1:15 **Question and Answer Period**

1:30 Open Public Hearing

2:30 **Committee Discussion / Questions**

3:30 Break

3:45 **Questions for the Committee**

5:00 **Adjourn**

MEETING ROSTER

Committee Members:

Karl Kiebertz, MD, MPH

Michael D. Hughes, MD

Temporary Voting Members:

Eric Ahlskog, MD, Ph.D.

Irene Litvan, MD

FDA Participants (Non-Voting):

Robert Meyer, MD

Russell Katz, MD

Lily K.F. Jung, MD, (CR)

Marshall Loeb (PR)

Ranjit B. Mani, MD

Sandra F. Olson, MD

Carol L. Koski, MD

TBN

Ralph L. Sacco, MD, M.S.

TBN

Non-Voting Member

TBN

Roger Porter, MD (IR)

TBN