

**FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)
Joint Meeting of the Nonprescription Drugs and the Endocrinologic
& Metabolic Drugs Advisory Committee
January 23, 2006**

(OTC) use of Orlistat (tetrahydrolipstatin) capsules to promote weight loss in adults.

AGENDA

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|------|-----------------------------------|--|
| 8:00 | Call to Order | Alastair Wood, M.D., Ph.D.
Chair, Nonprescription Drugs Advisory Committee,
NDAC |
| | Conflict of Interest Statement | LT Darrell Lyons, B.S.N
Executive Secretary, NDAC |
| 8:30 | Welcome and Introductory Comments | Andrea Leonard Segal, M.D.
Acting Director, Division of Nonprescription
Clinical Evaluation |
| 8:40 | History of Weight-Loss Drugs | Eric Colman, M.D.
Medical Team Leader, Division of Metabolism and
Endocrinology Products |
| 9:10 | History of the OTC Monograph | Arlene Solbeck, M.S.
Senior Regulatory Review Scientist, Division of
Nonprescription Regulation Development |

Sponsor Presentations:

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|------|---|---|
| 9:20 | Orlistat for Over-the-Counter Use | John Dent, Ph.D.
Senior Vice-President, Research & Development
GlaxoSmithKline |
| 9:30 | The Public Health Need for
FDA-Approved Weight Loss Tool | Caroline Apovian, M.D.
Associate Professor of Medicine and Pediatrics, Boston
University School of Medicine
Director, Center for Nutrition and Weight Management,
Boston Medical Center
Co-Principal, New England Centers for Obesity Res & Ed
Vice-Chair, Massachusetts Med Soc Committee on
Nutrition |
| 9:40 | Safety and Efficacy-Orlistat 60-120 mg | Vidhu Bansal, Pharm.D.
Director, Medical Affairs; GlaxoSmithKline |

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**