

**Food and Drug Administration
Center for Drug Evaluation and Research**

Endocrinologic and Metabolic Drugs Advisory Committee

**Holiday Inn Bethesda
8120 Wisconsin Avenue, Bethesda, MD**

**Agenda
July 26, 2001**

NDA 21-332, Symlin ä (pramlintide acetate) Amylin Pharmaceuticals, Inc.

8:00 Call to Order and Introductions: Robert A. Kreisberg, M.D., Acting Chair
Meeting Statement: Kathleen Reedy, Executive Secretary

8:15 Welcome and Introduction: David G. Orloff, M.D., Director
Division of Metabolic and Endocrine Drug Products

8:30 Amylin Pharmaceuticals, Inc. Presentation

Overview: Joann L. Data, MD, PhD, Sr. VP Regulatory Affairs and Quality Assurance
Unmet Medical Need: Kenneth Polonsky, MD, Adolphus Busch Professor of Medicine
Chairman, Department of Medicine, Washington University School of Medicine
Pharmacology of Pramlintide: Andrew Young, MD, PhD, VP, Research at Amylin
Clinical Program for Pramlintide: Orville Kolterman, MD, Sr. VP Clinical Affairs at Amylin
Risk/Benefit/Summary: Alain Baron, VP Clinical Research at Amylin

10:00 Break

10:15 FDA Presentation: Division of Metabolic and Endocrine Drug Products
Efficacy: Robert I. Misbin, M.D.
Safety: Dragos G. Roman, M.D.

11:15 Open Public Hearing

11:45 Lunch

1:00 Charge to the Committee: David G. Orloff, M.D., Director
Division of Metabolic and Endocrine Drug Products
Discussion and Questions:

Break

4:30 Summary and Review

5:00 Adjourn