

Agenda: Monday, November 4, 2002
Psychopharmacological Drugs Advisory Committee

Food and Drug Administration
Holiday Inn, Gaithersburg, Maryland

8:00 Call to Order, Introductions
Dan Oren, M.D., Acting Chair, PCNS

Conflict of Interest Statement
Sandra Titus, Ph.D., Executive Secretary, PCNS

Clozaril® NDA 19-758/SE1-047
(Clozapine, Novartis Pharmaceuticals Corporation)

8:15 Welcome and FDA Overview of Issues
Russell Katz, M.D., Director, Neuropharmacological Drug Products

8:20 Overview of Issues: Regulatory Implication of InterSePT Study
Thomas Laughren, M.D., Team Leader, Psychiatric Drug Products Group

8:35 Novartis Presentations
Introduction
Roy W. Dodsworth, Executive Director, Drug Regulatory Affairs, Novartis

Overview of Suicidal Behavior
Herbert Y. Meltzer, M.D., Bixler Professor, Psychiatry and Pharmacology, Vanderbilt University

InterSePT Study
Rocco Zaninelli, M.D., Executive Director, Clinical Research, Novartis

Suicide Monitoring Board
K Ranga Rama Krishnan, M.B, Ch.B., Professor, Psychiatry and Behavioral Sciences, Duke University

Benefit/Risk
John M. Kane, M.D., Chairman, Department of Psychiatry, Long Island Jewish Medical Center

Question and Answer Moderator
Rocco Zaninelli, M.D.

9:35 Questions from the Committee to Novartis

10:00 Break

10:30 FDA – Clinical inspection Summary
Ni Khin, M.D., Division of Scientific Investigations

10:45 Open Public Hearing
James McNulty, President of the National Alliance for the Mentally Ill (NAMI)
David Goldman, M.D., President, Expert Health Data Programming, Inc.

11:00 Questions to the FDA and Beginning of Discussion

12:00 Lunch

1:00 Continuation of Discussion

Adjourn