Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

Psychopharmacologic Drugs Advisory Committee

June 16, 2003

Marriott Washingtonian Center - Rio
9751 Washingtonian Boulevard, Gaithersburg, Maryland

AGENDA

8:00	Call to Order and Opening Remarks	Matthew Rudorfer, M.D Acting Chair
	Introduction of Committee	
	Conflict of Interest Statement	Anuja M. Patel, M.P.H. Executive Secretary, FDA

Discussions on the white blood cell (WBC) monitoring schedule for patients being treated long-term with clozapine. Currently, the WBC monitoring schedule is weekly for the first six months of continuous therapy and biweekly thereafter. The committee will consider the question of whether the frequency of WBC monitoring can be diminished further following some period of biweekly monitoring.

8:15	Opening Remarks	Russell Katz, M.D. Director, Division of Neuropharmacologic Drug Products, FDA
	Overview of Issues	Judith A. Racoosin, MD, MPH Safety Team Leader, Division of Neuropharmacologic Drug Products, FDA
8:45	**<u>Sponsor Presentations</u>** **Novartis Pharmaceuticals Corporation**	
	• Introduction	James Rawls, Pharm.D. Associate Director, Drug Regulatory Affairs Novartis Pharmaceuticals Corp.
	• Overview of Agranulocytosis	Stanton Gerson, M.D. Chief, Division of Hematology and Oncology Department of Medicine, Case Western Reserve University

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AGENDA (cont.)

Sponsor Presentations (cont.)

• Clozaril Registry Data	Vinod Kumar, M.D. Executive Director, Clinical Development and Medical Affairs Novartis Pharmaceuticals Corp.
• Quantitative Analysis of US Data	Lawrence Hauptman, Ph.D. Director, Drug Regulatory Affairs Novartis Pharmaceuticals Corp.
• Summary and Conclusion	John M. Kane, M.D. Professor of Psychiatry, Neurology and Neuroscience Albert Einstein College of Medicine

10:15 Questions from Committee to Sponsor

10:30 Break

10:45 **FDA Presentation**

• Discussion of Selected Safety Data	Tarek A. Hammad, M.D., Ph.D Safety Medical Reviewer, Division of Neuropharmacologic Drug Products, FDA

11:15 Questions from Committee to FDA

12:00 Lunch

1:00 Open Public Hearing

2:00 Continuation of Committee Discussion and Response to FDA Questions

Break

5:00 Adjourn

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Open Public Hearing Speakers