FOOD AND DRUG ADMINISTRATION

Center for Drug Evaluation and Research Oncologic Drugs Advisory Committee

AGENDA

May 10, 2007

8:00 a.m. Call to Order S.Gail Eckhardt, M.D.

Introduction of Committee Acting Chair, ODAC

Conflict of Interest Statement Johanna Clifford, M.Sc., RN

Designated Federal Officer (DFO), ODAC

8:15 a.m. Opening Remarks Richard Pazdur, M.D., Director

Office of Oncology Drug Products (OODP), FDA

The committee will discuss updated information on risks of erythropoeisis-stimulating agents (ARANESP, Amgen, Inc., EPOGEN, Amgen, Inc., and PROCRIT, Amgen, Inc.) for use in the treatment of anemia due to cancer chemotherapy.

8:25 a.m. Risks and Indications for RBCs

Transfusions

David Stroncek, MD

Chief, Laboratory Services Section

Department of Transfusion Medicine, NIH

8:45 a.m. **Sponsor Presentation**

Introduction

Amgen, Inc.

Roger M. Perlmutter, M.D., Ph.D. Executive Vice President Research & Development, Amgen Inc.

Clinical Perspectives on ESAs

Jeffrey Crawford, M.D.

George Barth Geller Professsor for Research in Cancer, Chief of Medical Oncology, Duke University

Benefit/Risk

Roy Baynes, M.D., Ph.D.

Vice President, Global Development, Oncology

Supportive Care

Alex Zukiwski, M.D.

Vice President, Head of Clinical Development

Oncology, Johnson & Johnson Pharmaceutical Research

and Development

Summary Roger Perlmutter, M.D., Ph.D.

9:45 a.m. **FDA Presentation**

Vinni Junega, M.D.

Medical Officer, DOBP, OODP, FDA

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10:30 a.m. Break

10:45 a.m. Open Public Hearing

11:45 a.m. Lunch

12:15 p.m. Questions from the Committee

1:15 p.m. Questions to the ODAC and ODAC Discussion

4:00 p.m. Adjourn