FOOD AND DRUG ADMINISTRATION

Center for Drug Evaluation and Research

Cardiovascular & Renal Drugs Advisory Committee (CRDAC) in Joint Session with the

Drug Safety & Risk Management Advisory Committee (DSaRM)

AGENDA

September 11, 2007

The committee will discuss updated information on the risks and benefits of erythropoeisis-stimulating agents (ARANESP, Amgen, Inc., EPOGEN, Amgen, Inc. and PROCRIT, Amgen, Inc.) when used in the treatment of anemia due to chronic renal failure.

8:00 a.m.	Call to Order Introduction of Committee	**Richard Platt, M.D., M.Sc.** Chair, DSaRM
	Conflict of Interest Statement	**Mimi Phan, Pharm.D., R.Ph.** Acting Designated Federal Officer, CRDAC
8:15 a.m.	Introduction	**Dwaine Rieves, M.D.** Acting Director, Division of Medical Imaging and Hematology Products (DMIHP), OND, CDER, FDA
8:30 a.m.	Anemia and Chronic Kidney Disease UPDATE	**Ajay K. Singh, M.D.** Clinical Director, Renal Division Director, Dialysis Services Assoc. Professor of Medicine, Brigham & Women's Hospital, Boston, MA
8:50 a.m.	Medical Technology and Practice Patterns Institute (MTPPI) Epoetin Outcomes Research	**Dennis J. Cotter, M.S.E** President, MTPPI, Bethesda, MD
		Miguel Hernan, M.D. Associate Professor of Epidemiology Harvard University, School of Public Health Boston, MA
		Yi Zhang, D.D.S. Senior Analyst, MTPPI, Bethesda, MD

SPONSOR PRESENTATIONS

	TREAT	**Marc Pfeffer, M.D., Ph.D.** Dzau Professor of Medicine, Harvard Medical School Cardiovascular Division, Brigham and Women's Hospital
	Introduction	**Paul Eisenberg, M.D., M.P.H., F.A.C.C.** Global Regulatory Affairs &Safety Amgen, Inc.
.	Clinical Perspective	**Allen R. Nissenson, M.D., F.A.C.P., F.A.S.N** Professor of Medicine, Associate Dean, Director, Dialysis Program, David Geffen School of Medicine, UCLA

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	Benefit/Risk	**Preston Klassen, M.D., M.H.S.** Global Development, Amgen, Inc.
10:10 a.m.	*Break*	
	Risk Management	**Paul Eisenberg, M.D., M.P.H., F.A.C.C.** Global Regulatory Affairs &Safety Amgen Inc.

FDA PRESENTATIONS

10:55 a.m.	Epoetin Alpha: FDA Overview of Patient Reported Outcome (PRO) Claims	**Ann Marie Trentacosti, M.D.** Study Endpoints and Labeling (SEALD), CDER, FDA
10:15 a.m.	FDA Perspectives on Erythropoiesis-Stimulating Agents (ESAs) Anemia of Chronic Renal Failure: Hemoglobin Target and Dose Optimization	**Ellis F. Unger, M.D.** Acting Deputy Director for Science Office of Surveillance and Epidemiology (OSE) CDER, FDA

11:30 a.m. *Questions to presenters*

12:00 p.m. Lunch

1:00 p.m. **Open Public Hearing**

2:00 p.m. *Committee Discussion*

3:30 p.m. Break

3:45 p.m. *Committee Discussion and Questions to the CRDAC/DSaRM*

5:00 p.m. Adjourn