

FOOD AND DRUG ADMINISTRATION

Center for Drug Evaluation and Research

*Cardiovascular & Renal Drugs Advisory Committee (CRDAC) in Joint Session with the
Drug Safety and Risk Management Advisory Committee (DSaRM)*

AGENDA

September 11, 2007

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

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| 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. | TBD | 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.
Harvard, School of Public Health
Boston, MA |
| | | Yi Zhang, D.D.S.
MTPPI, Bethesda, MD |
| | | AMGEN & JJ PRD |
| 9:20 a.m. | Introduction | Paul Eisenberg, MD, MPH, FACC
Global Regulatory Affairs & Safety
Amgen Inc. |
| 9:30 a.m. | Clinical Perspective | Allen R. Nissenson, MD
Professor of Medicine, Associate Dean,
Director, Dialysis Program,
David Geffen School of Medicine, UCLA |
| 9:45 a.m. | Benefit/Risk | Preston Klassen, MD, MHS
Global Development, Amgen Inc. |
| 10:10 a.m. | Break | |

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Amgen & JJ PRD (continued)

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| 10:25 a.m. | Benefit/Risk (continued) | Jesse Berlin, ScD
Pharmacoepidemiology, J&JPRD |
| | | Preston Klassen, MD, MHS
Global Development, Amgen Inc. |
| 10:45 am | Risk Management | Paul Eisenberg, MD, MPH, FACC
Global Regulatory Affairs & Safety
Amgen Inc. |
| 10:55 a.m. | | FDA |
| 11:30 a.m. | | Questions to presenters |
| 12:00 p.m. | Lunch | |
| 1:00 p.m. | Open Public Hearing | |
| 2:00 p.m. | <i>Questions to the CRDAC/DSaRM and Discussion</i> | |
| 3:30 p.m. | Break | |
| 3:45 p.m. | <i>Questions to the CRDAC/DSaRM and Discussion (continued)</i> | |
| 5:00 p.m. | Adjourn | |