

FOOD AND DRUG ADMINISTRATION
Center for Drug Evaluation and Research
Drug Safety & Risk Management Advisory Committee (DSaRM)
AGENDA
February 1, 2008

The committee will discuss the efficacy and safety of new drug application (NDA) 22-054, INJECTAFER® (Ferric Carboxymaltose), Luitpold Pharmaceuticals, Incorporated, used for the treatment of iron deficiency anemia in postpartum patients or iron deficiency anemia in patients with heavy uterine bleeding.

8:00 a.m.	Call to Order Introduction of Committee	Sean Hennessy, Pharm.D., Ph.D. Acting Chair, DSaRM
	Conflict of Interest Statement	Teresa Watkins, Pharm.D., R.Ph. Acting Designated Federal Officer, DSaRM
8:10 a.m.	Opening Remarks	Dwaine Rieves, M.D. Acting Director, Division of Medical Imaging and Hematology Products, CDER/FDA
8:15 a.m.	Overview of Iron Deficiency Anemia	Reema Batra, M.D. Assistant Professor of Medicine The George Washington University School of Medicine Washington, DC
8:45 a.m.	Sponsor Presentation	Luitpold Pharmaceuticals, Inc.
	Introduction	Marc Tokars Senior Director, Clinical Operations Luitpold Pharmaceuticals
	FCM Rationale, Overall Safety Summary and Risk Management, Overall Cardiac Safety	Antoinette Mangione, M.D., Pharm.D. Medical Director, Luitpold Pharmaceuticals
	Medical Need	Patricia Ford, M.D. Professor of Medicine, University of Pennsylvania Medical School
	Non-Cardiac Safety and Mortality	David Van Wyck, M.D. Professor of Medicine and Surgery, University of Arizona College of Medicine
	Preclinical Safety	James Connor, Ph.D. Distinguished Professor and Vice Chair, Department of Neurosurgery Pennsylvania State University
	Cardiac SAE Case Review	Leslie Cooper, M.D. Professor of Medicine, Mayo Clinic College of Medicine
	Mortality Epidemiology	Elizabeth Andrews, Ph.D., M.P.H. RTI International

Clinical Perspective

Lawrence T. Goodnough, M.D.
Professor of Pathology and Medicine,
Stanford University School of Medicine

Conclusion

Marc Tokars
Senior Director, Clinical Operations
Luitpold Pharmaceuticals

10:15 a.m. Break

10:30 a.m. FDA Overview of Parenteral Iron products

Kathy Robie Suh, M.D., Ph.D.
Team Leader, Division of Medical Imaging and
Hematology Products, CDER/FDA

FDA Clinical Pharmacology Review

Christy John, Ph.D.
Clinical Pharmacologist, Office of Clinical
Pharmacology, CDER/FDA

FDA Medical Review

Min Lu, M.D.
Medical Officer, Division of Medical Imaging
and Hematology Products, CDER/FDA

11:20 a.m. Questions to Presenters

12:00 p.m. Lunch Break

1:00 p.m. Open Public Hearing

2:00 p.m. Discussion and Questions to the DSaRM committee

3:30 p.m. Break

3:45 p.m. Questions to the DSaRM committee (continued)

5:00 p.m. Adjourn