FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)

Cardiovascular and Renal Drugs Advisory Committee Meeting
September 10, 2004

Holiday Inn, Versailles Ballrooms, Bethesda, MD

DRAFT AGENDA

8:30a.m.	Call to Order and Introductions	Jeffery Borer, M.D. Acting Chair Cardiovascular and Renal Drugs Advisory Committee
	Conflict of Interest Statement	LCDR Dornette Spell-LeSane, NP-C Executive Secretary Cardio-Renal Advisory Committee
8:45a.m.	Welcome and Comments	Norman Stockbridge, M.D. Acting Director, Division of Cardiovascular and Renal Drugs, FDA

The Committee will discuss new drug application (NDA) 21-686 proposed trade name Exanta (ximelagatran) tablets, AstraZeneca, for the proposed indication of the prevention of venous thromboembolism (VTE) in patients undergoing knee replacement surgery, the prevention of stroke and other thromboembolic complications associated with atrial fibrillation and the long term secondary prevention of VTE after standard treatment of an episode of acute VTE.

9:00 a.m.	**<u>Sponsor Presentation</u>**	
	Introduction	Hamish Cameron, M.D. Vice President, Exanta
	Clinical Pharmacology	Troy C. Sarich, Ph.D. Director, Clinical Pharmacology
	Safety	Sunita Sheth, M.D., FAHA Senior Director, Clinical Development
	Efficacy	Jay Horrow, M.D., MS Senior Director, Clinical Development

Sponsor Presentation Cont.

	Benefit and Risk Anticoagulation	Jonathan L. Halperin, M.D. Mount Sinai Medical Center New York, New York
10:30 – 10:45		Questions from the Committee
10:45 - 11:00		Break
11:00	**FDA Presentation**	
	Risk Benefit Assessment	Ruyi He, M.D., Medical Officer Division of Gastrointestinal and Coagulation Drug Products
	Drug Induced Liver Toxicity	TBA
	Risk Management of Hepatotoxic Drugs	Kate Gelprin, M.D., M.P.H., Medical Epidemiologist Division of Drug Risk Evaluation
11:55 – 12:15		Questions from the Committee
12:15 – 1:00		Lunch
1:00 – 2:00		Open Public Hearing
2:00 – 2:15	Charge to the Committee	Joyce Korvick, M.D., M.P.H. Acting Division Director Division of Gastrointestinal and Coagulation Drug Products, FDA
2:15 – 3:00		Committee Discussions
3:00 – 3:15		Break
3:15 – 4:50		Committee Questions/Summary
5:00 p.m.		Adjournment