Food and Drug Administration
Center for Drug Evaluation and Research

Advisory Committee for Reproductive Health Drugs

September 29, 2003

Hilton Hotel, the Ballrooms
620 Perry Parkway, Gaithersburg, MD

AGENDA

8:30	Call to Order and Opening Remarks Introduction of Committee	Linda Giudice, M.D., Ph.D. Chair
	Conflict of Interest Statement	Shalini Jain, PA-C, M.B.A. Executive Secretary, FDA
	Opening Remarks	Daniel Shames, M.D. Director, Division of Reproductive and Urologic Drug Products (DRUDP) FDA

Issues relevant to the conduct of clinical trials and outcome measures for consideration of approval of drug products for the indications of induction of ovulation and pregnancy in anovulatory, infertile women and development of multiple follicles, and pregnancy in ovulatory women participating in assisted reproductive technology (ART) programs.

8:45	Ovulation Induction & Assisted Reproductive Technology - Background & State of Practice	David L. Keefe, M.D. Director, Reproductive Medicine and Infertility Women & Infants Hospital Providence, RI
9:45	Questions from the Committee	
10:00	Break	
10:15	Gonadotropins in ART	James P. Toner, M.D., Ph.D. Director Atlanta Center for Reproductive Medicine Woodstock, GA

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AGENDA (cont.)

11:15	Questions from the Committee	
11:30	Lunch	
12:30	Human Gonadotropins – Regulatory History	Shelley R. Slaughter, M.D., Ph.D. Medical Officer Team Leader Division of Reproductive and Urologic Drug Products (DRUDP) FDA
1:30	Questions from the Committee	
1:45	Open Public Hearing	
2:45	Break	
3:00	Presentation of Questions and Committee discussion	
5:00	Adjourn	