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

Advisory Committee for Reproductive Health Drugs Meeting
August 29, 2006

Hilton, Gaithersburg, MD
8:00 a.m. – 5:30 p.m.

AGENDA

The Committee will discuss new drug application (NDA) 21-945, proposed trade name Gestiva, 17 alpha-hydroxyprogesterone caproate injection, 250 mg/mL (once weekly), Adeza Biomedical, for the proposed indication prevention of preterm delivery in women with a history of a prior preterm delivery.

8:00	Call to Order and Introductions	Ezra Davidson, M.D. Acting Chair, Advisory Committee for Reproductive Health Drugs (ACRHD)
	Conflict of Interest Statement	Teresa Watkins, PharmD. Designated Federal Official (ACRHD)
8:15	Welcome and Comments	Scott Monroe, M.D. Acting Director, Division of Reproductive and Urologic Products
8:20	**FDA Invited Speaker** Causes of Premature Birth: The Premature Parturition Syndrome	Roberto Romero, M.D. Chief, Perinatology Research Branch Intramural Division, NICHD, NIH, DHHS
9:00	**Sponsor Presentation** 17P for the Prevention of Recurrent Preterm Birth	Durlin E. Hickok, MD, MPH Vice President, Medical Affairs Adeza Biomedical
	The Unmet Medical Need to Reduce Preterm Birth	Michael P. Nageotte, MD Professor, Obstetrics and Gynecology University of California, Irvine Past President of Society for Maternal-Fetal Medicine (SMFM)
10:30	Break	
10:45	**FDA Presentation** Efficacy and Safety Findings and Issues	Barbara Wesley, MD, MPH Medical Officer Division of Reproductive and Urologic Products

11:45	Clarifying questions from the committee to either FDA or Adeza	
12:00	Lunch	
1:00	Open Public Hearing	
2:00	Statistical Presentation	Daniel Gillen, Ph.D. Assistant Professor, Department of Statistics University of California, Irvine
	Committee Discussion	
4:00	Committee vote	
4:30	Adjournment	