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