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

Advisory Committee for Reproductive Health Drugs Meeting
January 23 and 24, 2007

5630 Fishes Lane, Rm. 1066
January 23, 2007: 8:30 a.m. – 6:00 p.m.

AGENDA

On January 23 and 24, 2007, presentations and committee discussions will address current issues which influence the consideration for approval of oral and non-oral (i.e., transdermal and intravaginal) hormonal contraceptive drug products. Implantable and injectable hormone products will not be discussed. Issues for discussion will include clinical trial design, expectations for efficacy and safety outcomes, and measures of acceptability of the product to the user, including cycle control.

8:30	Call to Order and Introductions	Charles Lockwood, MD Acting Chair, Advisory Committee for Reproductive Health Drugs (ACRHD)
	Conflict of Interest Statement	Teresa Watkins, PharmD Designated Federal Official (ACRHD)
8:45	Welcome and Comments	Scott Monroe, MD Acting Director, Division of Reproductive and Urologic Products (DRUP)
9:00	Topic 1 - Clinical Trial Design Issues **(**2 hr**)**	FDA – Phill Price, MD
11:00	Break	
11:15	Topic 2 - Efficacy and Risk/Benefit Assessment **(**2.5 hr**)**	James Trussell, PhD/Daniel Gillen, PhD
12:30	Lunch	
1:30	Continue discussion of Topics 1 & 2	
2:45	Break	
3:00	Topic 3 – Translation **(**2 hr**)**	Mellisa Gilliam, MD/Paula Adams Hillard, MD
5:00	Topic4 – Cycle Control **(**1 hr**)**	James Trussell, PhD
6:00	Adjournment	