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

Advisory Committee for Reproductive Health Drugs Meeting
January 24, 2007

5630 Fishes Lane, Rm. 1066
January 24, 2007: 8:30 a.m. – 5:00 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	Shelley R. Slaughter, MD, PhD Clinical Team Leader, Division of Reproductive and Urologic Products
9:00	Topic 5 – Extended Dosing Regimens **(**1 hr**)**	FDA – Gerald Willett, MD
10:00	Open Public Hearing	
12:00	Lunch	
1:00	Topic 6 – Phase 4 commitments **(**1 hr**)**	Diana Petitti, MD, MPH
2:00	Topic 7 – Labeling **(**1 hr**)**	FDA – Lisa Soule, MD
3:00	Break	
3:15	Committee Discussion/Summary	
5:00	Adjournment	