

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

**Advisory Committee for Reproductive Health Drugs
September 8, 2008**

Hilton Washington DC/Rockville, Plaza Ballrooms I & II
1750 Rockville Pike, Rockville, MD

Tentative AGENDA

New drug application (NDA) 22-242, proposed trade name FABLYN (lasofoxifene tartrate) Tablets, 0.5 milligrams (mg), Pfizer Inc., for the proposed indication of the treatment of osteoporosis in postmenopausal women at increased risk of fracture.

8:00	Call to Order and Introductions	Sandra Carson, M.D. Chair, Advisory Committee for Reproductive Health Drugs (ACRHD)
	Conflict of Interest Statement	Kalyani Bhatt, B.S., M.S. Designated Federal Official, ACRHD
8:15	Welcome and Comments	Scott Monroe, M.D. Director Division of Reproductive and Urologic Products (DRUP)
8:30	Sponsor Presentation	Pfizer Inc.
10:00	Break	
10:15	FDA Presentation	
11:30	Questions from the Committee	
12:00	Lunch	
1:00	Open Public Hearing	
2:00	Committee Discussion	
5:00	Adjournment	