Food and Drug Administration
Center for Drug Evaluation and Research

Nonprescription Drugs Advisory Committee (NDAC)
in joint session with the
Advisory Committee for Reproductive Heath Drugs (ACRHD)

Hilton, 620 Perry Parkway, Gaithersburg, Maryland

Agenda **December 16, 2003**

8:00	Call to Order and Opening Remarks	Louis R. Cantilena, Jr., M.D., Ph.D. Chair, NDAC
	Introduction of Committee	
	Conflict of Interest Statement	Karen M. Templeton-Somers, Ph.D. Executive Secretary, NDAC

NDA 21-045, proposing over-the-counter (OTC) use of Plan B (levonorgestrel), Women's Capitol Corporation, for reducing the chance of pregnancy after unprotected sex

8:10	**Opening Remarks**	Sandra Kweder, M.D. Deputy Director, Office of New Drugs, FDA
8:15	**Introduction to the Issues**	Curtis Rosebraugh, M.D., M.P.H. Deputy Director, Division of Over-the-Counter Drug Products, FDA
8:30	**Sponsor Presentation**	**Women's Capitol Corporation** **Barr Research**
	Background Review How Plan B Works Rationale for OTC Switch	Carole Ben-Maimon, M.D. President and Chief Operating Officer Barr Research
	ACOG Presentation	Vivian Dickerson, M.D. American College of Obstetricians and Gynecologists Director, Obstetrics and Gynecology University of California-Irvine Medical Center
	Clinical Trials Label Comprehension Actual Use	Carole Ben-Maimon, M.D.
	Health Consequences of Plan B OTC	David Grimes, M.D. Vice President of Biomedical Affairs Family Health International Department of Obstetrics and Gynecology University of North Carolina School of Medicine
	CARE[SM] Program	Carole Ben-Maimon, M.D.
9:30	Questions to the Sponsor from the Committee	
9:45	Break	

10:00	**FDA Presentation**	
	Safety Review	Daniel Davis, M.D. Medical Officer Division of Reproductive and Urologic Drug Products
	Plan B Label Comprehension Study	Karen Lechter, J.D., Ph.D. Social Science Analyst Division of Surveillance, Research and Communication Support Office of Drug Safety
	Plan B Actual Use and Behavior Studies	Jin Chen, M.D., Ph.D. Medical Officer Division of Over-the-Counter Drug Products
10:50	Questions to the FDA from the Committee	
11:00	**Open Public Hearing**	
12:30	Lunch	
1:30	**Committee Discussion**	
	Questions to the Committee	
3:30	Break	
5:00	**Adjourn**	