

***Food and Drug Administration
Center for Drug Evaluation and Research***

***Pediatric Subcommittee of the Anti-Infective Drugs Advisory Committee
in joint session with the
Pregnancy Labeling Subcommittee of the
Advisory Committee for Reproductive Health Drugs
Hyatt Regency, One Metro Center, Bethesda, Maryland***

Tuesday, September 12, 2000, 1:00 – 5:30 p.m.

AGENDA

- 1:00 p.m. Call to Order/Introductions**
Michael Greene, M.D., Chair, Pregnancy Labeling Subcommittee
P. Joan Chesney, M.D., Chair, Pediatric Subcommittee
- Conflict of Interest Statement**
Jayne Peterson, R.Ph., J.D., Subcommittees Executive Secretary, FDA
- 1:15 p.m. Background Information and Overview**
Sandra L. Kweder, M.D., Acting Director, Office of Drug Evaluation IV, FDA
- 1:25 p.m. American Academy of Pediatrics Perspective on Breastfeeding**
Cheston Berlin, M.D.
Hershey Medical Center
Penn State University/College of Medicine
- 1:45 p.m. Counseling Nursing Mothers**
Philip O. Anderson, Pharm.D., FASHP, FCSHP
Director, Drug Information Service, UCSD Medical Center
- 2:05 p.m. Drug Therapy during Lactation: A Maternal and Pediatric Issue Requiring Research**
Robert M. Ward, M.D., FAAP, FCP
Prof., Pediatrics and Dir., Pediatric Pharmacology Program, University of Utah
- 2:25 p.m. Subcommittee Questions for Speakers**
- 2:40 p.m. Break**
- 3:00 p.m. Current Requirements for Providing Information in a Product's Labeling on Drug Use during Lactation**
Holli Hamilton, M.D., M.P.H., Pregnancy Labeling Initiative, FDA
- 3:15 p.m. Open Public Hearing** (**60 minutes allocated unless public participation does not last that long.)
- 4:15 p.m. Subcommittees Discussion of Questions**
- 5:30 p.m. Adjourn**