Food and Drug Administration
Center for Drug Evaluation and Research

Pregnancy Labeling Subcommittee
of the
Advisory Committee for Reproductive Health Drugs
Hyatt Regency, One Metro Center, Bethesda, Maryland

AGENDA

Tuesday, September 12, 2000, 10:00 a.m. – 12:00 noon

Issue: Identification and discussion of those drug and biologic products for which improved pregnancy labeling is critical for
(1) effective prescribing during pregnancy, or
(2) proper counseling of pregnant women who have been inadvertently exposed

10:00 a.m. **Call to Order/Introductions**
Michael Greene, M.D., Chair, Pregnancy Labeling Subcommittee

Conflict of Interest Statement
Jayne Peterson, R.Ph., J.D., Executive Secretary, Pregnancy Labeling Subcommittee, FDA

10:10 a.m. **Background Information and Overview**
Sandra L. Kweder, M.D., Acting Director, Office of Drug Evaluation IV, and Co-Chair, Pregnancy Labeling Task Force, FDA

10:15 a.m. **Setting Priorities for Implementing the Pregnancy Labeling Rule**
Dianne L. Kennedy, R.Ph., M.P.H
Pregnancy Labeling Initiative, FDA

10:40 a.m. **Subcommittee Discussion of Issues**

11:00 a.m. **Open Public Hearing**
(**60 minutes allocated unless public participation does not last that long.)

12:00 noon **Closing Remarks**
Sandra Kweder, M.D.

Adjourn