

***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.

QUESTIONS TO THE SUBCOMMITTEES

1. Is maternal drug therapy during lactation an important health issue for infants?
If so, how should fundamental data be derived to determine:
 - if a drug is expressed in breast milk;
 - whether a drug found in breast milk is available to the nursing infant; and,
 - when drug is available, risk (or lack of risk) to the nursing infant?

2. What products or types of therapies are most important to study:
 - those for conditions common in young women?
(depression; asthma; antibiotics)
 - those for chronic conditions?
(depression; epilepsy; hypertension)
 - those for life-threatening conditions?

What are the reasons for your recommendations? Are there characteristics that are common across products or groups that make them high priority?

3. What kinds of information about such products are needed for inclusion in labels to allow informed decisions as to the safety of breastfeeding while taking a medication?