DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

August 22, 2000

Dear Pediatric and Pregnancy Labeling Subcommittee Members, Speakers, and Guests:

Enclosed please find the background materials for the **September 12, 2000** joint meeting of the Pediatric Subcommittee of the Anti-Infective Drugs Advisory Committee with the Pregnancy Labeling Subcommittee of the Advisory Committee for Reproductive Health Drugs, which will convene at 1:00 p.m. in the Haverford/Baccarat Ballroom of the Hyatt Hotel in Bethesda, Maryland.

The following documents are included in this package:

- the Federal Register notice announcing the meeting;
- the draft Agenda and Questions for this session; and,
- a binder containing background materials from the Agency.

Please do not hesitate to contact me if you have any general meeting questions. You should have already received meeting travel documents from this office. Questions specifically about travel can be directed to: Karen Graves for Pediatric Subcommittee members and Rebecca Diaz for Pregnancy Labeling Subcommittee members and guests. Our general telephone number is (301) 827-7001.

I look forward to a very interesting meeting.

Sincerely,

Jayne E. Peterson, R.Ph., J.D.
Health Science Administrator/Executive Secretary
Advisors and Consultants Staff
Center for Drug Evaluation and Research (CDER)
Food and Drug Administration
(301) 827-7001 (301) 827-6776 (FAX)

Enclosures

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Joint Meeting of the Pediatric Subcommittee of the Anti-Infective Drugs Advisory Committee With the Pregnancy Labeling Subcommittee of the Advisory Committee for Reproductive Health Drugs; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Names of Committees: Joint meeting of the Pediatric Subcommittee of the Anti-Infective Drugs Advisory Committee with the Pregnancy Labeling Subcommittee of the Advisory Committee for Reproductive Health Drugs.

General Function of the Committees: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on September 12, 2000, 1 p.m. to 5:30 p.m.

Location: Hyatt Regency, Baccarat/Haverford Rooms, One Bethesda Metro Center, Bethesda, MD.

Contact Person: Jayne E. Peterson, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5630 Fishers Lane, Rockville, MD 20857, 301–827–7001, e-mail: PETERSONJ@CDER.FDA.GOV, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12530. Please call the Information Line for up-to-date information on this meeting.

Agenda: The subcommittees will meet jointly to discuss existing information and needs with respect to prescription drug therapy in nursing mothers.

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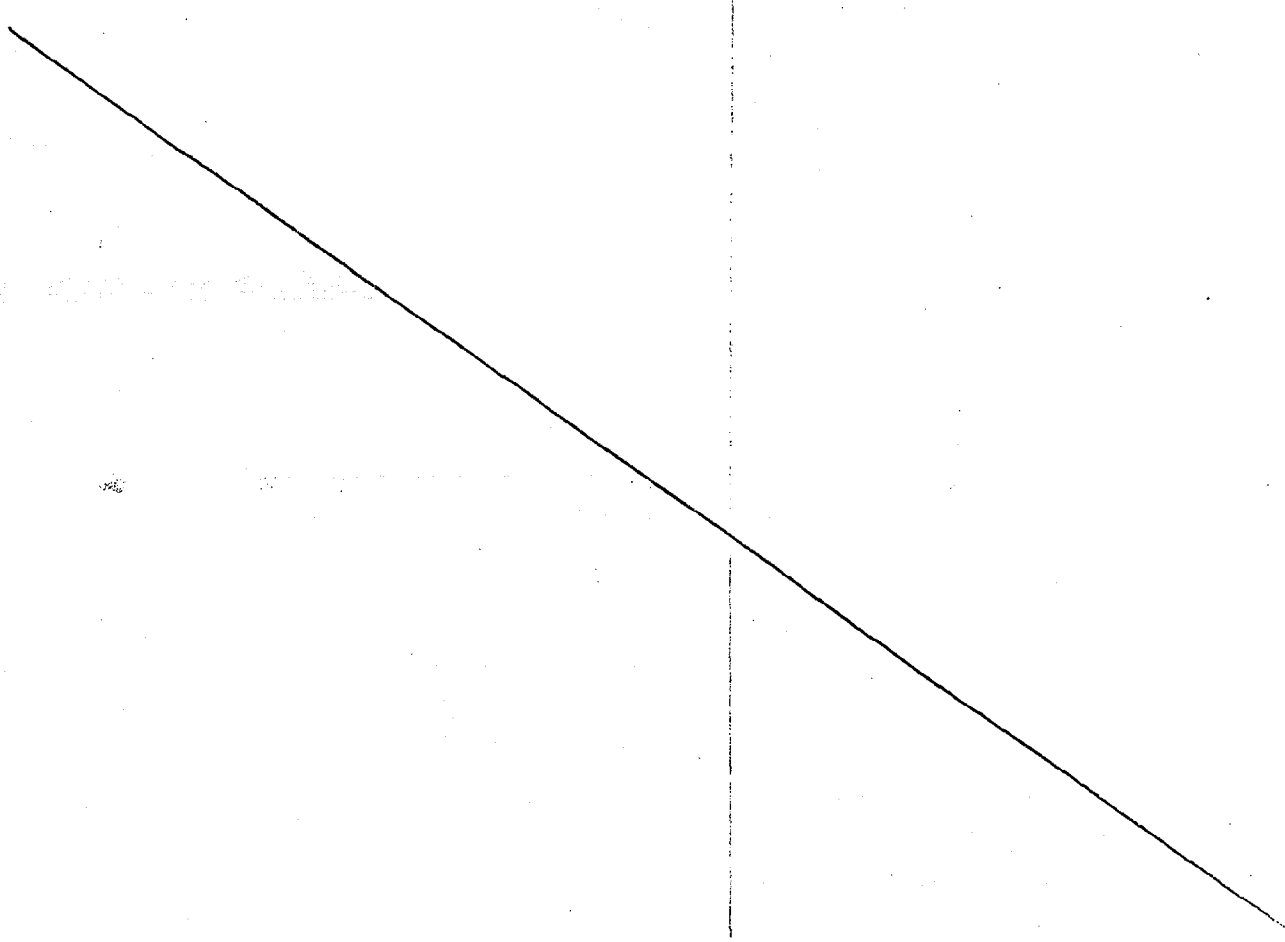
Procedure: Interested persons may present data, information, or views, orally or in writing on issues pending before the subcommittees. Written submissions may be made to the contact person by September 6, 2000. Oral presentations from the public will be scheduled between approximately 3:15 p.m. and 4:15 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 6, 2000, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.



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

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

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 Kweder, M.D., Acting Director, Office of Drug Evaluation IV, FDA
1:25 p.m.	**American Academy of Pediatrics Perspective on Breastfeeding** Chester Berlin, M.D.
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**
4:15 p.m.	**Advisory Subcommittee(s) Discussion of Questions**
5:30 p.m.	**Adjourn**

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.

DRAFT 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?

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

August 21, 2000

Dear Pediatric and Pregnancy Labeling Subcommittee Members, Guests and Speakers:

Thank you for your willingness to participate in the Food and Drug Administration, Center for Drug Evaluation and Research's joint meeting of the Pediatric and Pregnancy Labeling Subcommittees on the afternoon of September 12, 2000.

The focus of the meeting will be on therapeutic drug use in lactating women. FDA has a pediatric initiative through which we have increasingly focused attention on facilitating the study of the safety and efficacy of drugs in children. In addition, we have a pregnancy labeling initiative that is dedicated to improving the information available on drug use during pregnancy. Consideration of drug therapy during lactation and the impact on the nursing infant is a natural bridge between these two initiatives.

Currently, most labels are poorly informative about use during lactation. Too many product labels simply state, "It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when (drug) is administered to a nursing woman.", rather than providing data that can be used to make an informed decision as to whether to breastfeed or not while taking a particular medication.

We are seeking your advice to provide us with scientific direction in this important area. During the meeting we will be addressing such general areas as, "Is maternal drug therapy during lactation an important health issue for infants?","How much information is needed in product labels, if any?", and "What products, if any, would be most important to study?"

To prepare for the meeting you might find it helpful to read the articles included in this briefing package. A Table of Contents follows this page.

We look forward to seeing you at the meeting and thank you again for your help.

Sincerely,

Dianne Murphy, M.D.
Associate Director for Pediatrics

Sandra L. Kweder, M.D.
Acting Director, ODE IV

Enclosures

Recommended references for the joint meeting of the:

Pediatric Subcommittee
of the Anti-Infective Drugs Advisory Committee
and the
Pregnancy Labeling Subcommittee of the Advisory Committee for Reproductive Health Drugs

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