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M E M O R A N D U M

Date: November 5, 2007

From: Karen B. Feibus, M.D.
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To: Members of the Pediatric Advisory Committee and Invited Experts

Subject: Overview of the November 29, 2007, Advisory Committee Meeting on Clinical Lactation Studies

Many thanks to each of you for taking time out of your busy schedules to participate in the November 29, 2007, Pediatric Advisory Committee meeting on Clinical Lactation Studies. This memo supplements the information communicated by Dr. Dianne Murphy in her memo to the Committee. The Draft Guidance for Industry called “Clinical Lactation Studies – Study Design, Data Analysis, and Recommendations for Labeling published in February 2005. In the fall of 2006, the Maternal Health Team (MHT) reviewed the comments submitted to the Public Docket in response to this publication and recognized the need to update, expand, and clarify various sections of the document before publishing it as a Final Guidance. We have addressed some of the issues brought forth in the comments through internal discussion and review; however, we bring the larger issues surrounding subject selection and enrollment, study designs and their uses, milk collection techniques, data analysis, and issues surrounding breastfeeding support during lactation studies to you for your consideration and input. Your breadth of experience and expertise will be invaluable in optimizing the usefulness of this document to industry and the value of the data derived from lactation studies.

The background package for the November 29 session of the Pediatric Advisory Committee includes the following documents:

- Published version of the Draft Guidance for Industry on Clinical Lactation Studies

- Draft questions for the Committee (these may be modified prior to the AC meeting)
- Draft slide presentations from speakers (those that are not included in the initial mailing, will be added in a second mailing the following week). This is the list of the speakers and the general topics they will cover:
 - CDR Lisa Mathis, MD: Welcome and Introduction
 - Karen B. Feibus, MD: Overview of the Guidance and Issues for Discussion
 - Ruth A. Lawrence, MD: Benefits of breastfeeding, breastfeeding physiology, and factors impacting breastfeeding success
 - Thomas W. Hale, Ph.D.: Transfer of drugs into breast milk and clinical lactation study methodology
 - Robert Nelson, M.D., Ph.D.: Ethical Research in Mothers and Infants.
- Additional Background Materials
 - 45 CFR Part 46: Protection of Human Subjects
 - Begg E, Duffull S Hackett S, Ilett K. Studying drugs in human milk: time to unify the approach. J Hum Lact. 2002 Nov; 18(4): 323-32.

We look forward to working with each of you at the Advisory Committee meeting. Your collaborative efforts and knowledgeable advice will play an important role in the Maternal Health Team's continuing efforts to promote and protect the health and well-being of pregnant and lactating mothers and their babies.