M E M O R A N D U M **DEPARTMENT OF HEALTH AND HUMAN SERVICES**
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

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HFD-960

SUBJECT: Overview for the June 9th 2004 Meeting of the Pediatric Subcommittee of the Anti-Infective Drugs Advisory Committee (Peds AC)

TO: Members of the Pediatric Advisory Subcommittee

The main focus of the June 9th 2004 Pediatric Advisory Subcommittee meeting will be a discussion of adverse event reports for drugs granted exclusivity, including a focus on neonatal withdrawal following gestational exposure to a selective serotonin reuptake inhibitor (SSRI) or to a selective norepinephrine reuptake inhibitor (SNRI). In addition, the committee will hear a brief update about the implementation of the Pediatric Research Equity Act, and Robert Nelson will give a summary of the recently released Institute of Medicine Report entitled, *Ethical Conduct of Clinical Research Involving Children.* A draft agenda for the meeting follows this memorandum.

Following my brief introduction, Medical Officers within the Division of Pediatric Drug Development will report on adverse events for the first year of marketing following the granting of exclusivity for the following eight drugs that were granted market exclusivity under 505A of the Federal Food, Drug, and Cosmetic Act: Allegra®(fexofenodine), Hycamtin®(topotecan), Temodar®(temozolomide), Vigamox®(moxifloxacin), Ciloxan®(ciprofloxacin), Monopril®(fosinopril), Duragesic®(fentanyl transdermal), and Effexor®(venlafaxine). These reports are required under section 17 of the Best Pharmaceuticals for Children Act. Following the presentation on Effexor®(venlafaxine), the committee will hear several background presentations on neonatal withdrawal syndromes and a brief update on congenital eye malformations.

We will seek your guidance on how to best inform the public and practitioners about neonatal withdrawal syndromes following antidepressant exposure and on research needs in this area.

This background package includes the following documents in addition to this cover memo:

- Product labeling for all 8 drugs to be presented during the adverse event reporting portion of the meeting (please note that there is an indication in the margin of each label that identifies the pediatric sections of the product label);
- The Clinical and Pharmacology/Toxicology reviews of trials conducted for pediatric exclusivity for these 8 drugs;
- Nine recent peer-reviewed scientific articles on various aspects of neonatal withdrawal following gestational exposure to drugs and on the management of depression in pregnancy;
- The Pediatric Research Equity Act (PREA); and
- A pre-publication version of the executive summary of the Institute of Medicine report entitled, *Ethical Conduct of Clinical Research Involving Children.*

The FDA relies on the knowledge, judgement, experience and wisdom of scientists and practitioners like you to help determine how to address newly emerging issues of drug development. We thank you for your time and effort, and we look forward to seeing and hearing from you on June 9th .

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