DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

June 1, 2000

Dear Pediatric Advisory Subcommittee Members,

The next meeting of the **Pediatric Advisory Subcommittee** is **September 11 and 12, 2000**. During these two days, four topics will be discussed as outlined in the draft agenda (see Attachment 1). Enclosed as the first background package are materials to help you in preparation for the meeting. In addition to the draft agenda, the package contains the following materials:

First meeting day (September 11) materials, a.m. session (Ethics):

Attachment 2: Temple, R. (1996) Problems in Interpreting Active Control Equivalence Trials. *Accountability in Research* 4:267-75;

Attachment 3: Temple, R. (1983) Difficulties in Evaluating Positive Control Trials. *Proceedings of the American Statistical Association;*

Attachment 4: Draft International Conference on Harmonization (ICH) Guidance entitled, "E10, Choice of Control Group in Clinical Trials";

First meeting day materials, p.m. session (Neuropharm/Development of Psychotropic Drugs for Pediatrics):

Attachment 5: Zito, J.M., Safer, D.J., et al. Trends in the Prescribing of Psychotropic Medications to Preschoolers. *JAMA* 2000;283:1025-30;

Attachment 6: March 20, 2000, Press Release, "First Lady Hillary Rodham Clinton Launches New Public-Private Effort to Improve the Diagnosis and Treatment of Children with Emotional and Behavioral Conditions";

Please note: The last bullet on the second page of the press release states, "Today, FDA will announce that it will work with its Pediatric Advisory Committee to design research protocols that will be used to develop new pediatric dosage information to be included on the labels of drugs such as methylphenidate, clonidine, and other drugs

increasingly used in young children." We do not plan to ask the subcommittee to design research protocols. However, in the future we may ask the subcommittee for input on related issues.

Second meeting day (September 12) materials, a.m. session (Pediatric Oncology Issues):

The FDAMA incentive for pediatric oncology drugs did not appear to be working. After meetings and discussions with the relevant parties, it became recognized that the development of pediatric oncology drugs merits special consideration. Children with cancer are usually treated at specialized centers by pediatric oncologists who are members of a national pediatric cooperative study group. One of the highest priorities of these groups is to develop improved novel therapies. Studies for the development of drugs for pediatric oncology should proceed in the context of an overall development program. The approach being used for these drugs is being presented to the subcommittee. A draft FDA guidance for these drugs is in final sign off. Included in your briefing package are the bullet point slides on the key elements of the draft guidance and a "Written Request" template (see Attachment 8). Prior to availability of the draft guidance, the Agency has issued a "Letter of Interest" to the sponsors of oncology drugs (see Attachment 7).

Attachment 7: February 11, 2000, "Pediatric Cancer Therapeutics: Letter of Interest"; and,

Attachment 8: Key elements of the pediatric oncology guidance; and "Sample of a Written Request for a Pediatric Oncology Drug Product Plan".

Please call Jayne Peterson of the Advisors and Consultants Staff at (301) 827-6766 or Dianne Murphy at (301) 827-2353, if you have any questions. Thank you for your commitment to this activity and I hope you find the meeting as interesting as we think it will be.

Sincerely,

Jayne Peterson
for

Dianne Murphy, M.D.
Associate Director for Pediatrics
Center for Drugs Evaluation and Research (CDER)
Food and Drug Administration

Attachments