DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MEMORANDUM

DATE: 23 OCT

FROM: Janet Woodcock, M.D.
Deputy Commissioner and Chief Medical Officer of Food and Drugs
Acting Director, Center for Drug Evaluation and Research

TO: Andrew C. von Eschenbach, M.D.
Commissioner of Food and Drugs

SUBJECT: Establishment of the Pediatric Review Committee (PeRC)

In accordance with the requirements of Titles IV and V of the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Pub. L. No. 110-85, 121 Stat. 823), and in consultation with the offices affected by those titles, as Deputy Commissioner and Chief Medical Officer of Food and Drugs and as Acting Director of the Center for Drug Evaluation and Research (CDER), I propose the establishment of the Pediatric Review Committee (PeRC) with CDER as the designated lead. This memorandum briefly describes PeRC's responsibilities and organizational representation.

RESPONSIBILITIES

PeRC will provide consultation on and general review of pediatric information submitted to the Agency in pediatric plans, assessments and studies conducted by sponsors and applicants pursuant to sections 505A and 505B of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 355a and 355c), as amended by FDAAA, to help ensure quality and consistency across the Agency. PeRC will also provide reviews of deferrals and waivers granted under section 505B of the Act.

PeRC:

- Will review all written requests before issuance (section 505A(f)(2) of the Act)
- May review studies submitted in a response to a written request in order to make a recommendation on exclusivity determinations (section 505A(e)(1) of the Act)
- Will provide consultation to reviewing divisions on all pediatric plans and assessments prior to approval of an application or supplement for which a pediatric assessment is required (sections 505B(f)(1) and (4) of the Act)
- Will provide review of all deferrals and waivers from the requirement to submit pediatric assessments (section 505B(f)(1) and (4) of the Act)
- Will provide recommendations as needed to reviewing divisions as to whether a supplement containing studies conducted under section 505B of the Act will be considered for priority review when submitted (section 505B(f)(4) of the Act)
- Will provide consultation on tracking and making available to the public certain information about pediatric studies and labeling changes (sections 505B(f)(6) and 505A(f)(6) of the Act)

- Will provide consultation on tracking and making available to the public certain information about pediatric studies and labeling changes (sections 505B(f)(6) and 505A(f)(6) of the Act)

In addition, PeRC will conduct a retrospective review and analysis of a representative sample of assessments submitted and deferrals and waivers approved under section 505B of the Act since the enactment of the Pediatric Research Equity Act of 2003 (section 505B(f)(5) of the Act).

ORGANIZATION

Membership

PeRC will include employees of FDA, including representatives from CDER, the Center for Biologics Evaluation and Research, and the Office of the Commissioner, with expertise as follows:

- Pediatrics (including representation from the Office of Pediatric Therapeutics)
- Biopharmacology
- Statistics
- Chemistry
- Legal issues
- Pediatric ethics
- Appropriate expertise pertaining to the product under review (e.g., expertise in child and adolescent psychiatry)
- Other individuals as designated by the Secretary

PeRC need not convene all members of the committee to carry out its responsibilities and may form standing subcommittee(s) to carry out its responsibilities. In accordance with the requirements of FDAAA, PeRC will document which members of the committee participated in specified activities.

Please indicate your concurrence/non-concurrence below.

✓ I concur with the above referenced action.

____ I do not concur with the above referenced action.

Andrew C. von Eschenbach, M.D.
Commissioner, Food and Drugs

Oct 25, 2007
Date

CC: Jesse L. Goodman, M.D., M.P.H., Director, CBER
Gerald F. Masoudi, J.D., Assoc. GC/Chief Counsel, Food and Drug Division
Dianne Murphy, M.D., Director, Office of Pediatric Therapeutics