

rendered sterile. The document also identifies CGMP's for the manufacture of API's used in the production of drug products for clinical trials.

The draft guidance incorporates the following two fundamental concepts in API production: (1) Application of CGMP controls to all steps in the manufacturing process, beginning with the use of starting materials; and (2) validation of those steps determined to be critical to the quality and purity of the final API. The guidance clarifies the agency's expectations regarding application of CGMP's (i.e., extent of written instructions, in-process controls, sampling, testing, monitoring, and documentation) to different steps of an API process.

This draft guidance represents the agency's current thinking on the manufacture and control of API's. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statute, regulations, or both.

Written requests for single copies of the guidance "Manufacturing, Processing, or Holding Active Pharmaceutical Ingredients" should be submitted to the Drug Information Branch (HFD-210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Requests should be identified with the docket number found in brackets in the heading of this document. A copy the draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 14, 1998.

William K. Hubbard,
Associate Commissioner for Policy
Coordination.

[FR Doc. 98-10312 Filed 4-15-98; 11:29 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

HRSA Competitive Grants Preview; Long Term Training in Leadership Education in Neurodevelopmental and Related Disabilities (LEND)

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of extension of deadline date.

SUMMARY: This notice extends the due date for applications for Long Term Training in Leadership Education in Neurodevelopmental and Related Disabilities (LEND) program grants, previously published in the **Federal Register** on October 9, 1997 as part of the *General Notice: Availability of the HRSA Competitive Grants Preview* (62 FR 52894-52914). Authorized under Title V of the Social Security Act, these LEND grants are intended to improve the health status of infants, children, and adolescents with, or at risk for, neurodevelopmental and related disabilities, including mental retardation, neurodegenerative and acquired neurological disorders, and multiple handicaps. The LEND programs prepare health professionals to assist children and their families to achieve their developmental potentials by forging a community-based partnership of health resources and community leadership.

In the table on page 52893 and on page 52909 in the third column, the application deadline date published in the **Federal Register** has been extended to October 1, 1998.

Dated: April 13, 1998.

James J. Corrigan,

*Acting Associate Administrator for
Management and Program Support.*

[FR Doc. 98-10202 Filed 4-16-98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Availability of the HRSA Competitive Grants Preview; Correction

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Correction of deadline date.

SUMMARY: In notice FR Doc. 97-26645, in the issue of Thursday, October 9, 1997, make the following corrections:

In the table on page 52893, in the section HIV/AIDS Programs, under "Ryan White Title IV Adolescent Services," the deadline date is corrected to read "June 19, 1998."

On page 52898, in column 2, in the fourteenth line, the deadline date is corrected to read "June 19, 1998."

Dated: April 13, 1998.

James J. Corrigan,

*Acting Associate Administrator for
Management and Program Support.*

[FR Doc. 98-10201 Filed 4-16-98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Council; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), announcement is made of the following National Advisory body scheduled to meet during the month of June 1998.

Name: Maternal and Child Health Research Grants Review Committee.

Date and Time: June 17-19, 1998; 8:00 a.m.-5:00 p.m.

Place: The Executive Boardroom, the Bethesda Ramada, 8400 Wisconsin Avenue, Bethesda, Maryland.

The meeting is open to the public on Wednesday, June 17, 1998, 9:00 a.m. to 10:00 a.m. Closed for the remainder of meeting.

Agenda: The open portion of the meeting will cover opening remarks by the Director, Division of Systems, Education and Science, who will report on program issues, congressional activities, and other topics of interest to the field of maternal and child health. The meeting will be closed to the public on Wednesday, June 17, 1998 from 10:00 a.m. for the remainder of the meeting for the review of grant applications. The closing is in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., and the Determination by the Associate Administrator for Management and Program Support, Health Resources and Services Administration, pursuant to Public Law 92-463.

Anyone wishing to obtain a roster of members, minutes of meetings, or other relevant information should write or contact Gontran Lamberty, Dr. P.H., Executive Secretary, Maternal and Child Health Grants Review Committee, Room 18A-55, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, or by telephone at (301) 443-2190.

Agenda items are subject to change as priorities dictate.

Dated: April 10, 1998.

Jane M. Harrison,

*Acting Director, Division of Policy Review
and Coordination.*

[FR Doc. 98-10203 Filed 4-16-98; 8:45 am]

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