ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
New Hire Results Survey	54	4	.5	108

Estimated Total Annual Burden Hours: 108.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Information Services, 370 L'Enfant Promenade, SW, Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: April 13, 1998.

Bob Sargis,

Acting Reports Clearance Officer.

[FR Doc. 98–10188 Filed 4–16–98; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0193]

Draft Guidance for Industry on Manufacturing, Processing, or Holding Active Pharmaceutical Ingredients; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Manufacturing, Processing, or Holding Active Pharmaceutical Ingredients.'' This draft guidance is intended to provide guidance on current good manufacturing practices (CGMP's) for manufacturing, processing, packing, or holding active pharmaceutical ingredients (API's). The draft guidance is intended to help ensure the quality and suitability of API's for use in the manufacture of drug products.

DATES: Written comments may be submitted on the draft guidance by May 18, 1998. General comments on agency guidances are welcome at any time.

ADDRESSES: Copies of this draft guidance are available on the Internet at http://www.fda.gov/cder/guidance/index.htm or http://www.fda.gov/cber/guidelines.htm.

Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Edwin M. Rivera, Center for Drug Evaluation and Research (HFD–322), 7520 Standish Pl., Rockville, MD 20855, 301–594–0095; John A. Eltermann, Center for Biologics Evaluation and Research (HFM–205), 1401 Rockville Pike, Rockville, MD 20852, 301–827–3031; or Jose R. Laureano, Center for Veterinary Medicine (HFV–230), 7500 Standish Pl., Rockville, MD 20855, 301–594–1785.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance for industry entitled ''Manufacturing, Processing, or Holding Active Pharmaceutical Ingredients.'' It provides guidance on CGMP's for the manufacture, processing, packing, or holding (i.e., storage) of API's.

The draft guidance is a result of extensive efforts that began in July 1995 when FDA decided to develop an industry guidance for the manufacture and control of API's. An initial draft of this guidance for industry was widely distributed during 1996. It was reviewed at a September 1996 international conference on API's in Canberra, Australia, sponsored by the Pharmaceutical Inspection Convention/Pharmaceutical Inspection Convention Scheme (PIC–PIC/S), and at the October 1996 annual FDA/Parenteral Drug Association Forum in Bethesda, MD. It also was distributed to numerous pharmaceutical trade associations in a letter from the Center for Drug Evaluation and Research's (CDER) Office of Compliance, dated November 8, 1996. The initial draft was posted on CDER's website on November 12, 1996, with a request for comments by December 10, 1996. On December 9, the deadline for comments was extended until January 31, 1997. This draft guidance incorporates recommendations received at the two conferences and comments from 27 organizations, including API manufacturers, dosage manufacturers, and pharmaceutical associations.

At a February 4 and 5, 1998, meeting of the International Conference on Harmonisation (ICH) Steering Committee in Tyson's Corner, VA, FDA supported the decision to develop internationally harmonized guidance on CGMP's for API's through the ICH process. The agency agreed to participate in an expert working group that will review numerous guidance documents developed by industry and regulatory bodies to develop a single harmonized ICH guidance. API/CGMP guidances to be reviewed by the working group include those prepared by the European Chemical Industry Council/European Federation of Pharmaceutical Industries' Association, the Pharmaceutical Research and Manufacturers of America, PIC–PIC/S, and the World Health Organization. This draft guidance will also be considered by the working group.

The draft guidance applies to the manufacture and control of drug and biologic API's for use in human and veterinary drug products. In addition, it applies to the later chemical isolation and purification steps of API's derived from biological or fermentation processes and to sterile API's, but only up to the point where the API is

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]

BILLING CODE 4160–01–F

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]

BILLING CODE 4160–15–P

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]

BILLING CODE 4160–15–P

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]

BILLING CODE 4160–15–P