1996, and the antimicrobial drug effects on pathogen load in food-producing animals as pathogen load relates to the preapproval process of new animal drug applications (NADAs). Information concerning the discussion of import tolerances can be found in the August 13, 2001, CVM Update at: http://www.fda.gov/cvm/index/updates/importol.htm and in the **Federal Register** advance notice of proposed rulemaking of August 10, 2001 (66 FR 42167). Information concerning the issues of pathogen load will be made publicly available to the Veterinary Medicine Advisory Committee members and the public in advance of the meeting and posted on the CVM home page at: http://www.fda.gov/cvm. A limited number of paper copies of the background information will be available at the meeting.

Procedure: Interested persons may present data, information, or views, orally or in writing, on the issues pending before the committee. Written submissions may be made to the contact person by January 4, 2002. Oral presentations from the public will be scheduled between approximately 3 p.m. and 5 p.m. on January 22, and between approximately 8 a.m. and 10 a.m. on January 24, 2002. The time allotted for each presentation may be limited. Those desiring to make oral presentations should notify the contact person before January 4, 2002, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation. You will be notified of your allotted time prior to the meeting. Your entire statement should be submitted for the record.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: November 8, 2001.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 01–29003 Filed 11–20–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–2405]

''Guidance for Industry: Information Request and Discipline Review Letters Under the Prescription Drug User Fee Act;'' Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled ''Guidance for Industry: Information Request and Discipline Review Letters Under the Prescription Drug User Fee Act'' dated November 2001. The guidance document provides guidance to industry on the use of certain types of letters by the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) as part of the review of marketing applications for certain drug and biological products. The guidance document announced in this notice finalizes the draft guidance document entitled ''Guidance for Industry: Information Request and Discipline Review Letters Under the Prescription Drug User Fee Act'' dated August 1999.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The document may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800, or by fax by calling the FAX Information System at 1–888–CBER–FAX or 301–827–3844. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit written comments on the guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT:

Michael Anderson, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210; or

Paul Varki, Center for Drug Evaluation and Research (HFD–7), 5600 Fishers Lane, Rockville, MD 20852–1448, 301–594–2041.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled ''Guidance for Industry: Information Request and Discipline Review Letters Under the Prescription Drug User Fee Act'' dated November 2001. In a November 1997 letter to Congress regarding the reauthorization of the Prescription Drug User Fee Act (PDUFA) as part of the Food and Drug Administration Modernization Act of 1997 (Public Law 105–115), the Secretary of Health and Human Services (the Secretary) committed FDA to certain user fee performance goals and additional procedures related to the review of products in human drug applications as defined in section 735(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g(1) (PDUFA products)). The guidance document explains how the agency will issue and use information request letters and discipline review letters during the review of PDUFA products. The guidance document announced in this notice finalizes the draft guidance document entitled ''Guidance for Industry: Information Request and Discipline Review Letters Under the Prescription Drug User Fee Act'' dated August 1999 that was announced in the **Federal Register** of August 17, 1999 (64 FR 44741).

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance document represents the agency's current thinking on information request letters under PDUFA. 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 statutes and regulations.

II. Comments

Interested persons may, at any time, submit written comments to the Dockets Management Branch (address above) regarding this guidance document. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in the brackets in the heading of this document. A copy of the document

and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at http://www.fda.gov/cber/guidelines.htm.

Dated: October 29, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–29004 Filed 11–20–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources And Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Public Law 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) The proposed collection of information for the proper performance of the functions of the agency; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance 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.

Proposed Project: Children's Hospitals Graduate Medical Education Payment Program (CHGME) (OMB No. 0915–0247): Revision

The CHGME Payment Program was enacted by Public Law 106–129 to provide Federal support for graduate medical education (GME) to ''freestanding'' children's hospitals. This legislation attempts to provide support for GME comparable to the level of Medicare GME support received by other, non-children's hospitals. The legislation indicates that eligible children's hospitals will receive payments for both direct and indirect medical education. Direct payments are designed to offset the expenses associated with operating approved graduate medical residency training programs and indirect payments are designed to compensate hospitals for expenses associated with the treatment of more severely ill patients and the additional costs relating to teaching residents in such programs.

Technical assistance workshops and consultation with applicant hospitals resulted in an opportunity for hospital representatives to raise issues and provide suggestions resulting in proposed revisions in the CHGME application forms and instructions.

Eligible children's teaching hospitals submit relevant data such as weighted and unweighted full-time equivalent (FTE) resident counts, inpatient discharges and case mix index information by which direct and indirect payments are made to the participating hospitals. Data are submitted by children's hospitals in an annual CHGME application in order to receive funding. Through a reconciliation process, participating hospitals are required to correct and furnish final FTE resident count numbers reflecting changes in counts reported in the annual application form. The reconciliation process begins with fiscal year (FY)2002 and occurs before the end of the fiscal year.

The estimated burden is as follows:

Form	Number of respondents	Responses per respondents	Hours per response	Total burden hours
HRSA 99–1	60	1	24	1,440
HRSA 99–1 (Reconciliation)	60	1	8	480
HRSA 99–2	60	1	14	840
HRSA 99–4	60	1	14	840
Total	60			3,600

Send comments to Susan G. Queen, Ph.D., HRSA Reports Clearance Officer, Room 14–22, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: November 15, 2001.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 01–29058 Filed 11–20–01; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Training and Technical Assistance Cooperative Agreement Limited Competition Announcement

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of limited competition cooperative agreement.

SUMMARY: The Health Resources and Services Administration's (HRSA) HIV/AIDS Bureau (HAB) announces that applications will be accepted for fiscal year (FY) 2002 awards for a cooperative agreement to support an International AIDS Education and Training Center (IAETC). The IAETC will assist countries severely affected by the HIV/AIDS epidemic to build capacity for HIV care and support services through the training and education of HIV/AIDS care providers, including physicians, nurses, clinical administrators, and other key personnel. The IAETC will enhance training capacity in the areas of diagnosis, treatment, and prevention of HIV disease, including the prevention of perinatal transmission of the disease, measures for the prevention and treatment of opportunistic infections, and appropriate use of antiretroviral therapy. The IAETC will also develop training on the planning, design, and