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) was 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 2, 2001.

Bob Sargis,

Reports Clearance Officer.

[FR Doc. 01–8547 Filed 4–5–01; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0131]

Guidance for Hospitals, Nursing Homes, and Other Health Care Facilities; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance document entitled ''Guidance for Hospitals, Nursing Homes, and Other Health Care Facilities.'' This guidance is intended to alert hospitals, nursing homes, and other health care facilities of the potentially fatal hazards of medical gas mixups. This guidance makes recommendations that will help hospitals, nursing homes, and other health care facilities avoid the injuries and fatalities that have resulted from medical gas mixups.

DATES: Submit written comments on the guidance by July 5, 2001. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of this guidance 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. Submit written comments on the guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Duane S. Sylvia, Center for Drug Evaluation and Research (HFD–325), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855, 301–594–0095, ext. 8, Sylviad@cder.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance entitled ''Guidance on Hospitals, Nursing Homes, and Other Health Care Facilities.'' FDA has received reports during the past 4 years from hospitals and nursing homes involving 7 deaths and 15 injuries to patients who were thought to be receiving medical grade oxygen, but were receiving a different gas (e.g., nitrogen) that had been mistakenly connected to the oxygen supply system. As a result of these reports, FDA has decided to alert hospitals, nursing homes, and other health care facilities to the potentially fatal hazards associated with handling medical gases. The agency also is making recommendations that should help health care facilities avoid the tragedies that result from medical gas mixups.

Because of the potential danger to the public health of medical gas mixups, this guidance is being issued as a Level 1 guidance for immediate implementation, consistent with FDA's good guidance practices regulation (21 CFR 10.115; 65 FR 56468, September 19, 2000). As with other Level 1 guidances for immediate implementation, the agency is soliciting comments from the public. This guidance represents the agency's current thinking on how to avoid potentially fatal medical gas mixups. 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 requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit written comments on the guidance to the Dockets Management Branch (address above). 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. The 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.

III. Electronic Access

Persons with access to the Internet may obtain the document at http://www.fda.gov/cder/guidance/index.htm.

Dated: March 29, 2001.

Ann M. Witt,

Acting Associate Commissioner for Policy.

[FR Doc. 01–8474 Filed 4–5–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–2248]

International Cooperation on Harmonisation of Technical Requirements for Approval of Veterinary Medicinal Products (VICH); Final Guidances Entitled ''Effectiveness of Anthelmintics: General Recommendations'' (VICH GL7), ''Effectiveness of Anthelmintics: Specific Recommendations for Bovine'' (VICH GL12), ''Effectiveness of Anthelmintics: Specific Recommendations for Ovine'' (VICH GL13), and ''Effectiveness of Anthelmintics: Specific Recommendations for Caprine'' (VICH GL14); Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of four final guidances for industry (Nos. 90, 95, 96, and 97) entitled ''Effectiveness of Anthelmintics: General Recommendations'' (EAGR) (VICH GL7), ''Effectiveness of Anthelmintics: Specific Recommendations for Bovine'' (VICH GL12), ''Effectiveness of Anthelmintics: Specific

Recommendations for Ovine'' (VICH GL13), and ''Effectiveness of Anthelmintics: Specific Recommendations for Caprine'' (VICH GL14). These guidances have been adapted for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Approval of Veterinary Medicinal Products (VICH). They are intended to standardize and simplify methods used in the evaluation of new anthelmintics submitted for approval to the European Union, Japan, and the United States.

DATES: You may submit written comments at anytime.

ADDRESSES: Copies of the final guidances entitled ''Effectiveness of Anthelmintics: General Recommendations'' (VICH GL7), ''Effectiveness of Anthelmintics: Specific Recommendations for Bovine'' (VICH GL12), ''Effectiveness of Anthelmintics: Specific Recommendations for Ovine'' (VICH GL13), and ''Effectiveness of Anthelmintics: Specific Recommendations for Caprine'' (VICH GL14) may be obtained on the Internet from the CVM home page at http:www.fda.gov/cvm/guidance/guidance.html. Persons without Internet access may submit written requests for single copies of the final guidances to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests.

You may submit written comments any time on the final guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Thomas Letonja (HFV–135), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7576, e-mail: tletonja@cvm.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote the international harmonization of regulatory recommendations. FDA has participated in efforts to enhance harmonization and has expressed its commitment to seek scientifically based harmonized technical recommendations for the development of pharmaceutical products. One of the goals of harmonization is to identify and then reduce the differences in technical recommendations for drug development among regulatory agencies in different countries.

FDA has actively participated in the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use for several years to develop harmonized technical recommendations for the approval of human pharmaceutical and biological products among the European Union, Japan, and the United States. The VICH is a parallel initiative for veterinary medicinal products. The VICH is concerned with developing harmonized technical recommendations for the approval of veterinary medicinal products in the European Union, Japan, and the United States, and includes input from both regulatory and industry representatives.

The VICH Steering Committee is composed of member representatives from the: European Commission; European Medicines Evaluation Agency; European Federation of Animal Health; the U.S. FDA; the U.S. Department of Agriculture; the Animal Health Institute; the Japanese Veterinary Pharmaceutical Association; the Japanese Association of Veterinary Biologics; and the Japanese Ministry of Agriculture, Forestry, and Fisheries.

Two observers are eligible to participate in the VICH Steering Committee: One representative from the Government of Australia/ New Zealand, and one representative from the industry in Australia/ New Zealand. The VICH Secretariat, which coordinates the preparation of documentation, is provided by the Confédération Mondiale de L'Industrie de la Santé Animale (COMISA). A COMISA representative also participates in the VICH Steering Committee meetings.

II. Guidance on Effectiveness of Anthelmintics

These four guidances are entitled ''Effectiveness of Anthelmintics: General Recommendations'' (VICH GL7), ''Effectiveness of Anthelmintics: Specific Recommendations for Bovine'' (VICH GL12), ''Effectiveness of Anthelmintics: Specific Recommendations for Ovine'' (VICH GL13), and ''Effectiveness of Anthelmintics: Specific Recommendations for Caprine'' (VICH GL14).

In the **Federal Register** of July 16, 1999 (64 FR 38445), FDA published these VICH guidances in draft form, giving interested persons until August 16, 1999, to submit comments. FDA shared the comments with the appropriate VICH Expert Working Group and after considering the comments, the work group submitted the final guidance to the VICH Steering Committee. At a meeting held from November 16 to 19, 1999, the VICH Steering Committee endorsed the four final guidances for industry, VICH GL7, VICH GL12, VICH GL13, and VICH GL14.

VICH GL7 is intended to standardize and simplify the methods used for the effectiveness evaluation of new anthelmintics and generic copies for use in domesticated animals. Animal welfare will benefit by the elimination of duplicate studies that will reduce the number of animals required for necessary studies. Likewise this will benefit the industry by reducing research and development costs. VICH GL12, VICH GL13, and VICH GL14 should be read in conjunction with the EAGR, VICH GL7. The guidances for bovine, ovine, and caprine are part of the EAGR, and the aim of these three final guidances is to: (1) Be more specific for certain issues not discussed in the general guidance; (2) highlight differences with the EAGR on effectiveness data recommendations; and (3) give explanations for disparities with the EAGR.

This final level 1 guidance is being issued consistent with FDA's good guidance practices (21 CFR 10.115; 65 FR 56468, September 19, 2000). These final guidances represent the agency's current thinking on effectiveness recommendations for anthelmintic medicinal products. These guidances do not create or confer any rights for or on any person, and do not operate to bind FDA or the public. An alternative method may be used as long as it satisfies the requirements of applicable statutes and regulations.

III. Comments

As with all of FDA's guidances, the public is encouraged to submit written comments with new data or other new information pertinent to these guidances. FDA will periodically review the comments in the docket and, where appropriate, will amend the guidances. The agency will notify the public of any such amendments through a notice in the **Federal Register**.

Interested persons may, at any time, submit written comments to the Dockets Management Branch (address above) regarding these guidances. 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

brackets in the heading of this document. A copy of the guidances 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: March 29, 2001.

Ann M. Witt,

Acting Associate Commissioner for Policy.

[FR Doc. 01–8452 Filed 4–5–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Committee; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92–463), announcement is made of the following National Advisory body scheduled to meet during the month of May 2001.

Name: Advisory Committee on Training in Primary Care Medicine and Dentistry.

Date and Time: May 7, 2001; 8:30 a.m.–5 p.m.; May 8, 2001; 8:30 a.m.–4 p.m.

Place: The Hilton Washington Embassy Row, 2015 Massachusetts Avenue, NW., Washington, DC 20036.

The meeting is open to the public.

Purpose: The Advisory Committee shall (1) provide advice and recommendations to the Secretary concerning policy and program development and other matters of significance concerning activities under section 747 of the Public Health Service Act; and (2) prepare and submit to the Secretary, the Committee on Health, Education, Labor, and Pensions of the Senate, and the Committee on Energy and Commerce of the House of Representatives, a report describing the activities of the Advisory Committee, including findings and recommendations made by the Committee concerning the activities under section 747 of the PHS Act. The Advisory Committee will meet twice each year and submit its first report to the Secretary and the Congress by November 2001.

Agenda: Discussion of the focus of the programs and activities authorized under section 747 of the Public Health Service Act. Draft of the Committee's first report to Congress will be reviewed. Funding issues and recommendations for the future will be addressed.

Anyone interested in obtaining a roster of members, minutes of the meeting, or other relevant information should write or contact Dr. Crystal Clark, Acting Deputy Executive Secretary, Advisory Committee on Training in Primary Care Medicine and Dentistry, Parklawn Building, Room 9A–21, 5600 Fishers Lane, Rockville, Maryland 20857, phone (301) 443–6326, e-mail *cclark@hrsa.gov.* The web address for the Advisory Committee is http://www.bhpr.hrsa.gov/dm/actpcmd.htm.

Dated: April 2, 2001.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 01–8475 Filed 4–5–01; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Fiscal Year (FY) 2001 Funding Opportunities

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice of funding availability.

SUMMARY: The Substance Abuse and Mental Health Services Administration (SAMHSA) Center for Substance Abuse Treatment (CSAT) announces the availability of FY 2001 funds for grants for the following activity. This notice is not a complete description of the activity; potential applicants must obtain a copy of the Guidance for Applicants (GFA), including Part I, American Indian/Alaskan Native Community Planning Program, and Part II, General Policies and Procedures Applicable to all SAMHSA Applications for Discretionary Grants and Cooperative Agreements, before preparing and submitting an application.

Activity	Application deadline	Est. funds FY 2001	Est. number of awards	Project period
American Indian Alaskan Native Community Planning Program ..	July 10, 2001	$1 million	8–10	1 year.

The actual amount available for the award may vary, depending on unanticipated program requirements and the number and quality of applications received. FY 2001 funds for the activity discussed in this announcement were appropriated by the Congress under Public Law No. 106–310. SAMHSA's policies and procedures for peer review and Advisory Council review of grant and cooperative agreement applications were published in the **Federal Register** (Vol. 58, No. 126) on July 2, 1993.

General Instructions

Applicants must use application form PHS 5161–1 (Rev. 7/00). The application kit contains the two-part application materials (complete programmatic guidance and instructions for preparing and submitting applications), the PHS 5161–1 which includes Standard Form 424 (Face Page), and other documentation and forms. Application kits may be obtained from: National Clearinghouse for Alcohol and Drug Information (NCADI), P.O. Box 2345, Rockville, MD 20847–2345, Telephone: 1–800–729–6686.

The PHS 5161–1 application form and the full text of the activity are also available electronically via SAMHSA's World Wide Web Home Page: *http://www.samhsa.gov.*

When requesting an application kit, the applicant must specify the particular activity for which detailed information is desired. All information necessary to apply, including where to submit applications and application deadline instructions, are included in the application kit.

Purpose

The Substance Abuse and Mental Health Services Administration (SAMHSA) Center for Substance Abuse Treatment (CSAT) announces the availability of Fiscal Year (FY) 2001 funds for grants to American Indian and Alaskan Native (AI/AN) communities to support community planning and consensus building, leading to the development of local substance abuse treatment system plans. The plans would describe how tribal governments, organizations providing services to urban Indian communities, and other indigenous community organizations will work together to deliver integrated substance abuse treatment and related services, such as HIV/AIDS prevention, mental health services, primary care, and other public health services. The CSAT American Indian/Alaskan Native Planning Grants Program is made up of two types of grants: Phase I, which is the Development of a community planning process; and Phase II, which is the Implementation of a services integration plan. This announcement is