

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]

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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]

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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