

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D-0131]

DMB

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Certifier	<u>TA3</u>

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 [*insert date 90 days after date of publication in the Federal Register*]. 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.

NAD

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
March 29, 2001.



Ann M. Witt,
Acting Associate Commissioner for Policy.

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COPY OF THE ORIGINAL



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