July 20, 2001

FDA Public Health Advisory:
Potential for Injury from Medical Gas Misconnections of Cryogenic Vessels

(You are encouraged to copy and distribute this Advisory)

To: Hospital Administrators
Risk Managers
Directors, Biomedical Engineering
Directors, Respiratory Therapy
Nursing Home Administrators
Home Health Care Agencies

This advisory is to alert you to the potential for patient injury when cryogenic vessels containing medical gas are misconnected to oxygen delivery systems. Misconnections cause patients who should receive medical oxygen to receive another gas, such as nitrogen, instead. Over the past four years, FDA has received reports of seven deaths and fifteen injuries associated with medical gas misconnections that occurred in acute care and nursing home settings.

Nature of the Problem

Oxygen supply systems in medical facilities are equipped with gas-specific connectors that fit only the corresponding connectors on the cryogenic vessels in which oxygen is delivered. In the cases we have reviewed, deaths and injuries occurred when two errors were made in sequence. First, a cryogenic vessel containing another gas was mistakenly identified as containing oxygen. Then, the gas-specific connector on this cryogenic vessel was changed or misadapted so that it could deliver the wrong gas to an oxygen-delivery system. In many of the reported incidents, the person connecting the vessel to the oxygen delivery system (either the delivery person or the facility employee) did not understand that the gas-specific connector was a safeguard designed to prevent such mishaps from occurring.

Recommendations

We urge you to take every opportunity to promote proper handling of medical gases. Inform all personnel handling and using cryogenic vessels of these

recommendations. To avoid possible injuries from misconnected medical gases, we recommend the following:

- When connecting a cryogenic vessel, check the label carefully to ensure that it contains the appropriate gas for the intended application.

- Never use adapters or change the connectors or fittings on cryogenic vessels. **If a connector will not connect to the oxygen supply system, the contained gas is likely not oxygen and should not be used.** Contact the gas supplier for further information and guidance.

- Make sure that all personnel who will be handling medical gases are properly trained to understand the operations and connections of the medical gas system. Make sure that personnel are trained to examine and recognize medical gas labels.

- If your facility receives both medical and industrial grade gases, store them separately.

Reporting Adverse Events to FDA

The Safe Medical Devices Act of 1990 (SMDA) requires hospitals and other user facilities to report deaths and serious injuries associated with the use of medical devices, including devices used to deliver medical gases. We request that you follow the procedures established by your facility for such mandatory reporting.

We also encourage you to report other adverse events associated with the use of a medical gas. You can report these directly to the device or medical gas manufacturer. You can also report to MedWatch, the FDA's voluntary reporting program. You may submit reports to MedWatch one of four ways: online at http://www.accessdata.fda.gov/scripts/medwatch/ by telephone at 1-800-FDA-1088; by FAX at 1-800-FDA-0178; or by mail to MedWatch, Food and Drug Administration, HF-2, 5600 Fishers Lane, Rockville, MD 20857.

Getting More Information

Further information regarding medical gas misconnections may be found at http://www.fda.gov/cder/guidance/4341fnl.htm. Should you have questions regarding this letter, please contact Paula Simenauer, Office of Surveillance and Biometrics (HFZ-510), 1350 Piccard Drive, Rockville, Maryland, 20850, by fax at 301-594-2968, or by e-mail at phann@cdrh.fda.gov. Additionally, a

voice-mail message may be left at 301-594-0650 and your call will be returned as soon as possible.

All of the FDA medical device postmarket safety notifications can be found on the World Wide Web at http://www.fda.gov/cdrh/safety.html. Postmarket safety notifications can also be obtained through e-mail on the day they are released by subscribing to our list server. You may subscribe at http://list.nih.gov/archives/dev-alert.html.

Sincerely yours,

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