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FDA Proposes Regulations for Preventing Deaths and Injuries From Medical Gas Mix-Ups and Contamination

The Food and Drug Administration (FDA) is issuing a proposed rule designed to make the contents of medical gas containers more readily identifiable, in order to prevent deaths and injuries from inadvertent use of incorrect medical gas or from use of contaminated medical gas.

Medical gases such as oxygen, nitrous oxide, and nitrogen, are administered to patients in healthcare facilities and the home, for a variety of purposes. For example, oxygen is often administered to patients suffering from various respiratory conditions, such as emphysema.

In some cases, injury or death has resulted from a medical gas mix-up caused by one of several factors, including mistaken administration of industrial gas to patients, improper connection of industrial gases to medical oxygen supply systems, and contamination of medical gas cylinders with residues of industrial cleaning solvents. Between 1996 and 2006, the agency received reports of medical gas mix-ups that resulted in at least 8 deaths and 18 serious injuries.

"By issuing this proposal, FDA is heightening consumer and industry awareness about this specialty area of regulated products. Greater understanding of the possible problems associated with the use of medical gases and the steps we can take to eliminate them will only lead to safer use of these products," said Steven Galson, MD, Director, Center for Drug Evaluation and Research.

This regulation would apply to medical gas manufacturers and distributors and will require that certain portable medical gas containers comply with the following requirements:

- have gas use outlet connections (used to connect these containers to gas supply systems) that cannot be readily removed;
- be identified by labels that wrap all the way around the tops of these containers;
- have high-pressure medical gas cylinders painted according to a standard color-coding system that corresponds to the gases stored in them; and
- be dedicated to medical use and not converted from industrial use.

FDA has undertaken a careful evaluation of the operations and processes required to produce suitable medical gases. Since 2000, the agency has conducted several public meetings to elicit comments from the medical gas industry as well as patients, professional associations, and manufacturers.

In addition to agency efforts, the medical gas industry and other bodies, including the Joint Commission on Accreditation of Healthcare Organizations and the National Fire Protection Association have taken steps to help prevent medical gas mix-ups and ensure the safe use of medical gases.
The proposed rule is intended to supplement existing FDA regulations and guidance regarding the safe use of medical gases by adding requirements -- based largely on current, recommended, industry practice -- to minimize the incidence of medical gas mix-ups and contamination. It is intended to ensure that health care facilities and patients receive only appropriate, safe, effective, and high-quality medical gases.

There is a 90-day public comment period on the proposed regulation before FDA develops the final rule.