Questions and Answers on the Proposed Rule for Medical Gas Containers

1. What did FDA do today?

The agency published for comment a proposed rule that is intended to prevent deaths and injuries from medical gas mix-ups and contamination by making the contents of medical gas containers more readily identifiable, reducing the likelihood that containers of industrial or other gases will be inappropriately connected to medical oxygen supply systems, and reducing the risk of contamination of medical gases.

2. Why is the agency doing this?

Between 1996 and 2006, the agency received reports of medical gas mix-ups that resulted in at least 8 patient deaths and 18 serious patient injuries. These incidents were caused by industrial gas cylinders being mistakenly identified for medical use; improper connection of industrial gases to health care facilities’ medical oxygen supply systems, enabled when oxygen-specific gas use outlet connections were removed from portable medical oxygen containers and attached to containers holding the industrial gases; and contamination of medical gas cylinders with residues of industrial cleaning solvents, most likely as a result of improper cleaning during the cylinders’ conversion from industrial to medical use. Because nursing homes and hospitals are not required to report adverse events associated with medical gas mix-ups to FDA, it is likely that the actual number of these events exceeds the number reported.

FDA believes that incidents like this will be largely averted if:

- users can more readily and accurately identify containers of medical gases;
- the gas use outlet connections on these containers cannot be readily removed by persons other than manufacturers; and
- containers used to hold industrial gases are not converted to medical use.

3. Which gases are medical gases?

Medical gases include

- oxygen, United States Pharmacopeia (USP)
- nitrogen, National Formulary
- nitric oxide
- nitrous oxide USP
- carbon dioxide USP
- helium USP
- medical air USP
- any mixture of these gases or other gas products approved under a new drug application (NDA)
4. **What kinds of medical gas containers are subject to the proposed rule?**

The proposed rule applies to portable cryogenic containers and high-pressure cylinders. Portable cryogenic containers are stainless steel containers that are usually connected to health care facilities’ medical oxygen supply systems. High-pressure cylinders contain medical gases at very high pressure when stored at normal temperatures. They may be large or small, and are constructed of either steel or aluminum. They are used by patients, emergency workers, hospitals, and others.

5. **What are the specific requirements being proposed?**

The proposed rule, if finalized, will require that:

- Gas use outlet connections on portable cryogenic medical gas containers be permanently attached or otherwise locked to the valve body so they cannot be readily removed except by the manufacturer;
- A 360° wraparound label clearly identifying the container’s contents be affixed near the top of portable cryogenic medical gas containers;
- High-pressure medical gas cylinders be painted an FDA-designated, gas-specific standard color. Additionally, the proposal would prohibit the medical use of high-pressure cylinders or cryogenic containers that have previously been used to hold industrial gases. The exact requirements are described in the proposal.

6. **To whom would the final rule apply?**

It would apply to medical gas manufacturers and distributors. Medical gas manufacturers include individuals or firms that fill high-pressure medical gas cylinders or cryogenic medical gas containers. In industry vernacular, a manufacturer is more commonly referred to as a filler, a repackager, or a transfiller.

7. **Would the final rule apply to hospitals and other health care facilities?**

The proposed rule, if finalized, would not apply to hospitals or other health care facilities. However, the rule is designed to make the medical gas supplies of those facilities safer.

We recommend that health care facilities review our “Guidance for Hospitals, Nursing Homes, and Other Health Care Facilities--FDA Public Health Advisory” (66 FR 18257, April 6, 2001), [www.fda.gov/cder/guidance/4341fnl.htm](http://www.fda.gov/cder/guidance/4341fnl.htm). This public health advisory describes incidents of medical gas mix-ups and provides recommendations for avoiding these types of incidents. These recommendations include training facility employees to check the labels of medical gases and to be aware that gas-specific fittings (i.e., gas use outlet connections) on portable cryogenic medical gas containers should not be altered or removed.

8. **How would this rule affect patients’ personal gas containers?**

Personal gas containers used by patients in their homes for treatment of chronic obstructive pulmonary disease (COPD) would not be affected by this proposal. High-pressure cylinders used by patients would be subject to this rule if finalized as proposed. However, because the proposed rule’s color-coding requirements are already widely implemented by medical gas manufacturers, patients are not likely to see a difference as a result of this rule. This rule would not require patients to do anything differently.

9. **Has FDA worked with the medical gas industry to develop this proposal?**

The agency has worked closely with the industry and held numerous meetings since 2000 to help develop current industry standards. We wanted to assure that any proposed rule would not place a heavy financial burden on the industry, but would also protect the public health by averting deaths and injuries. Currently, most of the industry is following the proposed requirements, so the proposed regulation would not impose a great hardship on the industry; nor would it require major changes to current industry practice.

In addition to agency efforts, the medical gas industry and other bodies, including the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and the National Fire Protection Association (NFPA), have taken steps to help prevent medical gas mix-ups and
ensure the safe use of medical gases. The requirements proposed in this rule will supplement existing regulatory requirements and increase the adoption of certain presently voluntary recommendations that help enhance medical gas safety.

10. How does this proposed rule relate to other agency requirements and guidance?

All medical gases are prescription drugs regulated by FDA and, accordingly, must be manufactured and distributed in compliance with applicable laws and regulations, including existing FDA Current Good Manufacturing Practice (CGMP) regulations. In the Federal Register of May 6, 2003 (68 FR 24005), FDA announced the availability of a draft guidance for industry entitled “Current Good Manufacturing Practice for Medical Gases” [TXT] [PDF] (draft guidance). The draft guidance provides recommendations for CGMP compliance in the manufacture and distribution of medical gases which are intended to avoid medical gas mix-ups and contamination. The agency has solicited public input on the draft guidance, including from the medical gas industry, and is currently working to finalize the draft guidance. When finalized, it is expected to help manufacturers and distributors comply with CGMP requirements to ensure the identity, strength, quality, and purity of medical gases.

The proposed rule is intended to supplement, rather than supersede, existing regulations and guidance regarding the safe use of medical gases by adding requirements, based largely on current industry practices, to minimize the incidence of medical gas mix-ups and contamination. Several of the provisions in the proposed rule would codify recommendations from the draft guidance as CGMP requirements. Including these provisions in legally binding regulations is intended to increase the adoption of these presently voluntary recommendations that will help enhance medical gas safety. Among the recommendations from the draft guidance that are proposed for codification in this rule are the use of standard colors to identify medical gas cylinders and the use of 360º wraparound labels to identify medical gases in certain portable containers. When the proposed regulations are finalized, the draft guidance (as part of its finalization) will be amended to reflect their codification.

11. What will be the economic impact on the medical gas industry if this rule is finalized?

Because the majority of manufacturers have already implemented these standards, the agency believes the economic impact will not be significant, and will be justified by the lives saved and injuries prevented.

12. Will the public and industry have a chance to provide comments on the proposed regulation?

Yes, the agency is providing a 90 day public comment period on this proposed rule. In deciding whether to finalize the rule as proposed, FDA will consider all of the submitted comments. Written comments should be submitted to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Electronic comments should be submitted to http://www.fda.gov/dockets/comments or http://www.regulations.gov. Comments should be identified with the docket number found in brackets in the heading of the proposed rule.