



**AMERICAN SAFETY & HEALTH INSTITUTE**

*Programs that help save lives...*

A not-for-profit association  
of professional educators



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VIA REGULAR & EMAIL

September 3, 2003

Docket Management Branch (HFA-30)

Food and Drug Administration,

5630 Fishers Lane, rm.1061

Rockville, MD 20852.

Dear Sir/Madame:

ASHI is a non-profit association of more than 20,000 professional safety and health educators providing nationally recognized training programs through more than 4000 approved Training Centers across the United States and in several foreign countries. The purpose of this letter is to provide written comments concerning draft guidance *Current Good Manufacturing Practice for Medical Gases* (#03D-0165). Our main concern is that unusually narrow language would prohibit the use of emergency oxygen by trained laypersons by restricting its non-prescription use to "emergency medical services" (lines 748 & 749).

Oxygen should be used as soon as possible, in as near 100% as possible in all resuscitation situations, and for the early management of injury and illness by lay persons trained in CPR and first aid.<sup>i</sup> To advance the use of emergency oxygen in these circumstances, ASTM International has published a peer-reviewed, non-proprietary standard.<sup>ii</sup> First Aid Providers must be encouraged to administer, without hesitation, emergency oxygen for all suddenly ill or injured persons. Preventing appropriately trained first aid providers from using emergency oxygen when it is available is "a potentially grave error and makes emergency care in the workplace less efficient and valuable"<sup>iii</sup>. Emergency oxygen and its related components must remain available without a prescription to First Aid Providers properly trained in its use.<sup>iv</sup> In these times, when significant public and private initiatives are bringing lifesaving technology and training in automated external defibrillation to the public, we must not leave the emergency administration of oxygen behind.

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We recommend the language in draft guidance #03D-0165 (lines 745-756) be modified as follows (inserted bold text);

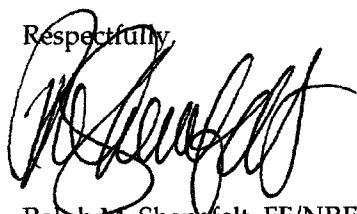
If a medical gas company sells medical oxygen to emergency medical services **or other properly trained person** for emergency use, the label would contain the statement:

For emergency use only when administered by properly trained personnel for oxygen deficiency and resuscitation. For all other medical applications, Rx Only.

FDA would not prohibit the sale of medical oxygen with this labeling to emergency medical services **or other properly trained persons** (see Glossary for definition of an EMS and "**properly trained**") without a prescription.

An addition to the glossary citing training consistent with ASTM Standard F 2171-02 as "proper training" for non-EMS (or pre-EMS) first aid providers would provide welcome clarification and encourage educational efforts consistent with current standards.

Respectfully,



Ralph M. Shenefelt, FF/NREMT-P

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Co-Investigator, National Guidelines for First Aid Training in Occupational Settings

Member, ASTM International Committee F30 on Emergency Medical Services, Subcommittee F30.02 on Personnel, Training, and Education

Chair, Pre-EMS Committee, National Association of EMS Educators

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<sup>i</sup>Oxer HF. Simply add oxygen: why isn't oxygen administration taught in all resuscitation training? Comment in: *Resuscitation*. 2000 Feb;43(3):163-9.

<sup>ii</sup> *Standard Guideline Defining the Performance of First Aid Providers in Occupational Settings* ASTM Standard F 2171-02 April 2002. ASTM International.

<sup>iii</sup> Starr LM. Proper oxygen use can help save lives in initial medical emergency response. *Occup Health Saf*. 1993 Mar;62(3):68-70, 72-3.

<sup>iv</sup> National Guidelines for First Aid Training in Occupational Settings, *Guidelines for First Aid Oxygen Administration Enrichment Programs*, November 1998, [Online]. Available: [www.NGFATOS.net](http://www.NGFATOS.net)