MEDIC First Aid® INTERNATIONAL

P.O. Box 21738
500 S. Danebo Ave
Eugene, Oregon
USA 97402

541-344-7099
800-800-7099
541-344-7429 fax

August 22, 2003

Docket Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket 2003D-0165
Guidance for Industry – Current Good Manufacturing Practice for Medical Gases

To Whom It May Concern:

MEDIC FIRST AID International is the largest privately held emergency care training development company in the United States and our cardiopulmonary resuscitation (CPR), automated external defibrillation (AED), first aid, and emergency oxygen training programs are designed to meet or exceed OSHA and other regulatory guidelines. A worldwide innovator in emergency care training, MEDIC FIRST AID has certified more than nine million people since 1980. Located in Eugene, Oregon, MEDIC FIRST AID serves clients in all 50 states including many Fortune 500 companies. A range of industries, including oil and gas, construction, and transportation along with thousands of other businesses, hospitals, and schools, training businesses and independent instructors use MEDIC FIRST AID Training Programs. In addition to over 10,000 active instructors in the United States, we have licensees in Canada, United Kingdom, Japan, New Zealand, Greece, and Australia.

After reviewing the proposed changes to the GMP for Medical Gases concerning the labeling requirements for the use of emergency oxygen, we have a few serious reservations regarding the impact of the changes if they were to go into effect as written.

The current FDA labeling requirement for oxygen reads, "For emergency use only when administered by properly trained personnel for oxygen deficiency and resuscitation. For all other medical applications, Rx only." The proposed changes would effectively eliminate the non-prescription application for medical oxygen and restrict the use of emergency oxygen to emergency medical services, who serve under medical direction, and to those individuals with a prescription. [Docket 2003D-0165 lines 743-751, 1839-1842]

There are three elements to consider when implementing an emergency response system that includes the use of emergency oxygen.

Oxygen Equipment: The FDA has defined emergency oxygen equipment and states, "Oxygen equipment intended for emergency use can be marketed for OTC distribution.

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Such equipment must deliver a flow rate of 6 liters per minute for a minimum of fifteen minutes." [FDA Compliance Policy Guide 7124.10] The proposed GMP would eliminate the OTC application for emergency oxygen equipment because unless you had a prescription or were affiliated with emergency medical services (EMS), you wouldn't be able to fill an oxygen cylinder for emergency use.

Currently, there are hundreds of portable, easy-to-use, and safe emergency oxygen units on the market that are effective in providing supplemental oxygen during emergency care. These units are designed to bridge the gap in time between initial bystander response and arrival of EMS. EMS response time varies widely throughout the United States; when coupled with limited access to large corporate facilities, that time is often greatly increased.

There are hundreds of thousands of emergency oxygen units in place throughout the United States. Another potential consequence of the proposed docket 2003D-0165 is that these units would be abandoned because they could no longer be refilled. In addition, all sales of new emergency oxygen units would effectively cease, except to emergency medical services.

Medical Oxygen Gas Manufacturing: Compressed gas manufacturers provide an excellent service ensuring appropriate procedures are followed when filling medical oxygen cylinders. These manufacturers require documentation of either: 1) a prescription or, 2) training in the use of emergency oxygen prior to filling an emergency oxygen cylinder.

Emergency Oxygen Training: Since the FDA has not further defined the term "properly trained personnel" as stated on the medical oxygen label, national training organizations such as the American Red Cross, American Health & Safety Institute, and MEDIC FIRST AID International have developed courses that meet medical and regulatory guidelines for the use of emergency oxygen. Emergency care program developers reference the most current medical guidelines prior to developing CPR, first aid, defibrillation, and emergency oxygen training programs.

The MEDIC FIRST AID Emergency Oxygen program uses the following medical references: Guidelines 2000 for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care; International Consensus on Science; *Circulation*, 2000: 102 (supp 1); and *Emergency Medical Technician-Basic: National Standard Curriculum*, 1994, National Highway Traffic Safety Administration, United States Department of Transportation.

In addition, MEDIC FIRST AID referenced the Compressed Gas Association, FDA, DOT, OSHA, and ASTM to ensure our emergency oxygen training programs met each group's recommendations and requirements.

Medical Concerns: The American Heart Association (AHA) states, "during cardiopulmonary emergencies use supplemental oxygen as soon as it is available." When

rescue breathing and CPR are required, low cardiopulmonary output can result in tissue hypoxia, and when ventilation using exhaled air is being performed, approximately 16-17% inspired oxygen (FiO2 =0.17) is being delivered. The AHA further asserts that "100% inspired oxygen (FiO2=1.0) is recommended during BLS and ACLS when available" and "short-term therapy with 100% oxygen is beneficial and not toxic."

While medical authorities note that oxygen toxicity can occur with long term administration of high concentrations of oxygen, it is not likely to happen in an emergency situation where the size of the oxygen cylinder limits the amount of oxygen that can be delivered. Another concern regards the use of emergency oxygen on patients with chronic obstructive pulmonary disease (COPD). There is a possibility that providing a patient with COPD a high concentration of oxygen may stop respiratory drive. However, in a cardiopulmonary emergency hypoxia is a potentially life-threatening concern; and thus, emergency oxygen should be provided anytime hypoxia is suspected.

No further harm can be done by providing emergency oxygen to an individual who is experiencing a medical condition resulting in hypoxia.

Effect of Docket 2003D-0165: The new proposed requirement that oxygen can only be provided by EMS or dispensed via a prescription conflicts with the reality of emergency response protocols.

This proposed change would affect numerous emergency care providers including lifeguards protecting families at beaches and local pools, police officers arriving first at emergency scenes, scuba diving professionals assisting injured divers, and employers seeking to provide the best emergency medical response to seriously ill or injured employees in the workplace.

The proposed changes would limit the availability of this simple, life-saving medical application.

MEDIC FIRST AID Recommendations:

1) In order of preference, MEDIC FIRST AID recommends the following revisions be made to lines 743-744 of Docket 2003D-0165:

> Preferred Option: "If a medical gas company sells medical oxygen ~~to emergency medical services~~ for emergency use, the label would contain the statement:"
>
> Alternative Option: "If a medical gas company sells medical oxygen to emergency medical services [insert "or"] for emergency use, the label would contain the statement:"

2) MEDIC FIRST AID recommends no changes to lines 746-748 of Docket 2003D-0165 regarding the existing labeling requirements so that medical oxygen label would read, "For emergency use only when administered by properly trained personnel for oxygen deficiency and resuscitation. For all other medical applications, Rx only."

3) In order of preference, MEDIC FIRST AID recommends the following revisions be made to lines 750-751 of Docket 2003D-0165:

Preferred Option: "FDA would not prohibit the sale of medical oxygen with this labeling to emergency medical services (see Glossary for definition of an EMS) [insert "or properly trained personnel"] without a prescription."

Alternative Option: FDA would not prohibit the sale of medical oxygen with this labeling to emergency medical services (see Glossary for definition of an EMS) [insert "or for emergency use"] without a prescription."

MEDIC FIRST AID strongly recommends that the preceding changes be incorporated into the final version of Docket 2003D-0165. If these proposed changes are not made to Docket 2003D-0165, an infant, child, sibling, parent, or loved one might not survive a medical emergency due to restricted access to emergency oxygen.

As the Special Investigator in the development of the National Guidelines for First Aid Training in Occupational Settings (NGFATOS) Oxygen First Aid Supplement, I am enclosing a sample of the most current document being used in the development of emergency training programs.

The enclosed *Guidelines for a First Aid Oxygen Administration Enrichment Program* is non-proprietary, public domain material. It is not the property of any individual or organization. The document was produced through a voluntary consensus process including expert and public peer-review. This document is not the product of any individual National Advisory Board (NAB) participant or investigator. There are no trademarks, license agreements, or copyrights associated with the document.

Please call me if you would like to discuss MEDIC FIRST AID's comments, recommendations, or concerns.

Sincerely,

Bill Clendenen
President

cc: Carl Johnson, President, Compressed Gas Association

enclosure