DAN
Divers Alert Network

August 27, 2003

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

RE: Docket 03D-0165
Guidance for Industry – Current Good Manufacturing Practice for Medical Gases

To Whom It May Concern:

Divers Alert Network (DAN), the world's largest scuba diving safety organization has been training scuba divers in the safe application of emergency medical oxygen as first aid for diving-related injuries since 1991. To date we have trained over 150,000 emergency medical oxygen providers worldwide, the majority here in the United States. After reviewing the proposed changes to the GMP for Medical Gases concerning the labeling requirements for the use of emergency oxygen, we have some serious reservations regarding the impact of the changes if they were to go into effect unchanged.

In cases of decompression illness (DCI), the administration of emergency medical oxygen at high flow rates (15 lpm or higher) via oronasal or non-rebreather mask is the definitive initial treatment. Rapid deployment of emergency medical oxygen to an injured diver has a significant impact upon DCI symptoms and improved outcomes following definitive recompression treatments under medical supervision.

The new proposed requirement that oxygen for emergency purposes can only be provided by emergency medical services or dispensed via a prescription does not integrate with the reality of emergency response protocols. In our opinion, the proposed changes would limit the availability of emergency medical oxygen seriously jeopardizing the initial treatment and outcome of divers suffering from DCI-related injuries.

DAN recommends the following language changes:

1) In order of preference, DAN recommends the following revisions be made to lines 743-744 of Docket 03D-0165 to read:

   Preferred Option 1: "If a medical gas company sells medical oxygen ~~to emergency medical services~~ for emergency use, the label would contain the statement:"

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Preferred Option 2: "If a medical gas company sells medical oxygen to emergency medical services [insert "or"] for emergency use, the label would contain the statement:"

2) DAN recommends no changes to lines 746-748 of Docket 03D-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, DAN recommends the following revisions be made to lines 750-751 of Docket 03D-0165 to read:

   Preferred Option 1: "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."

   Preferred Option 2: 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."

4) DAN recommends that the FDA add to the Glossary a definition of properly trained personnel that would read:

   Preferred Option 1: "Properly trained personnel – a person who provides documentation that they have received training in the use of emergency oxygen."

   Preferred Option 2: "Properly trained personnel – a person who provides documentation that they have received training within the past twenty-four months in the use of emergency oxygen including providing oxygen to both a breathing and non-breathing patient, and safe use and handing of emergency oxygen equipment."

Thank you for your consideration of our recommendations. If you have any questions or would like additional information about DAN or our training programs, please contact me at the address or phone number listed below.

Sincerely,

Jeff Myers
Vice President, Training
Divers Alert Network