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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:

I am writing on behalf of the Professional Association of Diving Instructors (PADI). PADI is the world's largest recreational diving certification and professional membership organization. In excess of 70% of individual dive instructors and dive retail businesses in the United States are members of the PADI Organization.

A portion of the training PADI provides its members includes rescue and first aid. Dive instructors and other diving supervisory personnel have a need to be proficient as emergency care providers in responding to diving, aquatic and other emergency situations. In that the immediate application of emergency medical oxygen is a primary response to virtually all dive accidents resulting from the use of compressed air, and for many aquatic accidents in general, as a part of developing and maintaining their emergency response proficiency, PADI members are encouraged to complete formal training in the application of emergency medical oxygen.

After review of the "Current Good Manufacturing Practice for Medical Gases" draft, we are concerned that several portions of the draft may tend to restrict emergency application of medical oxygen, or the availability of emergency oxygen, to such qualified emergency care providers. If such restrictions were to be put into practice, the diving public would be put at significantly increased risk, as emergency oxygen application could become less immediately available, especially in remote locations (such as on dive charter boats) where other sources of emergency response would not be present. As is adequately medically documented, such a lack of oxygen treatment would seriously jeopardize both the effectiveness of initial treatment and the ultimate outcome of total treatments for divers suffering from compressed air-related and certain other aquatic injuries.

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For these reasons, PADI wishes to make the following recommendations for revisions to the draft document:

1. Lines 743-744: Replace with the following: "If a medical gas company sells medical oxygen for emergency use, the label would contain the statement:"
2. Lines 750-751: Replace with the following: "FDA would not prohibit the sale of medical oxygen with this labeling, without a prescription, to emergency medical services (see Glossary for definition of an EMS) or for emergency use."
3. Add to the Glossary a definition of "Properly trained emergency oxygen provider."
   "Trained emergency oxygen provider: An individual who can provide documentation of training in the use of emergency oxygen."
4. Lines 1866-1868: Replace last sentence with the following: "We recommend against the use of ABO for medical therapeutic treatment of humans or animals." (Note: the phrase "recreational inhalation" in the original is vague and overbroad - even a recreational aviator's use could be technically considered recreational inhalation.)

Thank you for considering these recommendations. Please add PADI to your contact list, for future draft reviews. If you have further questions, please contact me directly.

Sincerely,

Al Hornsby
Vice President, Legal Affairs
PADI Worldwide