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July 21, 2003

Docket Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville MD 20851

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

To Whom It May Concern:

Complient provides emergency oxygen products and training to commercial customers through a license with SOS Technologies. SOS Technologies is a 30+ year-old manufacturer and distributor of emergency oxygen inhalators. We wish to comment on one aspect of the proposed new Guidance Document "Current Good Manufacturing Practice for Medical Gases."

On December 1, 1997, the FDA approved new labeling for medical oxygen, which now allows distribution of medical oxygen without a prescription for emergency use for oxygen deficiency and resuscitation, while retaining the prescription requirement for all other uses. That specific wording is as follows:

> FOR EMERGENCY USE ONLY WHEN ADMINISTERED BY PROPERLY TRAINED PERSONNEL FOR OXYGEN DEFICIENCY AND RESUSCITATION, FOR ALL OTHER MEDICAL APPLICATIONS, **CAUTION:** RX ONLY.

The wording for the present labeling is based upon the fact that a physician is generally not immediately available to write a prescription at the site of most cardio-respiratory emergencies and accidents that occur outside of a medical facility. In these instances, prompt administration of emergency oxygen to the victim by properly trained persons prior to the arrival of trained medical/EMS professionals may improve the incidence of survival.

The proposed new guidance document entitled *Current Good Manufacturing Practice for Medical Gases* appears to revert medical oxygen labeling back to prior labeling, restricting the distribution and use of emergency oxygen to medical professionals such as EMTs and Paramedics (see lines 1839-1842 in the draft document under Emergency Medical Services).

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Many recognized organizations, including the National Safety Council and the American Heart Association, have developed and published guidelines on the safe use of emergency oxygen by trained persons other than EMTs and Paramedics. Additionally, commercial entities routinely conduct CPR and emergency response training programs across the country, teaching emergency preparedness to laypersons. These programs include basic first aid, cardiac defibrillation using an AED, and administration of emergency oxygen.

In the interest of patient care, we would propose the following modifications to the draft guidance to industry.

1. **Add a definition for emergency oxygen following line 1869 as follows:** EMERGENCY OXYGEN: Oxygen that is administered by properly trained persons for oxygen deficiency and resuscitation. Equipment intended for such use must deliver a minimum flow of 6 liters/minute for a minimum of 15 minutes, and include an appropriate mask or administration device.

2. **Revise lines 743-744 to read:** If a medical gas company sells medical oxygen for emergency use, the label would contain the statement: (Lines 746-748 remain unchanged and are consistent with currently approved labeling for medical oxygen and as proposed in the new Guidance Document in lines 746-748).

Over the years, our customers have expressed to us that our emergency oxygen and training have helped to insure a higher success rate in the handling of emergency events. Indeed, the Federal government has gone to great lengths to encourage lay responders to act (ie. Good Samaritan Act.) The above change in the draft Guidance for Industry is important, and will retain enough of the current labeling requirements to allow for the continued distribution and use of emergency oxygen without a prescription for oxygen deficiency and resuscitation.

Sincerely,

Neil T. Glazer
Corporate Attorney