'03 JUL 11 P1:59

**SOS TECHNOLOGIES®**

On your team
. . . for life

3 July 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:

For over 30 years SOS Technologies has been a manufacturer and distributor of emergency oxygen inhalators across the country. I would like 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 allows the distribution of medical oxygen without a prescription for emergency use for oxygen deficiency and resuscitation while retaining the prescription requirement for all other uses. Wording is:

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

The rational for this labeling is based on the fact that a physician is usually not immediately available to write a prescription at the site of a cardio-respiratory emergency or other accident that occurs outside of a medical facility. In these cases, prompt administration of emergency oxygen to the victim by properly trained persons prior to the arrival of trained EMS professionals may improve the chance of survival.

The proposed new guidelines document *Current Good manufacturing Practice for Medical Gases* appears to revert the labeling of medical oxygen back to prior labeling which restricts 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).

03D-0165

C3

*1401 Franquette Ave., Suite A-3 • Concord, CA 94520 • (925) 691-9335 • Fax (925) 691-9445*

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. Many business entities, both large and small, conduct CPR and emergency response training programs across the country, teaching emergency preparedness to lay responders. These training programs follow the published guidelines in the instruction of basic first aid, use of an AED and the administration of emergency oxygen.

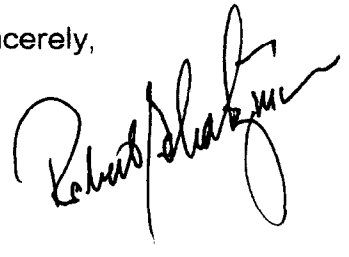
I would like to propose the following modifications to the draft guidance to industry:

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 approved labeling for medical oxygen as proposed in the new Guidelines Document in lines 746 – 748).

I feel strongly that this change in the draft Guidance for Industry is important to retain. It will allow the continued use of emergency oxygen by properly trained persons during oxygen deficiency and resuscitation incidents.

Sincerely,



Robert Schatzman
President
SOS Technologies
Concord, CA
925-691-9335