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August 26, 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

Gentlemen:

SOS Technologies is a 30+ year-old manufacturer and distributor of emergency oxygen inhalators. I wish to comment on one aspect of the proposed new Guidance Document, "Current Good Manufacturing Practice for Medical Gases."

On December 1, 1997, 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.

Rationale for the present labeling is based upon the fact that a physician is generally not available to write a prescription at the site of 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 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 EMT's and Paramedics (see lines 1839-1842 in the draft document under Emergency Medical Services).

Numerous recognized organizations, such as 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 EMT's and Paramedics. SOS Technologies, Pittsburgh trains over 2,000 people a year in CPR, First Aid, cardiac defibrillation using an AED, and administration of emergency oxygen. There are many

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similar companies across the United States conducting similar programs including administration of emergency oxygen.

In the interest of patient care, SOS Technologies, Pittsburgh proposes the following modifications to the draft guidance to industry: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).

This change in the draft Guidance for Industry is important to retain and will allow the continued distribution and use of emergency oxygen without prescription for oxygen deficiency and resuscitation.

Respectfully,

Sidney Stark, Jr.

Sidney Stark, Jr.
President