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July 9, 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:

It has recently come to my attention that there is a draft revision for changes to the "Current Good Manufacturing Practice for Medical Gases". The lines of the draft that are of specific concern to my organization are 1839-1842 under Emergency Medical Services.

On December 1, 1997, the FDA approved new labeling for medical oxygen, which currently allows for the use/distribution of medical oxygen without a prescription for emergency use for oxygen deficiency and resuscitation. All other uses and applications still require a prescription.

SOS Technologies has been providing organizations and corporations emergency medical equipment and training nationally for over 30 years. One of the cornerstones of our business is the provision of emergency oxygen units and the training to use them effectively. These units provide the coverage that these organizations desire to bridge the gap between an emergency situation and the arrival of EMS. The fact of the matter is that by taking the utilization of emergency oxygen away from the properly trained rescuer, their effectiveness in a resuscitation attempt may be adversely affected.

The current, 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 verbiage on the proposed changes appears to revert the indication for emergency oxygen back to prior labeling, restricting the use of emergency oxygen to medical professions, such as EMT's and Paramedics. While it is impossible to document how many lives have been saved by "lay-persons" coming to someone's aid with emergency oxygen, 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 "lay-persons" and have promoted its use as an effective life-saving measure.

In the interest of public safety, I would like to strongly urge the revision committee to reconsider the proposed changes and keep the wording consistent with the current indication for emergency oxygen.

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I would like to support the proposal for the following modifications:

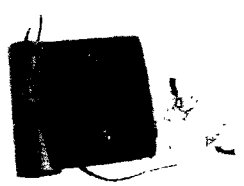
1. **Add a definition for emergency oxygen following line 1869 as follows:**
   EMERGENCY OXYGEN: Oxygen that is administered by properly trained persons for oxygen deficiency and resuscitation. Equipment intended for such use must deliver a minimum flow of 6 liters/minute for a minimum of 15 minutes,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

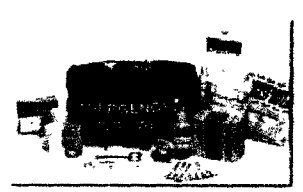
2. **Revise lines 743-744 to read**: If a medical gas company sells medical oxygen for emergency use, the label would contain the statement: (Lines 746-748 remain unchanged and are consistent with currently approved labeling for medical oxygen and as proposed in the new Guidance Document in lines 746-748).

These changes in the draft Guidance for Industry are vital for the continued use of emergency oxygen by trained lay responders in resuscitation attempts and in cases of oxygen deficiency.

Sincerely,

James R. McMillan
SOS Technologies - CT





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