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August 29, 2003

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

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

Dear Sirs/Madams:

I am the owner of a mobile first aid van service company and distribute first aid, medical and safety products to business customers. In addition, we also do a great deal of CPR/First Aid Training. In this business, we have carried medical oxygen for the use in emergency care for many years in addition to training our customers on the proper techniques and applications.

In have been in this field of business for several years with extensive experience of selling the above mentioned products. I am also a seasoned EMT-B of eight years and am a full-time member with my local volunteer rescue squad as a technician and driver. I feel that my additional training and knowledge in this area is all the more reason that Companies such as mine should be able to continue to sell emergency medical oxygen to our customers. I am sure you know as well as I, that the enhancement of oxygen to a patient in need is tremendous as opposed to any contraindications.

The proposed new Guidance document "current Good Manufacturing Practice for Medical Gases" will lead to a reduction in the effectiveness of a "Good Samaritan" responding to a medical emergency of a patient with a condition related in any way to "difficulty in breathing" or lack of oxygen due to illness or trauma.

As I understand it, the new guidance document entitled "Current Good Manufacturing Practice for Medical Gases seems to revert medical oxygen labeling back to previous labeling which restricted the distribution and or use of emergency oxygen to medical professionals such as myself, being a EMT-B and Paramedics.

The FDA approved new labeling on December 01, 1997 for medical oxygen which allowed distribution of such medication without a prescription for emergency use for oxygen deficiency and resuscitation, while retaining the prescription requirements for all other uses. The specific wording is:

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

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Considering my EMT-B skill level and full time affiliation with my local EMS Service Provider, I honestly feel that is appropriate to assume that in most instances a physician is not available to dispense a prescription at the time or place that the vast majority of cardio-respiratory emergencies occur outside of a medical setting. If this were the case, the patient would have already been under medical supervision and prompt administration of emergency oxygen would be administered by protocols and standing orders awaiting EMS/ALS arrival.

Several organizations including the National Safety Council and the American Heart Association; who EMS professionals are trained through, have developed and published guidelines on the safe and effective use of emergency oxygen by those persons trained in administering the medication outside the licensed professional personnel such as EMTs and Paramedics. In fact, it has been a proven fact the emergency oxen greatly enhances the outcome of the patients condition and prognosis related to cardio-respiratory emergencies.

As stated previously, through my Company we teach several programs including CPR/First Aid; which encompasses cardiac defibrillation using AEDs and the administration of emergency oxygen.

I strongly advocate that in the best interest of patient care that we propose the following modifications to the draft guidelines to industry:

1. ADD A DEFINITION FOR EMERGENCY OXYGEN FOLLOWING LINE 1869 TO THE EFFECT OF:

   EMERGENCY OXYGEN:
   Oxygen that is administered by properly trained persons for oxygen deficiently and resuscitation. Equipment intended for such use must deliver a minimum flow of six liters per minute for a minimum of fifteen minutes and should include an appropriate mask or equivalent administration device.

2. Revise lines 743 - 744 to read as follows: 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 746 - 748).

In order to retain and allow the continued use and distribution of emergency medical oxygen without a prescription for oxygen deficiency and resuscitation this change in the draft Guidance for industry must be changed.

Sincerely,

Doris A. Busse

Doris A. Busse
Owner/ EMT-B