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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:

Erie Medical is a 60+ year old manufacturer of medical oxygen components and complete oxygen systems used in homecare, hospitals, long term care facilities, and in emergency care. We 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 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 ).

Numerous 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, numerous commercial entities including Compliant, Cintas First Aid and Safety, and other similar companies routinely conduct CPR and emergency response training

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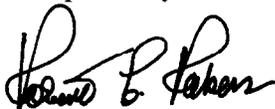
programs across the country, teaching emergency preparedness to laypersons. These programs include basic first aid, cardiac defibrillation using an AED, and administration of emergency oxygen.

In the interest of patient care, Erie Medical 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 a prescription for oxygen deficiency and resuscitation.

Respectfully



Robert C. Rakers  
Vice President