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August 25, 2003

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

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

Gentlemen:

We are a distributor of first aid, medical and safety products to business customers. In that role, we have carried medical oxygen for use in emergency care applications for many years. One aspect of the proposed new Guidance document "current Good Manufacturing Practice for Medical Gases" will lead to a reduction in the effectiveness of layperson response to medical emergencies.

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).

On December 1, 1997, FDA approved new labeling for medical oxygen, which 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 ADMINISTERD BY PROPERLY TRAINED PERSONNEL FOR OXYGEN DEFICIENCY AND RESCUSCITATION. FOR ALL OTHER MEDICAL APPLICATIONS, CAUTION: RX ONLY

The rationale for the current 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.

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Numerous recognized organizations, among them 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. In addition, Respond Distributors and other first aid service and supply companies typically conduct CPR and emergency response training programs around the country, teach emergency preparedness to laypersons. These programs include basic first aid, CPR, cardiac defibrillation using AEDs and administration of oxygen. In the interest of patient care, we 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 six liters / minute for a minimum of fifteen 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 allow the continued distribution and use of emergency oxygen without a prescription for oxygen deficiency and resuscitation.

Sincerely,

Mark McDevitt
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