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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:

U O Equipment Company is the manufacturer of the United Oxygen line of portable emergency oxygen equipment. We have been in business since 1981 selling mainly to the industrial safety market through safety distributors. Our products are most likely used in hard to get to workplaces such as chemical plants and refineries, steel plants, and even offshore rigs and NOAA dive boats. Most of these units are designed for the layman to administer oxygen promptly while waiting for the emergency medical professionals to arrive.

Training for these laymen is offered by a variety of organizations including but not limited to the National Safety Council, the American Heart Association, the Red Cross, the American Safety & Health Institute, and some oxygen equipment manufacturers.

With that in mind, 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).

In the interest of patient care, U O Equipment Company proposes the following modifications to the draft guidance to industry: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 per 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 is 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This change in the draft Guidance for Industry is important to retain and will allow the continued distribution and use of emergency oxygen without a prescription for oxygen deficiency and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.

Regards,

Robert R. Wright, Jr.
President

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