COMPLIENT™
27070 Miles Road, Suite 100, Solon, Ohio 44139
ph: 440.498.8800 fax: 440.349.7998

03 AUG 18 A3:40

August 13, 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

ATTENTION: Duane Sylvia

Dear Mr. Sylvia:

I am writing on the behalf of "Complient" to provide comments on the Food and Drug Administration's (FDA) draft guidance for "Current Good Manufacturing Practice for Medical Gases" issued in May 2003. Specifically, we seek clarification on lines 743-753 of the guidelines, which appear to further restrict the distribution of emergency oxygen from previous FDA policy.

Complient provides comprehensive health and safety consulting, training, equipment and management programs in the workplace for private companies, state and federal agencies throughout the nation. We deliver our services to thousands of clients and, last year alone, trained more than 32,000 people. The main purpose of our program is to ensure that victims of cardiac arrest in the workplace receive initial emergency aid within the first crucial minutes of the occurrence. For every minute a victim remains un-resuscitated, chances of survival drop 7 to 10 percent. In just 9 minutes, survival rates drop to almost zero.

To achieve this result, Complient prepares an Emergency Medical Response System that includes such items as an Automated External Defibrillator (AED), bloodborne pathogens protection kit, first aid kit and emergency oxygen. We train and certify teams in the workplace for emergency use on all of these items. Our program has resulted in many saves in the workplace. ***The use of emergency oxygen has served as a key component in many of these saves.*** We agree with the American Heart Association's position that emergency oxygen is vital in improving outcomes from cardiac events when used by properly trained lay responders.

2003D-0165 C 7

We are deeply concerned that the draft guidelines could be interpreted as restricting the distribution of emergency oxygen to strictly defined "emergency medical services" (lines 743-751). Such services are defined by the guidelines to include "fire departments, ambulance companies, and rescue squads that are usually government affiliated emergency services (lines 1839-1842)." This would mean that emergency oxygen could not be supplied to the many thousands of people that we certify each year for emergency response. This change would certainly impair the ability of these trained responders to resuscitate victims of cardiac arrest -- translating to less saves in the workplace.

We strongly urge you to keep intact the current FDA policy on emergency oxygen, which allows for use by "properly trained personnel for oxygen deficiency and resuscitation," and not restrict such use to "emergency medical services" as defined by the draft guidelines.

Thank you for this opportunity to provide our input, we would like to meet with you further to discuss this issue.

Please feel free to contact me if you have any questions.

Sincerely,

Robert I. Thompson
Chief Executive Officer

RIT/eh