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

July 8, 2003

RE: Docket 03D-0165
Guidance for Industry
Current GMP for Medical Gases

Gentlemen:

LIFE® Corporation has been a Registered #2183615 Manufacturer of Medical Devices since 1985. We manufacture LIFE® and LIFE OxygenPac® and SoftPac™ emergency oxygen units and related CPR equipment for markets through distributors in every state of the USA and to over 60 countries worldwide. Your Docket #03D-0165 has come to our attention, and requires our response.

Since 1985, we and the entire industry, and the users of emergency oxygen have relied on various FDA rules and guidelines, the most recent of which were the "Fresh Air Act 2000, A Look at FDA's Medical Gas Requirements", which included (pg13 par3) the 1997 FDA labeling requirement for medical oxygen which now reads:
"For emergency use only when administered by properly trained personnel for oxygen deficiency and resuscitation. For all other medical applications, Rx Only."

Your present Docket #03D-0165 Current Good Manufacturing Practice for Medical Gases in fact would repeal the non-prescription implication of *"for emergency use"* of oxygen in all prior FDA rules and guidelines, and would restrict the use of medical oxygen to "*emergency medical services*" (EMS –def.) (ref. lines 743, 750-751, and 1839-1842)

Current portable easy-to-use emergency oxygen units are used for providing on-site first-aid supplemental oxygen in industrial, office, public, and government workplace, first-aid, and safety programs. They are intended for use prior to arrival of EMS emergency medical services professionals when available timely, or in many situations totally lacking such availability of EMS professional response teams, such as, for a few examples, thousands of off-shore workboats and public transport boats and trains in transit, remote workplaces such as mines, recreation parks, vast rural areas with a major agricultural workforce population, Indian reservations, remote schools with hundreds of thousands of children....and most recently emergency oxygen has become an essential component of Federal Homeland Security first-aid programs. The list of places where emergency oxygen units are part of first-aid programs saving lives is *ad infinitum*. There are hundreds of thousands of emergency oxygen units now in use that would have to be abandoned, not being able to be refilled because of proposed Docket # 03D-0165, which would stop all such sales and use of life-saving emergency oxygen equipment.

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Training - Very adequate guidelines and training for basic CPR and first-aid, AED use, and emergency oxygen administration have been provided to trained laypersons, *other than EMS "emergency medical services"* by: many "emergency medical services" themselves such as fire departments; various national organizations such as the American Heart Association, National Safety Council, and American Red Cross; numerous businesses including Medic First-Aid, American Safety Health Institute, Complient, and SOS/OTI; and thousands of small professional for-profit or volunteer community CPR training groups, programs and individual persons....thus reaching even the remotest locations for use of emergency oxygen units for *"emergency use"* where no such "*emergency medical service*" can respond in time, or can respond at all.

When the above is considered, with many other aspects not mentioned for brevity, it is our sincerest proposal, for the general health and welfare for all the public, that Document #033D-0165, (Draft) Guidance for Industry, Current GMP for Medical Gases, be modified, consistent with past and current rules and guidelines, as follows:

1) **[Revise** (add)**]** lines 743-744 as follows:
   If a medical gas company sells medical oxygen to emergency medical services **[or]** for emergency use, the label would contain the statement:
   (lines 746-748 same, as is current approved labeling)

2) **[Revise** (add)**]** 750-751 as follows:
   FDA would not prohibit the sale of medical oxygen with this labeling to emergency medical services **[or for emergency use]** without a prescription.
   (see Glossary for definition of an EMS **[or EO]**)

3) **[Add definition]** of "oxygen for emergency use" in Glossary (say line 1869) as follows:
   [Oxygen for emergency use – (Emergency Oxygen (EO)): oxygen that is administered by properly trained persons for oxygen deficiency and resuscitation.**]**
   (Edit.Option:) - It may be timely to update previous guidelines here for enforcement objectives, by adding:
   [Equipment intended for such use must deliver a minimum flow rate of 6 liters of oxygen per minute for a minimum of 15 minutes, and must include a contents gauge and an appropriate mask or administration device.**]**

Respectfully submitted,

John Kirchgeorg
President
LIFE Corporation