B&R Compliance Associates LLC

# Regulatory Update Bulletin

**Bulletin Number**

**BR08-006**

**1/16/08**

## Emergency Oxygen: Drug or Non-Drug?



***Issue***

In response to frequent questioning on the above subject, this bulletin is being issued to provide guidance on the topic. B&R Compliance has consulted with the Food & Drug Administration to obtain the following clarification.

Section 201(g)(1), 503(b)(1)(A), and (4)(A) of the Federal Food, Drug, and Cosmetic Act defines drugs as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals" and "articles (other than food) intended to affect the structure or any function of the body of man or other animals". Oxygen intended to treat or prevent illness or injuries is considered to be “a drug” and should be labeled “USP”. High pressure “Medical Oxygen” cylinders must bear a drug label containing the following statement:

**"For emergency use only when administered by properly trained personnel for oxygen deficiency and resuscitation. For all other medical applications, Rx Only."**

Emergency medical oxygen is a prescription drug as described by the Federal Food, Drug, and Cosmetic Act. Therefore, in order to fill and/or distribute emergency oxygen you must either obtain a prescription or documentation of proper training of the first responder who is asking to have his bottle refilled. Under no circumstances can an untrained individual be given emergency oxygen, as this would be a violation of section 503(b)(4)(A) of the Federal Food, Drug, and Cosmetic Act.

"First responders must have received training in the use of emergency oxygen within the past twenty-four months, including providing oxygen to both breathing and non-breathing patients, and the safe use and handling of emergency oxygen equipment. This training is available from any nationally recognized professional organization, such as the National Safety Council, the American Heart Association, the American Red Cross, etc. A first responder must provide documentation of the above training to a medical oxygen supply company. Once all of these conditions are met, a first responder may receive "oxygen for emergency use."

If you produce gases, which bear the “USP”, or “NF” label and meet the definition of a “drug” (see above), you are a drug manufacturer. As such, the FDA expects you to comply with Current Good Manufacturing Practices which includes developing written operating procedures (SOPs), testing product with properly calibrated equipment, isolating drug product from industrial grade product, training employees, and maintaining appropriate documentation (which would include the documentation covered in this article). Current Good Manufacturing Practices (cGMP's) relative to human drug products are found in 21 CFR, §210 and 211. Failure to comply with these requirements and the requirements of your own SOPs can result in serious consequences.

**For more information on this subject, or any other medical gases compliance issue please contact Ron Ball at (317) 297-8518, or ron.ball@brcompliance.com.**