



B&R Compliance Associates LLC
Regulatory Update Bulletin

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**FDA Communications Regarding
Drug Shortages in the US**

Page 1 of 1

What does the above mean for you as a medical gas producer?

You may have recently received or might receive in the near future a letter from the FDA regarding the above issue.

The following is an introduction excerpted from the full letter:

“The FDA is contacting all drug manufacturers to express our concern about the rising incidence of drug shortages in the United States, particularly those involving drugs for which no good alternative therapies exist, and the serious impact these shortages have for patients and health care providers. The number of drug shortages annually has tripled from 61 in 2005 to 178 in 2010. Some of these shortages delay or deny needed care for patients since they involve critical drugs used to treat cancer, to provide required nutrition, or to address other serious medical conditions.

Today, we released a report about this serious public health issue, emphasizing that its root causes are complex, as is the path to resolving them. ”

To read the full letter you may follow the link below:

<http://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm277675.htm>

To view the full report referenced in the letter you may follow the link below:

<http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/ucm275051.htm>

While this is a serious issue for the pharmaceutical/drug industry as a whole, it is B&R's evaluation after reviewing the letter and report that this initiative will have minimal impact on the medical gases industry due to the large numbers of medical gas suppliers and the ready availability of medical gases, but we still wanted to bring this to your attention, as part of the continuing industry leading service we provide our customers.

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.