



B&R Compliance Associates LLC
Regulatory Update Bulletin

**Bulletin
Number**

BR09-002

9/15/01

**Expiration Dates for Medical
Gases**

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In the late 80's our industry filed a citizen's petition with FDA to exempt medical gases from expiration dating requirements. In the early 90's through 2000 FDA published guidance documents indicating they agreed with industry's request. The following statement is excerpted from the FDA Document - *Fresh Air 2000 - A Look at FDA's Medical Gas Requirements*.

EXPIRATION DATING AND STABILITY TESTING

Sections 211.137 & 166

The Compressed Gas Association submitted a citizens petition to exempt medical gases from compliance with the expiration dating requirements of 21 CFR 211.137. While FDA evaluates the data, we are not enforcing this requirement. However, if a firm's written procedures call for an expiration date, then we would expect a firm to be following their procedures and apply an expiration date to the product.

Medical gases or medical gas mixtures that are considered new drugs or investigational new drugs are required to undergo stability testing in order to establish an appropriate expiration date.

In May of 2003 FDA published a new (draft) guidance document on Medical gas requirements, in which they re-instituted a requirement for medical gases to have an expiration date supported by stability testing. During the nearly 15 years FDA chose not to enforce expiration dating they told industry in numerous meetings they agreed with the exemption request. In light of this information, many firms dropped expiration dating from their SOP manuals, however, some firms elected to keep it. This is why you will find some cylinders of medical gases with expiration dates, and others without.

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.



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Industry has held numerous meetings with the agency since the new draft guidance document was published, and expiration dating requirements is a key topic at those meetings. FDA concerns for expiration dating of high pressure cylinders are not related to potential product degradation. Industry data shows that medical gases do not lose purity or strength when stored for extended periods of time, and in our meetings FDA acknowledged they concur with this data. FDA concerns extend around small cylinders used as backups to concentrators, or in emergency situations, may leak over time, causing a reduction of contents in the container. Additional industry data shows this is not the case; however, FDA is seeking to have this data confirmed through a formalized stability test for medical gases. The industry is working with the agency to develop the testing protocols for this stability test, but have not reached a final decision of test methodologies as of yet.

We expect at some point in the future there will be a uniform, industry wide, requirement for expiration dating, supported by a stability test. We are not aware of any instances in the last 3 years where FDA has issued a citation for not complying with expiration dating requirements to a medical gas firm. The medical gas industry's position is that firms that currently do not apply expiration dates should not implement that process, until the requirements are established, and the appropriate stability tests have been conducted.

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