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Via FedEx

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July 6, 2004

Dockets Management Branch (HFA-305)
U.S. Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

Re: Docket No. 2004N-0133: Electronic Record; Electronic Signatures; Public Meeting, Federal Register, Vol. 69, #68, pgs. 18591-18593, April 8, 2004

Dear Sir or Madam:

BOC Gases appreciates the opportunity to comment on the Electronic Record; Electronic Signatures (rule Part 11).

The medical gas industry constitutes over half of all registered drug manufacturers and we consider ourselves to be a Major contributor to that industry. BOC is committed to applying safe practices in the industrial and medical gas industry and we consider our policies and procedures to be best in class in applying those concepts.

BOC, as an active and participating member of various Compressed Gas Association (CGA) committees, contributes ideas that help create the various gas industry standards intended to promote safe and reliable products.

BOC applauds the initiative taken by FDA to encourage the application of science and risk assessment to meet compliance requirements. As a contributor to the comments submitted by CGA regarding this docket, BOC fully supports the philosophy of using risk assessments to determine one's approach for achieving regulatory compliance.

FDA's philosophy of applying risk assessment to compliance and enforcement is not only logical but also a sound decision making tool used successfully and effectively by many industries to better serve public safety. When these risk assessments focus on the ultimate safety and effectiveness of the application of medical products and their effect on the general public, a win-win situation exists where the regulator and regulated have one common goal in mind. That goal is to maintain a level of public health that is the best in the world.

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We agree with the direction FDA is taking to simplify the Part 11 requirements and believe that this common sense approach will stimulate and encourage all FDA regulated industries to move forward in utilizing the technologies available to remain competitive in the global marketplace.

We appreciate the opportunity to comment on this subject docket.

If you have any questions related to the comments we have provided, or wish to discuss them further, please do not hesitate to contact me at (908-771-1834)

Sincerely,

A handwritten signature in black ink, appearing to read "John Hoffer", with a long horizontal flourish extending to the right.

John Hoffer
Medical Gas Quality Director