

SOUTHERN WELDING SUPPLY, INC.

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SAVANNAH, GEORGIA 31402

October 27, 2003

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

Comment: Docket No. 03D-0165: Draft Guidance for Industry on Current Good Manufacturing Practice for Medical Gases: 68 Federal Register 24005, May 6, 2003.

Ladies and Gentlemen:

Southern Welding Supply, Inc., is a small, family owned industrial gas distribution business. We produce two (2) medical products: Oxygen USP and Nitrogen NF. For over 30 years, we have served the industrial and medical gas needs of the Savannah area.

Your Draft Guidance, if enacted in its present form, will cause serious operational difficulties for our company, but provide few, if any, of the benefits you seek.

1. Requiring that medical and industrial containers be segregated during all areas of cylinder preparation, staging, production, and delivery is unnecessary and time consuming. Our current cGMP is designed to prevent mixing of industrial and medical containers prior to labelling and distribution. Since your proposal deviates significantly from long-standing industry practice, compliance will be expensive, time consuming, operationally difficult, and awkward to document.
2. All of our bulk purchases are of oxygen USP and nitrogen NF. To require a separate bulk storage vessel for that portion of our purchases that will ultimately be sold as medical product will accomplish nothing other than require a very substantial additional investment on our part. The current cGMP requires assay of each batch of medical product. Those assays and the related QC procedures, in our judgment, provide sufficient assurance of product purity and quality. Prior to this Draft Guidance, FDA concurred in that judgment.

We realize that the medical gas production business offers some significant regulatory challenges to FDA, since the overall production process is so much different than traditional pharmaceuticals.

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Southern Welding Supply hopes that legitimate concerns of smaller companies will be taken into account during this rule making process.

Sincerely,

Kirk M. Duffy

Kirk M. Duffy
President