



September 8, 2000

BY FEDERAL EXPRESS

457 '00 SEP 11 P1:25

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane - Room 1061- HFA-305
Rockville, MD 20852

Re: Docket No. 00P-1406, Petition to Stay Fresh Air

Dear Madam or Sir:

MG Industries (MG) is a manufacturer of compressed and liquid gases for medical and industrial applications, with numerous locations throughout the United States. MG distributes gases for medical applications to customers such as hospitals and medical offices. With over 1,000 employees in production and distribution facilities across the country, MG has been doing business in the United States for over 25 years.

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MG respectfully submits these comments to the above docket in support of the action requested by the Compressed Gas Association and the National Welding Supply Association in their Petition for Stay. Specifically, MG supports the position of the Petitioners that promulgating, presenting and otherwise issuing Fresh Air speeches and documents in lieu of formal rulemaking is inappropriate.

MG believes that the Fresh Air presentation and the application of cGMP standards that were designed specifically for drug products in traditional dosage forms rather than medical gases, creates an unpredictable regulatory climate. While cGMP principles address some of the quality assurance and control issues that MG maintains and promotes as part of its medical gas operations, these regulations do not appear to apply, in many instances, to the production, handling and distribution of liquid and compressed gases used in medical applications. In addition, the Fresh Air presentations, which appear to expand cGMP standards, do not allow for industry participation or comment, and therefore, do not conform to the FDA's own established rulemaking procedures. It is our belief that Fresh Air is not an appropriate or effective vehicle for interpreting existing regulatory requirements or establishing new ones.

00P-1406

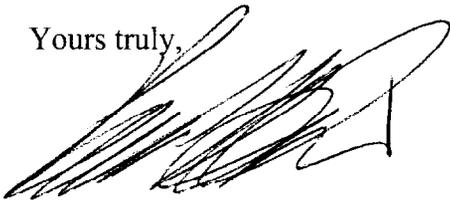
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MG believes that the Agency and industry trade associations can and should work together to formalize regulations or guidance so that evolving standards are maintained and developed through an iterative, collaborative process that effectively addresses the mutual objective of promoting public health and safety. Accordingly, MG respectfully urges the FDA to grant the Petition and discontinue further Fresh Air presentations. Furthermore, MG urges the Agency to work with industry to develop and publish regulations or guidance specific to medical gases.

Yours truly,



Paul G. Weiss, Esq., Vice President
Regulatory Affairs

c: Carl T. Johnson, President, Compresses Gas Association
J. David Mahoney, President, National Welding Supply Association

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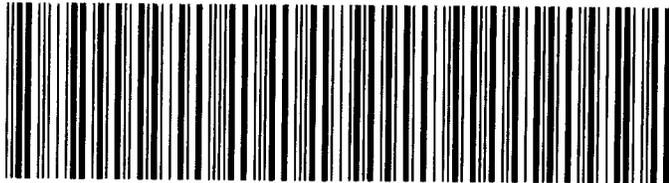
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