



COMPRESSED GAS ASSOCIATION

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September 25, 2006

Attn: FDA Desk Officer
Office of Information and Regulatory Affairs
Office of Management and Budget
Food and Drug Administration

RE: REQUEST FOR EXTENSION OF COMMENT PERIOD

Docket No. 2005N-0403

RIN 0910-AA49

Proposed Rule on Requirements for Foreign and Domestic Establishment Registration and Listing for Human Drugs, Including Drugs that are Regulated Under Biologics License Application, and Animal Drugs, Vol 71 No. 167 Federal Register page 51276, August 29, 2006.

The Compressed Gas Association (CGA) and the Gases and Welding Distributors Association (GAWDA) respectfully request an extension of 60 days to comment on the Proposed Rules on Requirements for Foreign and Domestic Establishment Registration and Listing for Human Drugs, Including Drugs that are Regulated Under Biologics License Application, and Animal Drugs issued on August 29, 2006, 71FR51276. Comments are due by September 28, 2006, which does not give our member companies sufficient time to fully evaluate the economic impact of this proposed rule and report their findings to the Agency.

We believe that FDA failed to adequately consider the compressed gas industry in its financial impact study.

- Table 2 on page 51327 states a total annual cost of 5.6 million dollars for industry to comply with the proposed rule. Early estimates indicate that it could cost just one of our member companies more than this amount. We believe the total cost to the compressed gas industry will far exceed 5.6 million dollars and need additional time to complete our total cost estimates.
- Table 2A on page 51327 states that there are 666 pharmaceutical manufacturers (human) affected by the proposed rule. In fact, there are over 1,800 medical gas manufacturers registered with the Agency. The Agency may want to consider that the number of manufacturers in other segments of the pharmaceutical industry may also have been underestimated or not included at all, as this would significantly change the economic impact numbers.

Please let us know if you require any further information in considering our request for extension.

Sincerely,

Marc J. Meteyer
President and CEO,
Compressed Gas Association

J. Robert Yeoman,
President and CEO,
B&R Compliance, Medical Gas Consultant to GAWDA