



COMPRESSED GAS ASSOCIATION

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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

REQUEST FOR 90-DAY EXTENSION OF COMMENT PERIOD

Docket No. 2004D-0443

Draft Guidance for Industry on Quality Systems Approach to Pharmaceutical Current Good Manufacturing Practice Regulations

Vol. 69, No. 191 Federal Register 59256, October 4, 2004

The Compressed Gas Association (CGA), CGA's member companies, and the Gases and Welding Distributors Association (GAWDA) appreciate the opportunity to comment on the Draft Guidance for Industry on Quality Systems Approach to Pharmaceutical Current Good Manufacturing Practice Regulations, which the U.S. Food and Drug Administration issued on October 4, 2004.

The medical gas industry constitutes over half of all registered drug manufacturers. CGA, founded in 1913, is dedicated to the development and promotion of safety standards and safe practices in the industrial and medical gas industry. CGA represents over 150 member companies in all facets of the industry—manufacturers, distributors, suppliers, and transporters of gases, cryogenic liquids, and related products and services. Through the committee system, CGA creates technical specifications, safety standards, training and educational materials, and works with government agencies to formulate responsible regulations and standards and to promote compliance with these regulations.

GAWDA, founded in 1946, is dedicated to the safe operations and economic vitality of independent distributors of industrial and medical gases and equipment. It represents over 800 member companies and provides them with compliance assistance and guidance directly through internal consultants. It is also very active in providing training and educational materials that promote safe operations and cGMP compliance. GAWDA participates actively with the CGA and its activities to create and promote responsible regulations and standards for the industry.

CGA and GAWDA respectfully requests an extension of 90 days, to March 3, 2005, for the comment period on the referenced draft guidance. CGA and GAWDA, being consensus organizations, require additional time to review the document and prepare an appropriate industry response to the guidance document.

We believe that by allowing this extension for review of the document by the industry and with proper consideration of the CGA and GAWDA comments, the end result will better serve both the Agency and the industry we represent.

Sincerely,

A handwritten signature in black ink, appearing to read 'Carl T. Johnson', is written over a horizontal line.

Carl T. Johnson
Compressed Gas Association

cc: David Horowitz, Director, Office of Compliance, FDA
Peter O. Safir, Covington & Burling
Bob Yeoman, GAWDA