



1900 Arch Street
Philadelphia, PA 19103-1498
t: 215.564.3484
f: 215.564.2175
www.gawda.org

2002 - 2003
BOARD OF DIRECTORS

August 6, 2003

1456 '03 AUG -7 10:34

JAMES A. KISSLER
President
Norco, Inc
Boise, ID

WALTER L. BRANT
President-Elect
Indiana Oxygen Co.
Indianapolis, IN

ROBERT THORNTON, JR.
1st Vice President
South Jersey Welding Supply
Vineland, NJ

JAMES E. MADISON
1st Past President
Prest-O-Sales & Service, Inc
Long Island City, NY

D. SHERON CARTER
2nd Past President
Independent Welder Repair
Jacksonville, FL

Vice Presidents

ROBERT D'ALESSANDRO
Welco-CGI Gas Technologies, LLC
Newark, NJ

DUELL STONE
Oxygen Service Company
Macon, GA

RANDY KERSEY
Wright Welding Supply, Inc
Des Moines, IA

SCOTT B. CHENOWETH
Texas Welders Supply Co., Inc
Houston, TX

JOSEPH CHURILLA
Cameron Welding Supply
Stanton, CA

Directors

MARK C. HAUN
Haun Welding Supply
Syracuse, NY

N. BRITT LOVIN
Andy Oxy Co., Inc
Asheville, NC

GARY STONEBACK
Metro Welding Supply Corp.
Detroit, MI

JOHN HENDERSON
Red Ball Oxygen Co., Inc
Shreveport, LA

MICHAEL SUTLEY
Oxarc, Inc.
Spokane, WA

Management Staff

Fernley & Fernley, Inc
Philadelphia, PA

Henry W. "Rick" Doyle, III
G A Taylor Fernley
Jaime Lloyd
Jean McCann
Colleen McCauley

David Horowitz
Director, Office of Compliance
Food and Drug Administration
Center for Drug Evaluation & Research
11919 Rockville Pike, Room 405
Rockville, MD 20852

REQUEST FOR COMMENT PERIOD EXTENSION

Docket No. 2003D-0165

Draft Guidance for Industry on Current Good Manufacturing Practices for Medical Gases
68 Federal Register 24005, May 6, 2003

Dear Mr. Horowitz,

The Gases and Welding Distributors Association (GAWDA) respectfully requests an extension of 60 days, to November 3, 2003, for the comment period on the above referenced draft guidance.

While we were encouraged by the very productive meeting last week there are a large number of elements to the draft document that require industry input, and on which GAWDA and its members intend to comment. Our concerns center on new and potentially burdensome compliance requirements, as well as several larger policy issues regarding the appropriate scope of GMP regulation of our industry.

Because of the size of our membership and the difficulty of coordinating the development of such a large number of responses over the summer months we are requesting a 60 day extension of the comment period. Our membership is actively engaged in this process and working diligently with the CGA to provide meaningful and comprehensive comments to the guidance draft.

GAWDA believes that by allowing this comprehensive review of the document by industry and with proper consideration of the GAWDA comments, preparation and implementation of a final guidance document will be expedited. Therefore, GAWDA respectfully requests an extension of the comment period to November 3, 2003.

Sincerely,

Bob Yeoman
GAWDA Medical Gases Consultant

cc: Carl Johnson – CGA, Dockets Management Branch

03D-0165

EXT 1