

COMPRESSED GAS ASSOCIATION

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August 5, 2003

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 EXTENSION OF COMMENT PERIOD

Docket No. 2003D-0165

Draft Guidance for Industry on Current Good Manufacturing Practice for Medical Gases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

Dear Mr. Horowitz,

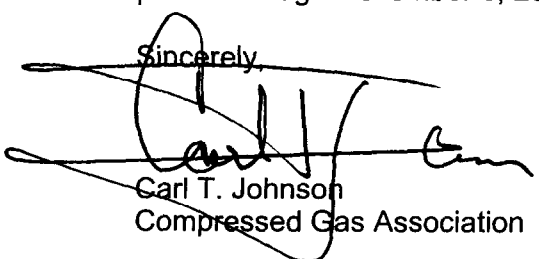
The Compressed Gas Association (CGA) respectfully requests an extension of 60 days, to November 3, 2003, for the comment period on the referenced draft guidance.

We greatly appreciated the opportunity to meet with you last week and the extremely productive discussion regarding several of our most pressing concerns about this draft Guidance. As a result of our discussion we were greatly reassured in a number of areas, but as stated in our July 21 letter and at the July 31 meeting, there are still many elements of this draft Guidance on which we intend to comment. These elements appear to relate to new and potentially burdensome compliance obligations for industry as well as several of the larger policy issues regarding the appropriate scope of GMP regulation of our industry.

Although we appreciate that 120 days were provided for comment, because of the large number of questions generated from our members and the need for us to have received the responses you provided at our meeting, as well as the difficulty of obtaining necessary clearance from our membership over the summer months, we are requesting the 60 day extension. We wish to assure you that we are working diligently with our membership as well as with our regulatory counsel and believe that we will provide meaningful and comprehensive comments to the Guidance and also address the specific points that were raised at our meeting.

We believe that by allowing this comprehensive review of the document by industry and with proper consideration of the CGA comments, preparation and implementation of a final Guidance will in fact be expedited. Accordingly, CGA respectfully requests an extension of the comment period through November 3, 2003.

Sincerely,


Carl T. Johnson
Compressed Gas Association

2003D-0165

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cc: Dockets Management Branch
Peter O. Safir, Covington & Burling