



**AIR LIQUIDE**

Via FedEx

October 22, 2004

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

Re: **Docket No. 2004D-0443: Draft Guidance for Industry on Quality Systems Approach to Pharmaceutical Current Good Manufacturing Practice Regulations, Availability**

Dear Sir or Madam:

Air Liquide America respectfully requests a ninety-day (90-day) extension to the comment period stated in the Notice of Availability for comment on the referenced draft guidance, appearing in the Federal Register on October 4, 2004 at page 59256.

An extension to March 3, 2005, will provide Air Liquide America the time necessary to discuss the Draft Guidance within our company which has an international basis. We would also request an extension to allow us time to discuss the impact of the Draft Guidance within our industry association, and with affiliated health care delivery and industry professional associations.

Air Liquide America is one of the largest manufacturers and distributors of medical gas in the USA. A significant percentage of our customers are hospitals, home health care companies, and medical supply companies. An important aspect we wish to explore in depth is the potential impact of the Draft Guidance on the manufacture and/or distribution of medical gases to these customers.

We appreciate your consideration of this request for extension to the comment period deadline.

Sincerely,

Harold Jones  
Director FDA-CGA Relations

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