

November 19, 2004

2004D-0443 - 11/19/04

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**RE: Docket No. 2004D-0443: Draft Guidance for Industry on Quality Systems Approach to Pharmaceutical Current Good Manufacturing Practice Regulations, Availability**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

Linde Gas LLC is a leading manufacturer and supplier of Medical, Industrial and Specialty Gases. Linde Gas LLC is located in over 50 countries with the Corporate Headquarters for the United States regional office located in Cleveland, Ohio.

As a manufacturer and supplier of medical gases, the company has an interest in *the Draft Guidance for Industry on Quality Systems Approach to Pharmaceutical Current Good Manufacturing Practice Regulations* and respectfully requests a ninety-day (90-day) extension to the comment period stated in the Notice of Availability for comment on the referenced draft guidance, appearing in the Federal Register on October 4, 2004 at page 59256.

Specifically, Linde Gas LLC requests the agency to extend the comment period for Docket No. 2004D-0443 - "Draft Guidance for Industry on Quality Systems Approach to Pharmaceutical Current Good Manufacturing Practice Regulations" to March 3, 2005. This will permit Linde the time to perform a review of the document and prepare meaningful comments to the agency.

Linde Gas LLC, appreciates in advance the consideration of an extension to the comment period deadline on this proposed draft guidance. If you have any questions, please do not hesitate to contact me at 216-642-6790

Sincerely,



Michael Skrjanc  
Regional SEQ Manager  
Linde Gas LLC

**2004D-0443**

**EXT 5**