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Via UPS

October 12, 2004

Dockets Management Branch (HCFA-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Re:      **Docket No. 2004D- 0443: Draft Guidance for Industry on Quality Systems Approach to Pharmaceutical Current Good Manufacturing Practice Regulations, Availability**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 Products Healthcare respectfully requests a minimum of a ninety-day (90-day) extension to the comment period stated in the Notice of Availability for comment on the above referenced draft guidance, which appeared in the Federal Register on October 4, 2004 at page 59256. We are requesting that the agency extend the comment period for Docket No. 2004D-0443 – "Draft Guidance for Industry on Quality Systems Approach to Pharmaceutical Current Good Manufacturing Practice Regulations" until at least March 3, 2005. This extension would permit a more thorough and thoughtful review, which in turn would allow us to provide commentary that is more meaningful

Air Products Healthcare, a wholly owned subsidiary of Air Products and Chemicals, Inc., provides comprehensive home healthcare services, including respiratory care services, home medical equipment, home infusion services and rehabilitative and assistive technology services to well over 100,000 Medicare and other government and private payor's beneficiaries. Our locations cover primarily the New England, Northeast, Mid-Atlantic and Atlanta regions in more than thirteen states. In addition, several of our locations provide medical gases, primarily oxygen (classified as a pharmaceutical subject to 21 CFR Parts 210 and 211 requirements and impacted by the provision of this draft guidance), to respiratory care patients at their residences. Air Products Healthcare will limit its comments to those issues affecting the manufacture and/or distribution of medical gases provided to patients at their residences.

We appreciate in advance the consideration of an extension to the comment period deadline on this proposed draft guidance.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 1-888-243-3456, ext. 10226.

Sincerely,

Bob Cucuel  
President and Chief Executive Officer  
Air Products Healthcare

CC:      Nitin Patel, Chief Procurement and Client Services Officer, APH  
Mindy Eberhart, Vice President of Regulatory & Clinical Affairs, APH  
Stephen S. Ferrara, Esquire – Law Department, Air Products

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