AIR PRODUCTS

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Via FedEx

October 6th, 2003

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

Re: **Docket No. 00N-1484**
Safety Reporting Requirements for Human Drug and Biological Products

Dear Sir or Madam:

Air Products Healthcare provides the following comments related to the proposed rule, "Safety Reporting Requirements for Human Drug and Biological Products," Docket No. 00N-1484, appearing in the Federal Register on March 14, 2003, pages 12406 through 12497.

Air Products Healthcare, a wholly-owned subsidiary of Air Products, Inc., provides comprehensive home healthcare services, including respiratory care services, home medical equipment, rehabilitation and assistive technology, and infusion therapy services to over 100,000 Medicare and other government and private payors' beneficiaries. Our 50 locations covering primarily the New England, Northeast and Mid-Atlantic regions, provide medical gases to respiratory patients at their residences. We, therefore, limit our comments to the impact this rule has on our manufacturing of medical gases classified as drugs, Oxygen, USP, and specifically to the changes proposed to 21 CFR §310.305.

Every day, we supply medical oxygen to thousands of patients in the home setting. Annually, several thousand patient deaths occur as the result of their primary disease process. As discussed in this letter, if the rule remains as proposed, home care medical gas manufacturers, such as Air Products Healthcare, may be required to generate a report on each one of those deaths. This would result in an insurmountable negative financial impact for medical gas manufacturers. Including medical oxygen in this ruling would be of no benefit to the medical community and home medical oxygen users.

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Accredited by JCAHO

We believe that including medical oxygen in the proposed rule would not fulfill the intended safety rule objective of reporting noxious and unintended responses to drug therapy. From our review of the studies cited in the Federal Register notice (pages 12470 through 12471, and others within the document), medical gas manufacturers were not included in the primary financial data estimates provided. Ensuring that medical gas manufacturers are exempt from certain aspects of this ruling is paramount to our industry. As stated previously, this rule, as proposed, would potentially create a financial burden and hardship.

While we understand and applaud the need for global harmonization, and we are convinced that incorporating the recommendations detailed in this letter into the proposed changes to 21 CFR 310.305 will enhance the quality and effectiveness of the submissions and analyses of these safety reports, thereby improving patient safety.

We propose that the agency:

1. Exempt from the clarification of the definition of a SADR, situations where medical oxygen is "unlikely related" to that SADR or SAR.

   On page 12417 of the Federal Register Notice, guidance is provided on the definition of a SADR. We feel that including those incidents where the "relationship cannot be ruled out" may cause extensive reporting when persons do not have a SADR that is "caused" by medical oxygen. Patients prescribed supplemental medical oxygen have some type of significant disease process or abnormality. Medical oxygen is typically and extensively used as an adjunct to the primary prescribed drug therapy.

   Including supplemental oxygen therapy in the agency's required SADR reporting would be non-productive and would create an extraordinary amount of documentation with no benefit. In addition, if a patient expires or experiences a medical deterioration requiring medical intervention from his or her underlying disease process (while using medical oxygen), this would result in increased and unnecessary submissions of complex reports.

2. Exempt medical oxygen from the expedited report (15-day alert) requirement specified in the proposed rule, if the agency does not agree with modifying its guidance toward "unlikely related" incidents in number one above.

   We request that the agency exempt medical oxygen from the 15-day alert requirement where incidents of acute respiratory failure have occurred, as well as the other listed conditions. This request would only be required if the agency does not agree with modifying its guidance regarding "unlikely related" incidents, as we described in item #1 above.

For example, if a patient would experience acute respiratory failure while using medical oxygen, this occurrence would result in the need for our company to perform Expedited Reporting (15-day alert). As the guidance currently states that the "relationship cannot be ruled out," we (as the medical oxygen filler) may need to complete the 15-day expedited report. Although a SADR associated with "acute respiratory failure" may be the most obvious example, most conditions listed in the Federal Register notice would also include the adjunct use of medical oxygen. This means that all SADRs could thousands of unnecessary expedited reports associated with the use of medical oxygen.

This ruling would make compliance with the timeframe of fifteen days extremely difficult, if not impossible. As a medical gas manufacturer/filler, we would need to have access to each patient's medical records from applicable healthcare facilities, the patient's physician and/or other entities (healthcare provider, coroner, etc.). Access to the records would not be permitted without appropriate written consent from the patient or his/her power of attorney.

3. Expand the definition of a "contact person" to include other medical healthcare professionals besides physicians, allowing these individuals to be responsible for the content of post-marketing safety reports submitted to the FDA.

   We, like other medical gas manufacturers/fillers, do not typically have licensed physicians on staff or on contract. We do have healthcare professionals, such as nurses, respiratory care practitioners, etc. available on staff or via contract. The process of manufacturing and distributing medical oxygen does not require the oversight of a physician.

   We propose that the agency permit a company representative (healthcare professional) to be responsible for the content of post-marketing safety reports submitted to the FDA. To require firms like ours to hire physicians for the sole purpose of meeting the requirements of this proposed rule, if it is even possible to locate a physician willing to accept such a position, would cause undue financial hardship, with no increased patient safety achieved.

4. Exempt DMEPOS companies like Air Products Healthcare, who fill medical oxygen containers, from using MedDRA to code safety reports even when medical oxygen usage may be indicated as a SADR or SAR.

   We propose that the agency exempt all home healthcare providers who fill medical oxygen containers from the use of MedDRA. In the unlikely event that medical oxygen is determined to be the cause of a SADR or SAR, the use of MedDRA in our industry would not be economically feasible.

The financial impact would be significant if our exemption requests are not granted. Contrary to the overall goal of trying to stem the increased cost of healthcare in the United States, this rule will significantly add to the cost for manufacturing and distributing Oxygen, USP. Users of medical oxygen, such as healthcare institutions and patients, would receive little or no benefit from the unnecessary reporting.

Our review of the studies cited in the Federal Register notice reveals that medical gas fillers, especially those manufacturing medical oxygen used to treat patients in their residences, were not included in the primary data estimates provided in this document. We do not believe that the agency intended to include our industry, as the rule does not address the uniqueness of our operations.

We have documented our issues in the above response with the understanding that the agency's intention was to not include medical gas manufacturers. Ensuring that medical gas manufacturers, such as Air Products Healthcare, are not included in this ruling is extremely important.

If the agency does not concur with our reasoning presented, which requests exemption from certain cited sections of the proposed rule, we strongly urge the agency to meet with the American Association for Homecare prior to issuing a final rule. The purpose of the meeting would be to discuss the impact of this regulation upon our industry, and to further discuss the minimal potential health benefit to the patient, if any, that this proposed regulation would have on the safe administration of medical gases.

We appreciate the opportunity to comment on this proposed rule. If there are any questions regarding the request for exemption, please do not hesitate to contact me at 1-888-243-3456, ext. 226.

Thank you for your consideration.

Sincerely,

Bob Cucuel
President and Chief Executive Officer
Air Products Healthcare

Cc: Nitin Patel, Chief Procurement and Client Services Officer
Mindy Eberhart, Corporate Director of Regulatory & Clinical Affairs
Stephen S. Ferrara, Esquire – Law Department, Air Products
Debbie Thomas, Director of Regulatory Compliance and Quality, Air Products and Chemicals, Inc.