AIR PRODUCTS

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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Dear Sir:

RE: Draft Guidance for Industry on the Current Good Manufacturing Practices (cGMP) for Medical Gases - Docket No. 2003D-0165

Air Products and Chemicals, Inc. is a leading international supplier of medical and industrial gases and related equipment and selected chemicals. Our company has annual revenues in excess of $5 billion, operations in over 30 countries, and 17,000 employees. Corporate headquarters are near Allentown, Pennsylvania.

We have an interest in Docket No. 2003D-0165, Draft Guidance for Industry on the Current Good Manufacturing Practices for Medical Gases, and we are, therefore, providing our comments to this Draft Guidance. Air Products is one of the largest manufacturers of medical gases in North America.

Air Products supports the intent of the proposed regulation to provide recommendations on how to comply with cGMPs for manufacturing, filling, transfilling, cascading, and transferring compressed and cryogenic medical gases. Although we believe the U.S. Federal FDA will be receiving comments from the Compressed Gas Association, Air Products would like to submit a small number of written comments on the Draft Guidance recommendations.

Quality Control Unit (QCU) Independent of Production Process
Draft Guidance Line #: 113 - 122

The medical gas industry employs cross utilization of personnel in quality control and production processes. These individuals receive cGMP training specific to their job functions that emphasizes the need to comply with FDA regulations and the manufacture of a product that is protective of human health as their first responsibility. Air Products has also developed specific Quality Procedures that ensure that controls are in place that prevent cross contamination of the product in the manufacturing process. QCU personnel receive training in these procedures and are responsible for adherence to them. Air Products recommends that industry be permitted to continue the cross utilization of personnel and that it not be required to maintain a QCU that is independent of the production process.

Calculation of Yield
Draft Guidance Line #: 627 – 638

Due to the uniqueness of our product, it would be very difficult to perform yield reconciliation. There are significant amounts of product loss through venting, purging and evaporation. There does not appear to be any benefit to the performance of any type of product yield reconciliation. Based upon Air Products' operating experience it is recommended that medical gases be exempted from calculation of yield. It is not practical to develop procedures that address normal storage and operating losses of medical gases. The amount of losses will vary greatly from manufacturing facility to manufacturing facility depending on the type of equipment used in the manufacturing process. The losses can even vary considerably within the same facility due to changes in production demands.

Expiration Dating
Draft Guidance Line #: 778 – 786

Air Products believes that medical gases should be exempted from expiration dating. Based upon Air Products' participation in the original industry-wide stability testing, which was also submitted to the FDA, and its own manufacturing experience, we have determined that these types of gases (medical oxygen and medical nitrogen) do not degrade. In addition, since medical gases are contained in a pressure vessel and are not exposed to ambient conditions, other than temperature, they can not degrade chemically or allow the introduction of contaminants to come in contact with the gas. If FDA does not agree to this exemption, we request that consideration be given to a resubmission/update of the previous stability testing.

Stability Testing
Draft Guidance Line #: 1134 – 1154

In the event that the exemption from expiration dating is granted, there would be no need for stability testing to support an expiration date. Consequently, Air Products believes that medical gases should also be exempted form stability testing.

Air Products appreciates the efforts of the U.S. Federal FDA in issuing this Draft Guidance. We respectfully request the Agency's consideration of our comments.

Deborah M. Thomas
Director, Quality and Regulatory Compliance