

Food and Drug Administration  
Baltimore District Office  
900 Madison Avenue  
Baltimore, MD 21201-2199  
Telephone: (410) 962-3461 x122  
FAX: (410) 962-2219

July 22, 1998

**WARNING LETTER**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Mr. Michael E. DeDomenico  
President and Chief Executive Officer  
Praxair Distribution, Inc.  
39 Old Ridgebury Road  
Danbury, Connecticut 06810-5113

Dear Mr. DeDomenico:

A Food and Drug Administration (FDA) inspection was conducted from June 9 through 29, 1998 at your Baltimore, Maryland medical gas manufacturing facility. Medical gases are drug products as defined by Section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act).

During our inspection, deviations from the Current Good Manufacturing Practice (GMP) requirements (Title 21, Code of Federal Regulations (CFR), Part 211) were observed. These deviations cause your medical gases to be adulterated within the meaning of Section 501(a)(2)(B) of the Act, in that the methods used in, or the facilities or controls used for, manufacturing, processing, packing, storage, or holding, are not in conformance with GMP regulations.

The deviations included the following:

- Failure to establish and to document the accuracy, sensitivity, specificity, and reproducibility of test methods employed by the firm.
- Failure to follow and to document written production and process control procedures or to record and justify any deviations.
- Failure to have equipment used in the manufacture, processing, packing, or holding of the product of the appropriate design, of adequate size, and suitably located to facilitate operations.
- Failure to test each component for conformity with all appropriate specifications for purity, strength, and quality, or to have adequate reports of analysis from the suppliers of the components.
- Failure to define separate areas or other control systems as necessary to prevent mixups during storage of cylinders at various stages of processing.

- Failure to establish and to follow a written procedure by which the distribution of each lot of product can be readily determined to facilitate its recall if necessary.
- Failure to follow a written procedure whereby the oldest approved stock is distributed first.

At the conclusion of the inspection, Mr. Charles Hayes, Plant Manager, was given a written list of inspectional observations (FDA-483) which was discussed with him. On July 13, 1998, a completed FDA-483 was given to Ms. Elena Rountree, Assistant Operations/Facilities Manager. A copy was sent to you on July 20, 1998.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to all requirements of the Act and regulations at the Baltimore facility and at all facilities operated by your firm. The specific violations noted in this letter and in the FDA-483 issued at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If you determine the causes to be systems problems, you must promptly initiate permanent corrective action.

Federal agencies are advised of the issuance of all Warning Letters concerning drug products so that they may take this information into account when awarding contracts. By copy of this letter, we are advising the Health Care Financing Administration (HCFA) that our inspection revealed significant deviations from the Act. They may elect to defer or discontinue payment for any health care product in violation of state or federal law.

You should take prompt action to correct these deviations. Failure to do so may result in regulatory action without further notice. These actions include, but are not limited to, seizure and/or injunction.

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to the Food and Drug Administration, Baltimore District, 900 Madison Avenue, Baltimore, Maryland 21201, to the attention of Thomas C. Knott, Compliance Officer. Mr. Knott can be reached at (410) 962-3461, extension 122.

Sincerely,



William M. Ment  
Acting Director, Baltimore District

Mr. Timothy Sear

Page 3

August 11, 1998

Your reply should be sent to the Food and Drug Administration, Richmond Resident Post, 10710 Midlothian Turnpike, Suite 424, Richmond, Virginia 23235, to the attention of Scott J. MacIntire, Compliance Officer. Mr. MacIntire can be reached at (804) 379-1627, extension 14.

Sincerely,

A handwritten signature in black ink, appearing to read "Elaine Knowles Cole". The signature is fluid and cursive, with a large initial "E" and "K".

Elaine Knowles Cole  
Director, Baltimore District

Enclosure