



2/10/98 RPB

CERTIFIED/RETURN RECEIPT REQUESTED

February 9, 1998

Food and Drug Administration
Kansas City District Office
11630 West 80th Street
P.O. Box 15905
Lenexa, Kansas 66285-5905

Telephone: (913) 752-2100

WARNING LETTER

William Lichtenberger
Chief Executive Officer
Praxair, Inc.
39 Old Ridgebury Road
Danbury, CT 06810

Ref.# - KAN-98-009

Dear Mr. Lichtenberger:

During an inspection of your Praxair medical gas manufacturing facility, located at 6701 St. John Avenue, Kansas City, Missouri, conducted on January 12 through 16, 1998, Food and Drug Administration Investigators from this office documented deviations from the Current Good Manufacturing Practice (CGMP) Regulations (Title 21, Code of Federal Regulations, Part 211). These deviations cause your firm's Oxygen USP and Nitrogen NF to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (Act).

Significant CGMP deviations include, but are not limited to the following:

Failure to provide documentation for the computer system used to control the production and release of Oxygen USP and Nitrogen NF, to show it has been validated on site [21 CFR 211.68].

Failure to establish that the test procedures used to determine the strength and identity of Oxygen USP and Nitrogen NF will provide test results that are equivalent or superior to the official test procedure [21 CFR 211.165(e)].

You are using the Servomex Xentra 4100 Analyzer for Oxygen USP, and the Teledyne 316RAX Trace Oxygen Analyzer for Nitrogen NF, both of which are unrecognized non-USP/NF testing methodologies.

Failure to provide adequate documentation that the Oxygen being used as a calibration gas is a certified standard [21 CFR 211.160(b)(4)].

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At the conclusion of the inspection Form FDA 483, Inspectional Observations, was prepared, issued to and discussed with Mr. Gaylen W. Fridell, Production Team Leader. A copy of this form is included for your information.

The above identified deviations is not intended to be an all-inclusive list of deficiencies at the Kansas City, Missouri facility. It is your responsibility to ensure that all of your facilities adhere to each requirement of the Act and regulations. Federal agencies are advised of the issuance of all Warning Letters about drugs so that they may take this information into account when considering the award of contracts. You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Such actions may include seizure and/or injunction.

You should notify this office in writing within fifteen (15) working days of receipt of this letter of the specific steps that are being 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 Clarence R. Pendleton, Compliance Officer, at the above address.

Sincerely,



W. Michael Rogers
District Director
Kansas City District

Enclosure - Form FDA 483

cc: June A. Anderson, Plant Manager
Praxair, Inc.
6701 St. John Avenue
Kansas City, MO 64125