



PIRGED

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

cc: HFI-35/FOI Staff
DWA

January 30, 1997

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 97-31

William Lichtenberger
Chief Executive Officer
Praxair, Incorporated
30 Old Ridgebury Road
Danbury, Connecticut 06810

Dear Mr. Lichtenberger:

During our December 13, 1996, inspection of your medical gas manufacturing facility located in Bismarck, ND, the investigator documented serious violations of Good Manufacturing Practice Regulations for Finished Pharmaceuticals (GMPs). Medical oxygen is a drug within the meaning of Section 201(g)(1) of the Federal Food, Drug and Cosmetic Act (the Act). Drugs which are manufactured in a facility that is not in conformance with GMPs are adulterated within the meaning of Section 501(a)(2)(B) of the Act.

The violations observed during our inspection include but are not limited to the following:

1. Failure to adequately test for potency and identity of oxygen. The oxygen analyzer used in this facility was not calibrated according to the manufacturer's instructions or according to instructions in the firm's SOP. The results obtained with an improperly calibrated analyzer cannot be relied upon as accurate.

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2. Failure to establish a single Standard Operating Procedure (SOP) for the gas filling operation. The firm has two different SOPs and the filling operations observed were not performed in compliance with either SOP.
3. The Pumper's Log and Quality Control Log in use are not the same as the Pumper's Log and Quality Control Log in either of the two SOPs at the facility.
4. A single lot number was assigned to more than one manifold of medical oxygen filled into K cylinders. The same lot number was used for the entire day's production.
5. Each cryogenic vessel filled from the stand tank is not tested for purity and identity as required for these distinct lots.

The above list of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Good Manufacturing Practice 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. Additionally, pending Antibiotic Form 6, NDA, ANDA, or export approval requests may not be approved until the above violations are corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Such action includes seizure and/or injunction.

Please notify this office 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.

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Your reply should be sent to Compliance Officer Lawrence R. Murphy at the address indicated on the letterhead. Mr. Murphy may be reached at (612) 334-4100 ext. 158.

Sincerely yours,



John Feldman
Director
Minneapolis District

LRM
LRM/ccl

xc: Michael Dodd
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