



June 3, 1999

Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863

WARNING LETTER
CHI-23-99

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Francis M. Martin
Chief Executive Officer
Fox Med-Equip Services, Inc.
1831 Vandalia
Collinsville, Illinois 62234

Dear Mr. Martin:

An investigator from FDA's Springfield Resident Inspection Post, Roger J. Adams, conducted an inspection, on April 21, 1999, of your facility. The inspection determined that your firm manufactures liquid Oxygen, U.S.P., and distributes oxygen gas in high-pressure cylinders. These medical gas products are drugs as defined by Section 210(g) of the Federal Food, Drug, and Cosmetic Act (the Act). The inspection revealed that your high-pressure compressed oxygen is adulterated under the Act.

Your high-pressure oxygen in cylinders is adulterated under Section 501(a)(2)(B) of the Act in that the methods used in, or the facilities or controls used for their manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with the current Good Manufacturing Practice regulations (cGMPs) for drugs specified in Title 21, Code of Federal Regulations (CFR), Parts 210 & 211, as follows:

1. Failure to have supervisory review performed on all batch production control records.
2. Failure to complete all compressed oxygen processing records. For example:
 - on April 20, 1999, your firm filled [REDACTED] cylinders of compressed oxygen, lot 67-3, and did not document purity analytical results;
 - your firm filled compressed oxygen cylinders on January 15 & 20, 1999, and did not document [REDACTED] oxygen analyzer calibration; and
 - your firm does not document valve assembly checks and heat checks on batch production control records.

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These findings were discussed with you at the conclusion of the inspection when the FDA-483, List of Observations, was given to you by Mr. Adams.

The above identified violations are not intended to be an all inclusive listing of deficiencies at your firm. It is your responsibility to assure adherence with each requirement of the CGMP 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. These may include seizure and/or injunction.

We have enclosed a copy of a speech by our National Expert, Mr. Duane Sylvia, entitled "Fresh Air '98" – A Look at FDA's Medical Gas Requirements." This copy of the speech will assist you in understanding your responsibilities as a medical gas manufacturer.

If you wish to obtain a copy of the Act [DHHS Publication No. (FDA) 93-1051] or 21 CFR Parts 200-299 (SN 869-026-00071-9), you should contact the Superintendent of Documents, Attn: New Orders, P.O. Box 371954, Pittsburgh, PA 15250-7954. Charge orders can be telephoned to the GPO Order Desk at (202) 512-1800 from 8:00am to 4:00pm Eastern time, Monday through Friday, or FAX'd to (202) 512-2233. You can also obtain these publications in Chicago by calling the Government Bookstore at (312) 353-5133. The CFR is approximately \$9.00.

You should notify this office in writing within 15 working days of receipt of this letter regarding the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason(s) for the delay and the timeframe within which the corrections will be completed.

Your written response should be directed to the attention of Richard Harrison, Director, Compliance Branch.

Sincerely,

/s/

Raymond V. Mlecko
District Director