



August 5, 1998

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

WARNING LETTER
CHI-33-98

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Dale S. Strausshiem, President
Bromenn Healthcare
Virginia & Franklin Streets
Normal, IL 61761

Dear Mr. Strausshiem:

An inspection of your firm located at 1322 S. Main St., Normal, Illinois, was conducted by Investigator James L. Finn on July 27, 1998. The inspection determined that your firm manufactures Oxygen U.S.P. in a compressed gas form. This medical gas is a drug as defined by Section 201(g) of the Federal Food, Drug, and Cosmetic Act (Act). This inspection revealed your medical oxygen is adulterated under the Act.

Your medical oxygen is adulterated under Section 501(a)(2)(B) of the Act in that the methods used in, or the facilities or controls used for, its manufacturing, packing, holding, or shipping are not in conformance with the Current Good Manufacturing Practice Regulations (CGMPs) for drugs as specified in Title 21, Code of Federal Regulations, Parts 210 & 211, as follows:

1. You failed to assure proper assay of each filling sequence of medical oxygen for identity and strength prior to distribution.

Our investigator observed that on several occasions verification of proper assay was not recorded on your Batch Production Records. Examples include 6 – “E” cylinders filled 7/22/98, 6 – “D” cylinders filled 7/11/98, and 6 – “D” cylinders filled 7/7/98.

2. You failed to maintain documented evidence of proper calibration of your [REDACTED] Oxygen Analyzer used for required batch release testing.
3. You failed to properly calibrate measurement equipment including your pressure, temperature, and vacuum gauges.
4. You failed to perform any reconciliation of quantities of labels used on your product.
5. You failed to maintain records of effective employee training.

6. Your Batch Production Records are incomplete in that they fail to contain actual test results and have not been reviewed or approved by a responsible person.
7. You failed to establish complete written procedures for production and process controls covering all aspects of your firm's operations designed to assure your medical oxygen has the identity, strength, quality, and purity it purports, or is represented, to possess.

These findings were discussed with Hans C. Peterson, Medical Equipment Coordinator, at the conclusion of the inspection. A copy of the form FDA-483, Inspectional Observations, issued to Mr. Peterson is enclosed. The above does not represent an all-inclusive listing of the deficiencies noted during the inspection of your firm. It is your responsibility to assure adherence with each requirement of the Current Good Manufacturing Practice regulations and to assure that your products are correctly labeled. Federal agencies are advised of the issuance of all warning letters concerning drugs and devices 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 include seizure and/or injunction. **This is your official notification that we expect all of your facilities to be in compliance.**

We have enclosed the latest copy of a speech by our National Expert, Mr. Duane Sylvia, entitled "Fresh Air '98' - A Look at FDA's Medical Gas Requirements." This 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 to 299 (SN 869-026-00071-9), you should contact the Superintendent of Documents, Attention: New Orders, P.O. Box 371954, Pittsburgh, PA 15250-7954. Charge orders may be telephoned to the GPO Order Desk at (202) 512-1800 from 8:00 a.m. to 4:00 p.m. Eastern Time, Monday through Friday, or faxed to (202) 512-2233. You can also obtain these publications in Chicago by calling the Government Bookstore at (312) 353-5133. The Act is approximately \$10 and the CFR is approximately \$7.

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 for the delay and the time within which the corrections will be completed.

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Your written response should be directed to the attention of George F. Bailey, Compliance Officer, Food & Drug Administration, 300 South Riverside Plaza, Suite 550 South, Chicago, Illinois 60606.

Sincerely,

/s/

Raymond V. Mlecko
District Director

cc: Catherine M. Rousey, Service Leader
Bromenn Medical Supply & Equipment
1322 S. Main Street
Normal, IL 61761