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DEPARTMENT OF HEALTH & HUMAN SERVICES

**Public Health Service
Food and Drug Administration**

Refer to: CFN 1123941

Baltimore District
900 Madison Avenue
Baltimore, Maryland 21201
Telephone: (410) 962-4017

December 4, 1996

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Charles E. Bradford, Jr.
Roberts Oxygen
1601 Caton Avenue
Baltimore, Maryland 21227

Dear Mr. Bradford:

During an inspection of your facility, conducted by the Food and Drug Administration from November 13 to November 15, 1996, deviations from the Current Good Manufacturing Practice Regulations (Title 21, Code of Federal Regulations, Parts 210 & 211) were observed in your firm's oxygen repacking operation. These deviations cause your Oxygen, USP products to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act). The deviations are as follows:

1. Failure to perform adequate testing to ensure Oxygen, USP, conforms to specifications, including the identity and strength, prior to release, in that the oxygen analyzer was not properly calibrated. [211.165(a)]
2. Failure to calibrate the oxygen analyzer used for the assay of Oxygen, USP; for example, your firm did not use either high purity oxygen or nitrogen, as recommended in the manufacturer's instructions; the certificate of analysis for the argon/oxygen mixture used did not list the amount of oxygen; the employee performing calibration was not knowledgeable about the operation of the equipment; and your firm did not have a certificate of analysis for the nitrogen used in calibration. [21 CFR 211.160(b)(4)]
3. Failure to perform prefill operations on each high-pressure cylinder, prior to filling. [21 CFR 211.84(d)(3)]

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4. Failure to document that employees have the education, experience, and/or training to enable the employees to perform their assigned functions. [21 CFR 211.25]
5. Failure to identify drug products with lot numbers that permit control of the batch; for example, your firm failed to assign a new lot number to each manifold-filling sequence of high-pressure tanks, and failed to assign a new lot number to each cryogenic vessel filled. [21 CFR 211.130(c)]

In addition, your oxygen in cryogenic vessels is misbranded within the meaning of Section 503(b)(4) of the Act, in that the vessels do not carry a prescription legend.

The above violations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with 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.

By copy of this letter, we are advising the Health Care Financing Administration that our inspection of your firm 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 deficiencies. Failure to do so may result in regulatory action without further notice. Possible actions include seizure and/or injunction.

You should 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. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which corrections will be completed.

Your reply should be directed to the Food and Drug Administration, Baltimore District Office, 900 Madison Avenue, Baltimore, Maryland 21201, Attention: Jennifer A. Thomas, Compliance Officer.

Sincerely,


William M. Ment
Acting District Director