

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

D1272 B

Refer to: CFN 1123186

Baltimore District
900 Madison Avenue
Baltimore, Maryland 21201
Telephone: (410) 962-4040

March 19, 1997

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. David A. Schuette, President
Regal Medical Services, Ltd.
P.O. Box 1134
Bedford, Virginia 24523

Dear Mr. Schuette:

The Food and Drug Administration (FDA) conducted an inspection of your Bedford, Virginia facility on March 11, 1997. During the inspection, deviations from the Current Good Manufacturing Practice (GMP) Regulations (Title 21, Code of Federal Regulations (CFR), Parts 210 & 211) were observed. These deviations cause your Oxygen, U.S.P. to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act). The deviations included the following:

1. Failure to adequately calibrate the oxygen analyzer. Your firm failed to document the calibration of the analyzer on the low end of the scale. [21 CFR 211.160(b)(4)]
2. Failure to assure that each person engaged in the transfilling of compressed medical oxygen has the education, training, or experience to enable that person to perform the assigned function. [21 CFR 211.25]
3. Failure to establish written procedures designed to assure the identification of the drug product with a lot or control number that permits determination of the history of the manufacture and control of the batch. Your cylinders fail to have an assigned lot number for each manifold filling sequence. [21 CFR 211.130(c)]
4. Failure to establish adequate written procedures for the production and process controls covering calibration of the oxygen analyzer; the training of your employees; pre-fill, fill, and post-fill operations; and labeling control, designed to assure that the drug product has the identity, strength, quality, and purity it purports or is represented to possess. [21 CFR 211.100(a)]

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5. Failure to perform adequate pre-fill and filling operations on each high-pressure cylinder filled. Your firm failed to perform hydrostatic testing date inspection, heat, temperature, and pressure tests on each cylinder filled. [21 CFR 211.84(d)(3)]
6. Failure to establish adequate batch production and control records for each batch of Oxygen, U.S.P., including documentation that each significant step in the manufacture, processing, packing, or holding of the batch was accomplished at the time of performance. Your firm's batch production records for the filling of high-pressure cylinders lacked the required pre-fill, fill, and post-fill operations performed on each cylinder filled. Additionally, batch records failed to document that they were checked by a person directly supervising each significant step in the operation. [21 CFR 211.188(b)]
7. Failure to establish written procedures describing the handling of all written and oral complaints regarding Oxygen, U.S.P. [21 CFR 211.198(a)]

The above listed violations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that your establishment is in compliance with all requirements of the federal regulations. Federal agencies are advised of the issuance of all Warning Letters about drugs and devices 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 (HCFA) that our inspection 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 deviations. Failure to do so may result in regulatory action without further notice, such as seizure and/or injunction. Enclosed is a compressed medical gases guideline which discusses the applicability of the Current Good Manufacturing Practice Regulations to medical gas manufacturers.

You should notify this office in writing, within 15 working days of receipt of this letter, of specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 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 the Food and Drug Administration, Richmond Resident Post, 10710 Midlothian Turnpike, Suite 424, Richmond, Virginia 23235, to the attention of Scott J. MacIntire, Compliance Officer.

Sincerely,



Douglas I. Ellsworth

Acting Director, Baltimore District

Enclosure

bec: EI file, HFR-MA1, HFR-MA200, HFR-MA240 (Simmons), HFR-MA250, HFA-224,
HFC-210, HFI-35 (purged), HFC-240, HFD-300, HFR-MA2545, HFR-MA2550,
HFR-MA295, SJM

Mr. Dennis Carroll
Associate Regional Administrator
HCEA
Room 3100
3535 Market Street
Philadelphia, PA 19101 (purged)

Virginia Board of Pharmacy
6006 West Broad Street
Richmond, VA 23230-1717 (purged)

Tracking #: 97-BLET-23