



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
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October 23, 2000

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA-01-01

Gregory H. Walmsley, President
Oxarc Incorporated
4003 E. Broadway
Spokane, Washington 99202

WARNING LETTER

Dear Mr. Walmsley:

A Food and Drug Administration (FDA) inspection was conducted on August 17, 2000, at your medical oxygen gas manufacturing and liquid oxygen repacking facility located at 291 Ohme Gardens Road, Wenatchee, Washington. Medical gases are drug products as defined by Section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act).

During our inspection, deviations from the Current Good Manufacturing Practice (GMP) requirements (Title 21, Code of Federal Regulations (CFR), Part 211) were observed. These deviations cause your medical gases to be adulterated within the meaning of Section 501(a)(2)(B) of the Act, in that the methods used in, or the facilities or controls used for, their manufacturing, processing, packing, storage, or holding, are not in conformance with the GMP regulations.

The deviations included the following:

- Failure to test five batches of medical oxygen gas packed in high pressure metal cylinders for identify and purity. These batches were identified as #0021-1; #0021-2; and #0021-3, manufactured on 1/21/00; #5101808 manufactured on 6/28/00; and #5102005 manufactured on 7/18/00. These batches were released for distribution after the fill logs with the discrepancies were reviewed.
- Failure to perform and/or document the fill pressure and temperature, and post fill leak test by the quality control unit. For example, discrepancies in the fill log for medical oxygen gas packed in high pressure cylinders were detected. These included not recording the fill pressure for batch #5102145 manufactured on 8/1/00, and not recording the fill pressure and temperature as well as not performing the post fill leak test for batch #5102231 manufactured on 8/10/00.
- Failure to follow own written procedures for the label inventory log and storage of industrial gas labels. Also, pressure and vacuum gauges were calibrated 5/19/99 and 4/11/00, whereas written procedures require calibration every six months.

Mr. Gregory H. Walmsley, President
Oxarc Incorporated, Spokane, Washington
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- Failure to provide ongoing training of your employees in GMPs as evidenced by the deficiencies found during the inspection such as completing production records, reviewing records for discrepancies, and taking appropriate action when discrepancies are found. Also, an unauthorized employee was acting as a "reviewer" and signing the fill log for approximately a five month period.
- Failure to perform the calibration of thermometers used during gas filling operations.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to all requirements of the Act and regulations at your facility. The specific violations noted in this letter and in the FDA-483 issued at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If you determine the causes to be systems problems, you must promptly initiate permanent corrective action.

Federal agencies are advised of the issuance of all Warning Letters concerning drug products so that they may take this information into account when awarding 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. These actions, include, but are not limited to, seizure and/or injunction.

Please 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 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.

Your reply should be sent to the Food and Drug Administration, Seattle District Office, 22201 23rd Drive SE, Bothell, Washington, 98021-4421, to the attention of Lisa M. Elrand, Compliance Officer. Ms. Elrand can be reached at (425) 483-4913.

Sincerely,



Charles M. Breen
Director, Seattle District

Enclosure:
FDA 483