



g1075d

Food and Drug Administration
Denver District Office
Bldg. 20-Denver Federal Center
P.O. Box 25087
6th Avenue & Kipling Street
Denver, Colorado 80225-0087
Telephone: 303-236-3000
FAX: 303-236-3100

PURGED

March 1, 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ms. Sharron K. West
President/Owner
Mountain West Medical, Inc.
120 S. State St., Suite B
Clearfield, UT 84015

Ref. # DEN- 01-23

Dear Ms. West:

During an inspection of your firm, Mountain West Medical, Inc., 280 S. State St., Unit 7018, Clearfield, UT, on February 9&12, 2001, Consumer Safety Officer Ricki A. Chase-Off determined that your firm distributes Oxygen U.S.P. for medical purposes. Medical Oxygen is a drug product as defined by section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above stated inspection revealed that your compressed medical oxygen is adulterated under section 501(a)(2)(B) of the Act in that the controls used for the manufacturing, processing, packing, or holding of this product are not in conformance with current good manufacturing practice regulations (GMPs) under Title 21, Code of Federal Regulations, parts 210 and 211 (21 CFR 210 and 211). Deviations noted during the inspection include, but are not limited to the following:

1. Failure to properly calibrate the [XXXXXXXXX] used for the assay of Oxygen, U.S.P., in that your firm is not using a documented certified standard of Oxygen as required by 21 CFR 211.160(b)(4).
2. Failure to establish complete written procedures designed to assure that correct labels and labeling are used, as required by 21 CFR 211.130. For example, your written procedure for labeling does not identify or contain examples of the current and approved labels. Additionally, three cylinders, ready for distribution, were noted with improper labeling including one that was illegible; one that lacked a lot number; and one that had multiple lot number stickers applied.

PURGED

3. Failure to document the periodic calibration of instruments, apparatus and gauges as required by 21 CFR 211.194(d). Specifically, there is no documentation of the periodic calibration of thermometers, pressure gauges and vacuum gauges.
4. Failure to document the review of daily fill records and analytical results to assure that product is approved by the firm's quality control unit prior to distribution as required by 21 CFR 211.192. Specifically, Oxygen Transfilling Logs may not be reviewed for up to two days after filled cylinders are transferred to the delivery vehicle for distribution.
5. Failure to have written quarantine procedures for drug products pending release by the quality control unit, as required by 21 CFR 211.142(a).
6. Failure to assure that each person engaged in the packing or holding of a drug product has the training and experience to enable that person to perform the assigned functions, as required by 21 CFR 211.25(a).

The above violations are not intended to be an all inclusive list of deficiencies at your facility. At the conclusion of the inspection, Investigator Chase-Off advised you of additional deficiencies on the form FD-483, List of Observations.

By copy of this letter, we are advising the Health Care Financing Administration (HCFA) that our inspection of your firm revealed significant deviations from the Food, Drug and Cosmetic 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 promptly correct these deviations may result in regulatory action, including seizure or injunction, without further notice. Federal agencies are advised of the issuance of all warning letters so that they may take this information into account when considering the award of contracts.

Please advise this office in writing, within fifteen (15) working days after receipt of this letter, of the specific actions you have taken to correct the violations. Your response should include: (1) each step that has or will be taken to completely correct the current violations and prevent the recurrence of similar violations; (2) the time when correction will be completed; (3) any reason why the corrective action is not completed within the response time and (4) any documentation necessary to indicate correction has been achieved. Your response should be directed to H. Tom Warwick, Compliance Officer, at the above address.

Sincerely,



Thomas A. Allison
District Director