



DEPARTMENT OF HEALTH AND HUMAN SERVICE

Southwest Region

Food and Drug Administration  
Denver District Office  
Bldg. 20-Denver Federal Center  
P O. Box 25087  
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Denver, Colorado 80225-0087  
Telephone: 303-236-3000  
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August 28, 2000

**WARNING LETTER**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Ms. M. Francis Sponer, C.E.O.  
Southwest Utah Home Health Agency  
dba Ascentra Home Medical Equipment  
2251 South Jones Boulevard  
Las Vegas, Nevada 89146

Ref. # - DEN-00-36

Dear Ms. Sponer:

During an inspection of your firm, Southwest Utah Home Health Agency, dba Ascentra Home Medical Equipment, Utah Division, 1825 N. Main Street, #4, Spanish Fork, Utah on July 5, 2000, Consumer Safety Officers Ricki A. Chase-Off and Shelley H. Roberts determined that your firm transfills Medical Oxygen U.S.P. to patient home units. 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 product, Medical Oxygen, U.S.P., is adulterated under Section 502(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 (21 CFR), parts 210 and 211. Deviations noted during the inspection included, but were not limited to the following:

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1. Failure of each person engaged in the manufacturing, processing, packing, or holding of a drug product to have the education, training, or experience, or any combination thereof, to enable that person to perform the assigned functions, as required by 21 CFR 211.25(a). For example, personnel at your facility are not trained adequately in GMPs because they do not know how to perform all required pre-fill, fill, and post-fill tests; and they do not know that complete labels with your firm's name and address, and identity of gas are required on filled cylinders.
2. Failure to have a quality control unit that shall have the responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, labeling, and drug products, and the authority to review production records to assure that no errors have occurred, as required by 21 CFR 211.22(a). While we recognize that your facility is not a large operation, quality control functions must be performed by a designated, trained individual to assure that the drug product repacked at your facility is properly manufactured and labeled.
3. Failure to exercise strict control over labeling issued for use in drug product operations, as required by 21 CFR 211.125(a), failure to establish written procedures for the control of labeling, as required by 21 CFR 211.125(f), and failure to include a specimen of labels used in the batch record, as required by 21 CFR 211.188(b)(8). For example, your firm has six filled, ready to distribute oxygen containers which have either torn/illegible labels, two labels, or partial or torn labels, many of which do not bear the name and address of your firm. This was not corrected during our inspection.
4. Failure to establish adequate written procedures for production and process control to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess, as require by 21 CFR 211.100(a). For example, your written procedures for repacking oxygen do not include all required pre-fill, fill, and post-fill tests.
5. Failure to establish master production and control records to assure uniformity from batch to batch, as required by 21 CFR 211.186. Among other requirements, the master production and control record must contain label specimens [21 CFR 211.186(b)(8)] and complete manufacturing and control instructions, sampling and testing procedures, specifications, special notations, and precautions to be followed [21 CFR 211.186(b)(9)].

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6. Failure to establish written procedures with correct directions for the calibration of instruments, as required by 21 CFR 211.160(b)(4). For example, the standard operating procedure for the calibration of your Servomex 570A oxygen analyzer requires standardization with ambient air, instead of standardized calibration gases.
7. Failure to calibrate automated or mechanical equipment according to a written program designed to assure proper performance, as required by 21 CFR 211.68(a). For example, your firm does not calibrate the vacuum/pressure gauges appropriately nor are daily vacuum gauge checks performed or documented.

At the conclusion of this inspection, Consumer Safety Officers Chase-Off and Roberts issued a written report of observations (FDA 483) to Shawna L. Snider, Manager.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. As CEO, it is your responsibility to assure adherence with all requirements of the Act and Good Manufacturing Practice Regulations.

These deviations may be indicative of corporate wide non-compliance. We recommend that internal audits be conducted at all your medical gas facilities and appropriate action be taken to assure that similar violations are not occurring at other locations. Guidance for the requirements for compressed medical gases can be found at our web site <http://www.fda.gov/cder/dmpq/cgmpnotes.htm>.

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

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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 Ms. Shelly L. Maifarth, Compliance Officer, at the above address.

Sincerely,

A handwritten signature in cursive script that reads "Karen S. Kreuzer".

Karen S. Kreuzer  
Acting District Director

cc:

Ms. Shawna L. Snider and  
Mr. Boyce M. Johnston, Managers  
Southwest Utah Home Health Agency, Inc.  
1825 N. Main Street, #4  
Spanish Fork, Utah 84660

Ms. Mary Kay Smith, Regional Administrator  
Health Care Financing Administration, DHHS Region VIII  
Byron G. Rogers Federal Building  
1961 Stout Street, Fifth Floor  
Denver, Colorado 80294-3538

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