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Food and Drug Administration
Denver District Office
Building 20 - Denver Federal Center
P. O. Box 25087
Denver, Colorado 80225
TELEPHONE: 303-236-3000

November 27, 1996

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Richard E. Lofgren
President and CEO
U.S. Welding, Inc.
600 South Santa Fe Drive
Denver, Colorado 80223

Ref. # - DEN-97-05

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Dear Mr. Lofgren:

During an inspection of your firm, U.S. Welding, located at 999 South Redwood Road, Salt Lake City, Utah, on October 21 through 23, 1996, Investigators James E. Moore II and Jill Mielziner determined that your firm repacks liquid and compressed medical oxygen, as well as other medical gases. Medical gases are drug products as defined by section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act). The above stated inspection revealed that your products are adulterated within the meaning of Section 501(a)(2)(B) of the Act in that the controls used for the manufacture, processing, packing, or holding of these products are not in conformance with current Good Manufacturing Practice Regulations under Title 21, Code of Federal Regulations (21 CFR), parts 210 and 211. Deviations noted during the inspection include, but are not limited to the following:

1. Failure to test each lot of bulk oxygen to determine conformance with appropriate specifications for identity and strength, as required by 21 CFR 211.84(d)(2). For example:
 - a. Lack of an analysis for purity and identity on bulk liquid oxygen, nitrogen and carbon dioxide in bulk storage tanks. Newly received lots are commingled with old lots and no analysis is performed on the newly formed lots prior to the first production run. Additionally, no analysis is performed on the first compressed cylinders filled from the first manifold filled from these bulk storage tanks.

- b. Certificates of Conformance are inadequate in that they are lacking Air Liquefaction statements, lot number or unique identification number, actual analytical results obtained for identity and strength, and the testing methods used for analysis.
 - c. Lack of finished product testing (purity and identity) for each lot of oxygen, nitrogen and carbon dioxide high pressure cylinders. For example, there is no record of finished product testing for all lots filled, such as testing of one cylinder per manifold filling sequence.
 - d. Use of the _____ Analyzer to analyze Oxygen, U.S.P. for purity, which has an accuracy specification of _____ %. The minimum purity for Oxygen, U.S.P. is _____ % and thus this analyzer does not have the accuracy range necessary to perform this measurement. The _____ is also used to measure the oxygen content in Nitrogen, NF which also has a minimum purity of _____ %.
 - e. Failure to test Carbon Dioxide, U.S.P., either in bulk form or as finished product, for purity and identity.
 - f. Failure to test Compressed Breathing Air, U.S.P. for purity and identity.
2. Failure to routinely calibrate medical gas analyzers in accordance with manufacturer's directions to assure proper performance, as required by 21 CFR 211.160(b)(4). For example:
- a. Failure to calibrate oxygen analyzers including: _____, _____, and _____, in accordance with the manufacturer's directions. For example, there has been no calibration performed since April 1996; and, certified reference cylinders of high purity nitrogen and oxygen have not been used for calibration of the analyzers as required by the operator's manual.
 - b. Failure to calibrate the _____ Analyzer, Model _____ once per year as required by the operator's manual.
 - c. Failure to calibrate the _____ Analyzer, Model _____ at least once per week as required by the operator's manual.
3. Failure to establish written specifications and test procedures designed to assure that the drug products manufactured conform to appropriate standards of identity, strength, quality, and purity, as required by 21 CFR 211.160(b). For example, there are no written specifications or test procedures for Oxygen, U.S.P., Nitrogen, NF, Carbon Dioxide, U.S.P. or Compressed Breathing Air, U.S.P. produced by your firm.
4. Failure to establish written procedures for production and process control designed to assure that the drug products have the identity, strength, quality and purity they purport or are represented to possess, as required by 21 CFR 211.100(a). For example, there are no

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written procedures for handling incoming bulk gases, filling/transfilling cylinders, identity and purity testing of finished products, training, and distribution of finished product.

5. Failure to establish a quality control unit with the responsibility and authority to approve or reject all components and drug products, as required by 21 CFR 211.22.
6. Failure to prepare and maintain batch production and control records for each batch of drug product produced, including documentation that each significant step in the manufacture, processing, packing, or holding of the batch was accomplished, as required by 21 CFR 211.188(b). For example, Oxygen Packaging Control (batch) records exist for only lots of Oxygen, U.S.P. during the period of July 22, 1996 through October 19, 1996. There are no such batch records for the months of August and September 1996. Additionally, Oxygen, U.S.P. batch records which were available for review were found to be incomplete in that:
 - a. records lacked purity and identity results;
 - b. records lacked prefill inspection;
 - c. records lacked an authorized reviewing official's signature and date;
 - d. record lacked a lot number; and,
 - e. records lacked the residual bulk lot number and vendor's new lot number.

Similar deviations were noted in the batch records reviewed for Nitrogen, NF, Carbon Dioxide, U.S.P., and Compressed Breathing Air, U.S.P. produced by your firm.

7. Failure to appropriately train each person engaged in the manufacture, processing, packing, or holding of drug products to enable those persons to perform their assigned functions, as required by 21 CFR 211.25(a). For example, the Lead Production Individual has not been trained in the area of quality control, for which he is responsible.

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

At the conclusion of the inspection, Investigators Moore and Mielziner issued a written report of observations (FDA 483) to Mr. Harry James Green, Jr. A copy of this report is enclosed for your reference.

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 for drug products 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

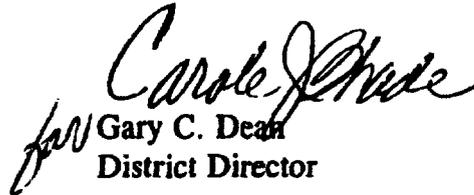
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prevent the recurrence of similar violations; (2) the time when correction will be completed; (3) any reason why the corrective action is not completed within the response time; and (4) any documentation necessary to indicate correction has been achieved.

During the exit interview with our investigators, Mr. Green stated that corrections for each item noted on the Form FDA 483 would be completed within six months. Based on our knowledge of the corporate resources and procedures already in place at U.S. Welding facilities, we believe six months is an excessive amount of time to bring this facility into compliance. In addition, this letter serves as official notification to you that we expect all of your gas repacking facilities to be in compliance with the requirements of the Federal Food, Drug and Cosmetic Act. Your response should be directed to Mr. David K. Glasgow, Acting Compliance Officer, at the above address.

Sincerely,


for Gary C. Dean
District Director

Enclosure
As stated

cc: Mr. Harry James Green, Jr.
Vice President, Sales
U.S. Welding, Inc.
999 South Redwood Road
Salt Lake City, Utah 84125

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