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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

July 14, 1997

**WARNING LETTER**

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

Mr. Frederick R. Petersen  
Owner  
Petersen's Medical Center Pharmacy, Inc.  
1275 North University Avenue  
Provo, UT 84604

Ref. # - DEN-97-23

PURGED

Dear Mr. Petersen:

During an inspection of your firm, Petersen's Medical Center Pharmacy, Inc., Provo, Utah, on June 9 through 10, 1997, Investigator James E. Moore II determined that your firm repacks compressed medical oxygen. 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 this product 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 calibrate oxygen analyzers in accordance with manufacturer's directions and your firm's written procedures to assure proper performance, as required by 21 CFR 211.160(b)(4). For example:
  - a. your firm does not have a Certificate of Analysis for the reference cylinder of nitrogen used in the calibration of the [REDACTED] oxygen analyzer, therefore the purity of the nitrogen cylinder in use is unknown;

- b. your firm is not following the Oxygen Analyzer calibration procedure in that certified oxygen is not being used to span the oxygen analyzer on a daily basis; and,
  - c. the [REDACTED] Oxygen Analyzer's filter is not being examined on a weekly basis as required by your firm's written procedures.
2. Failure to perform adequate prefill inspections on each high pressure cylinder prior to filling, as required by 21 CFR 211.84(d)(3). For example, cylinder marking examinations are not being performed and two aluminum oxygen cylinders past their expiration dates were observed filled and released for distribution.
  3. Failure to implement and follow written production and process control procedures as required by 21 CFR 211.100(b). For example, your firm has failed to implement a written procedure governing the use of a thermometer to monitor the temperature in the oxygen filling area. Further, your firm is not monitoring the temperature of this area during the filling operation and is only monitoring the pressure of the filled cylinders.
  4. Failure to provide training to employees to enable them to perform assigned functions in the manufacture, processing, packing or holding of drug products, as required by 21 CFR 211.25(a). For example, an employee was observed failing to follow written procedures for the calibration of equipment, the preparation of batch records, and performing prefill inspections of oxygen cylinders. Further, this employee did not know that he was not following your firm's written procedures.

Additionally, your medical oxygen is misbranded under Section 503(b)(4) of the Act, in that prescription drug product labeling is required to bear the statement, "Caution: Federal law prohibits dispensing without prescription." Your medical oxygen containers do not bear this required statement.

The above identification of violations is not intended to be an all inclusive list of deficiencies at your facility. 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.

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 Act. They may elect to defer or discontinue payment for any health care product in violation of state or federal law.

**PURGED**

Mr. Frederick R. Petersen  
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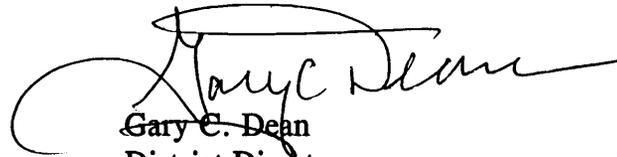
I am enclosing a copy of the Food and Drug Administration's booklet entitled Compressed Medical Gases Guideline; a copy of the Federal Food, Drug, and Cosmetic Act; a copy of the Fresh Air '97 speech by Mr. Duane Sylvia of FDA's Center for Drug Evaluation and Research; and 21 CFR 211. The Compressed Medical Gases Guideline contains useful information on how to comply with the requirements of 21 CFR 211.

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 Mr. David K. Glasgow, Acting Compliance Officer, at the above address.

Sincerely,

  
Gary C. Dean  
District Director

Enclosures:  
As Stated

FILED