



DEPARTMENT OF HEALTH & HUMAN SERVICES

HEI-35
D1210B
Public Health Service
2/2/97

Food and Drug Administration
1141 Central Parkway
Cincinnati, OH 45202

February 20, 1997

WARNING LETTER
CIN-WL-97-215

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

S. Frank Lemon, President
Pharmacy Forces, Inc.
20093 Thompson Road
Laurelville, Ohio 43135

Dear Mr. Lemon:

During a January 29, 1997 inspection of your compressed medical oxygen transfilling facility, Pharmacy Forces, Inc., located at 1603 11th St., Portsmouth, OH 45662, our investigator documented serious deviations from the Current Good Manufacturing Practices Regulations (Title 21 Code of Federal Regulations, Part 211). These deviations cause your drug product, Oxygen USP, to be adulterated within the meaning of section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act).

Specific observations made during the inspection include:

- (1) Failure to assure that each lot of medical oxygen gas manufactured conforms to the appropriate USP specifications for purity prior to shipment. Review of records over a one year period revealed a lack of purity results on at least three (3) production dates.
- (2) Failure to follow established written operating procedures and perform required control steps for the following:
 - a) Pressure gauges are not calibrated monthly as required by your written procedures. FDA requires calibration at least annually.
 - b) Oxygen analyzer filter is not checked weekly as required by the equipment manufacturer's instructions.
 - c) Transfilling records are not reviewed daily for accuracy and completeness. This review should be by someone other than the filler.

- d) Transfilling records are not completed. Two (2) records were not signed by the operator and at least four (4) records were not approved for distribution.
- (3) Failure to establish adequate control over medical oxygen labels in that there is no label inventory control nor secured control of label access.
- (4) Failure to calibrate or document calibration of your oxygen analyzer each day of use.
- (5) Failure to use an appropriately precise thermometer for filling of compressed gas cylinders in that the thermometer used is readable only in two degree increments.

Our review of your labeling reveals that some of your compressed medical oxygen cylinders in inventory are misbranded under section 502 and 503 of the Act as follows: the Oxygen USP labels does not bear the prescription legend - 503(b)(4); the Oxygen USP labels fails to bear the "Produced by air-liquefaction" statement as required by the United States Pharmacopeia (USP 23) - 502(f)(1); and the labels fail to bear the current and correct name and place of business of the manufacturer, packer, or distributor - 502(b)(1). It is your responsibility to assure that all medical Oxygen cylinders are examined at filling to ensure they bear adequate and current labeling, and are replaced if necessary.

Section 503(b)(4) of the Act requires that prescription drugs bear the statement: "Caution: Federal law prohibits dispensing without prescription." However, on September 19, 1996, FDA granted the Compressed Gas Association's petition regarding the labeling of medical oxygen which is required to contain the statement: **"For emergency use only when administered by properly trained personnel for oxygen deficiency and resuscitation. For all other medical applications, Caution: Federal law prohibits dispensing without prescription."** You should assure that the next printing of your labels specifically meets this requirement.

The above described violations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that you adhere to all current regulations applicable to your operations. Federal agencies are advised

of the issuance of all warning letters about drugs so that they may take this information into account when considering the award of contracts.

By copy of this letter, we are advising Health Care Finance 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.

You should take prompt action to correct these violations. Failure to achieve prompt correction may result in regulatory action without further notice. These include seizure and/or injunction.

For your information, I have enclosed a copy of the FDA speech "FRESH AIR '96" - A LOOK AT FDA'S MEDICAL GAS REQUIREMENTS", which describes current FDA requirements and policy on medical gases.

Please advise us in writing within fifteen (15) working days of receipt of this letter of the specific actions you are taking to correct these violations. Your response should explain each step you have taken to correct the noted violations, including steps taken to prevent recurrence of similar violations. Include any documentation showing these corrections.

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 U.S. Food and Drug Administration, 1141 Central Parkway, Cincinnati, Ohio 45202-1097, to the attention of Charles S. Price, Compliance Officer. Any questions regarding this letter may be directed to Mr. Price at telephone (513) 684-3501.

Sincerely,

Mary L. Womack for

John R. Marzilli
District Director
Cincinnati District

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Enclosure: Fresh Air

copy to: Steven R. Welton, Co-Owner
Pharmacy Forces, Inc.
1603 11th Street
Portsmouth, OH 45662