



DEPARTMENT OF HEALTH & HUMAN SERVICES

HFI 35 D1182B
Public Health Service

Food and Drug Administration
1141 Central Parkway
Cincinnati, OH 45202

February 10, 1997

WARNING LETTER
CIN-WL-97-210

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Steve T. Plochocki,
President
Apria Healthcare, Inc.
3560 Hyland Ave.
Costa Mesa, CA 92626

Dear Mr. Plochocki:

During a January 16-17 & 22, 1997 inspection of your home respiratory care, medical oxygen transfilling facility, Apria Healthcare, Inc., located at 329 North West St., Lima, OH 45805, 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.

Specific observations made during the inspection include:

- (1) Failure to assure that each lot of incoming liquid oxygen (LOX) conforms to the USP specifications for identity and strength prior to use.

Review of records over a seven month period, revealed your firm failed to receive a certificate of analysis or otherwise assay at least three lots of incoming LOX, prior to filling and distributing to patients.

- (2) Failure to maintain adequate written procedures in that procedures do not reflect the actual operations performed for acceptance of incoming LOX.
- (3) Failure to maintain adequate batch production and control records for each lot of LOX received and filled. Receipt of one lot of LOX was documented by receiving records and Certificate of Analysis. However, there are no records documenting whether this lot was distributed to patients, maintained in inventory or returned to the supplier.

It is our understanding that you have numerous Apria Healthcare facilities around the U.S. On 3/6/96, a previous Warning Letter was issued to you for similar deficiencies at your Ft. Loramie, Ohio facility. This letter will also serve as a warning to you to correct any similar deficiencies at all of your medical oxygen facilities.

The above described violations are not intended to be an all-inclusive list of deficiencies at your facilities. 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.

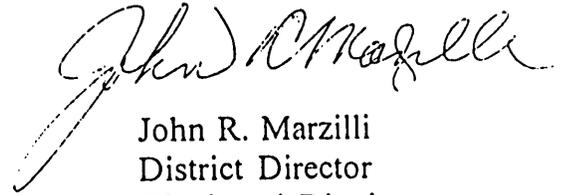
For your information, I have enclosed a copy of the FDA speech "FRESH AIR '96" - A LOOK AT FDA'S MEDICAL GAS REQUIREMENTS", which describes current FDA requirements and policy on medical gases.

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.

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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,



John R. Marzilli
District Director
Cincinnati District

Enclosure: Fresh Air

copy to:

Bonnie Berelsman,
Branch Manager
Apria Healthcare
311 Industrial Drive
Minster, OH 45865