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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Refer to: CFN 1121758

Baltimore District
900 Madison Avenue
Baltimore, Maryland 21201
Telephone: (410) 962-4040

October 14, 1997

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Jerry Jones
Chief Executive Officer
Apria Healthcare, Incorporated
3560 Hyland Avenue
Costa Mesa, California 92626

Dear Mr. Jones:

The Food and Drug Administration (FDA) conducted an inspection of your Beckley, West Virginia facility on September 26, 1997. During the inspection, deviations from the Current Good Manufacturing Practice regulations (Title 21, Code of Federal Regulations (CFR), Parts 210 & 211) were observed. These deviations cause your Liquid Oxygen, U.S.P. to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act). The deviations included the following:

1. Failure to assure that the Liquid Oxygen and drug product containers are retested for identity after service and/or repair and approved by the quality control unit prior to release.
2. Failure to establish adequate written procedures for the production and process controls designed to assure that the drug product has the identity, strength, quality, and purity it purports or is represented to possess.

At the conclusion of the inspection, a written list of inspectional observations (FDA-483, enclosed) was issued to Mr. William J. Banks, Branch Manager.

We acknowledge that your facility does witness the testing of each supplier filled cryogenic vessel by a person trained in the analytical methodology being witnessed. We have, therefore, removed Item #3 from the enclosed FDA-483. This will be made a part of our official file.

Mr. Jerry Jones
Page 2
October 14, 1997

The above listed violations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that your establishment is in compliance with all requirements of the federal regulations. Federal agencies are advised of the issuance of all Warning Letters about drugs and devices 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 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 deviations. Failure to do so may result in regulatory action without further notice, such as seizure and/or injunction. Enclosed is a compressed medical gases guideline which discusses the applicability of the Current Good Manufacturing Practice Regulations to medical gas manufacturers.

You should notify this office in writing, within 15 working days of receipt of this letter, of specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to the Food and Drug Administration, Richmond Resident Post, 10710 Midlothian Turnpike, Suite 424, Richmond, Virginia 23235, to the attention of Mr. Scott J. MacIntire, Compliance Officer. Mr. MacIntire can be reached at (804) 379-1627, extension 14.

Sincerely,



Loveen M. Beck

Acting Director, Baltimore District

Enclosures

cc: West Virginia Board of Pharmacy
236 Capitol Street
Charleston, West Virginia 25301

Mr. William J. Banks
Branch Manager
4210 First Avenue
Nitro, West Virginia 25143