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DEPARTMENT OF HEALTH AND HUMAN SERVICE

Public Health Service

Refer to: FEI 3001701620

Food and Drug Administration
Baltimore District Office
900 Madison Avenue
Baltimore, MD 21201-2199
Telephone: (410) 962-3396
FAX: (410) 962-2219

1133941

February 4, 2000

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ms. Tammy Snopps, Manager
Pharmacy Associates, Incorporated
d.b.a. OptionCare
3007 Dudley Avenue
Parkersburg, West Virginia 26101

Dear Ms. Snopps:

A Food and Drug Administration (FDA) inspection was conducted on January 20, 2000 at your medical gas manufacturing facility located at Parkersburg, West Virginia. Medical gases are drug products as defined by Section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act).

During our inspection, deviations from the Current Good Manufacturing Practice (GMP) requirements (Title 21, Code of Federal Regulations (CFR), Part 211) were observed. These deviations cause your medical gases to be adulterated within the meaning of Section 501(a)(2)(B) of the Act, in that the methods used in, or the facilities or controls used for, their manufacturing, processing, packing, storage, or holding, are not in conformance with GMP regulations.

The deviations included the following:

- Failure to ensure that each component is tested for conformity with written specifications, or when accepting each component based on a report of analysis from the component manufacturer, to conduct at least one specific identity test on such component.
- Failure to establish written procedures for the receipt and acceptance of untested components.
- Failure to establish and document the responsibilities of and the written procedures for the Quality Control Unit (QCU). For example, there were no written procedures detailing how or when the various QCU functions will be performed. Those functions specific to the QCU include re-testing of components, written procedures, in-process sampling and testing, reprocessing, laboratory controls, testing and release for distribution, and complaint files.

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At the conclusion of the inspection, Mr. Richard D. Hite, RT/DME Division Manager was presented with a written list of inspectional observations (FDA-483) which was discussed with him. A copy of the FDA-483 is enclosed for your reference.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to all requirements of the Act and regulations at your facility. The specific violations noted in this letter and in the FDA-483 issued at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If you determine the causes to be systems problems, you must promptly initiate permanent corrective action.

Federal agencies are advised of the issuance of all Warning Letters concerning drug products so that they may take this information into account when awarding 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. These actions include, but are not limited to, seizure and/or injunction.

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations and to prevent their recurrence. 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 Food and Drug Administration, Northern Virginia Resident Post, 101 West Broad Street, Suite 400, Falls Church, Virginia 22046, to the attention of Gerald W. Miller, Compliance Officer. Mr. Miller can be reached at (703) 235-8440, extension 504.

Sincerely,



Lee Bowers
Director, Baltimore District

Enclosure

cc: Mr. Thomas E. Menighan, President
Pharmacy Associates, Inc.
1308 Fourth Avenue
Huntington, West Virginia 25701