

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

7/11/97
ef
CB

Refer to: CFN 1124810

Baltimore District
900 Madison Avenue
Baltimore, Maryland 21201
Telephone: (410) 962-4012

July 7, 1997

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Harvey P. Barton, President
Pharmacy Associates, Inc.
d/b/a Option Care
1412 6th Avenue
Huntington, West Virginia 25701

Dear Mr. Barton:

The Food and Drug Administration (FDA) conducted an inspection of your Charleston, West Virginia facility on June 6 and 9, 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 and Compressed 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 test or have other appropriate documentation to demonstrate that each batch of Liquid Oxygen is in conformance with appropriate specifications for identity, strength, quality, and purity prior to release.
2. Failure to assure that drug product containers are suitable for their intended use, in that the cryogenic home vessels are not examined or their contents tested for identity, strength, quality, and purity after service or repair and prior to release.
3. Failure to establish the reliability of the supplier's analyses through appropriate validation of the supplier's test results at appropriate intervals.
4. Failure to establish written procedures for the production and process controls covering filling and testing of Liquid Oxygen, designed to assure that the drug product has the identity, strength, quality, and purity it purports or is represented to possess.

Mr. Harvey P. Barton

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5. Failure to establish written procedures for the handling of all written and oral complaints regarding Oxygen, U.S.P.
6. Failure to designate a Quality Control person, or unit, that has the responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, packaging material, labeling, and drug products, and the authority to review production records to assure that no errors have occurred or, if errors have occurred, that they have been fully investigated.

At the conclusion of the inspection, Mr. Jeffrey L. Brooks, Director, was given a written list of inspectional observations (Form FDA 483, enclosed) which was discussed with him. Also enclosed is a compressed medical gases guideline which discusses the applicability of the Current Good Manufacturing Practice Regulations to medical gas manufacturers.

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.

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 Scott J. MacIntire, Compliance Officer.

Sincerely,



Elaine Knowles Cole
Director, Baltimore District

Enclosures

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cc: Mr. Jeffrey L. Brooks, Director
Pharmacy Associates, Inc.
d/b/a Option Care
308 Hills Plaza
Charleston, WV 25312

Virginia Board of Pharmacy
6606 West Broad Street
Richmond, VA 23230-1717

bcc: EI file, HFR-MA1, HFR-MA200, HFR-MA240 (Simmons), HFR-MA250
(Wiedman), HFA-224, HFC-210, HFI-35 (purged), HFC-240, HFD-300,
HFR-MA2545, HFR-MA2530, HFR-MA295

Mr. Dennis Carroll
Associate Regional Administrator
HCFA
Room 3100
3535 Market Street
Philadelphia, PA 19101 (purged)

TRACKING #: 97-BLT-42