



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

D1287B

EB 3/26/97

Certified/Return Receipt Requested

March 25, 1997

Food and Drug Administration
Kansas City District Office
11630 West 80th Street
P.O. Box 15905
Lenexa, Kansas 66285-5905

Telephone: (913) 752-2100

WARNING LETTER

C. Arnold Renschler, President
Pharmacy Corporation of America
3611 Queen Palm Drive
Tampa, Florida 33619

Ref.# - KAN-97-011

Dear Mr. Renschler:

During an inspection of your medical oxygen manufacturing operation known as Pharmacy Corporation of America, 12767 Q Street, Omaha, Nebraska, conducted February 24 through March 3, 1997, a Food and Drug Administration Investigator from this office documented deviations from the Current Good Manufacturing Practice (CGMP) Regulations (Title 21, Code of Federal Regulations, Part 211) which cause your firm's medical oxygen to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (Act).

Significant deviations to 21 CFR, Part 211 include, but are not limited to the following:

failure to perform adequate prefill operations on each high pressure cylinder and each cryogenic home vessel, prior to filling [21 CFR 211.84(d)(3)];

failure to perform cylinder evacuation by pulling a vacuum to assure it is clear of foreign gas residues [21 CFR 211.94(c)];

failure to establish written procedures (SOP's) designed to assure that your medical oxygen products have the identity and strength they purport or are represented to possess [21 CFR 211.100(a)];

failure to properly calibrate the Oxygen Analyzer used for the assay of Oxygen, USP, in that your firm is not following established procedures or operators manual, and you are not using a certified cylinder of oxygen for calibration [21 CFR 211.160(b)(4)];

Page 2
March 25, 1997
Pharmacy Corporation Of America

failure to assay the filled high pressure cylinders of medical oxygen for identity and strength prior to release, and incoming liquid oxygen for identity prior to filling liquid home units [21 CFR 211.165(a)].

At the conclusion of the inspection Form FDA 483, Inspectional Observations, was prepared, issued to and discussed with Michael D. Sells, Business Office Manager. A copy is enclosed for your information.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations.

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. You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Such actions may include seizure and/or injunction.

You should notify this office in writing within fifteen (15) working days of receipt of this letter of the specific steps, that are being taken to correct the noted violations and to prevent their recurrence.

Your reply should be sent to Clarence R. Pendleton, Compliance Officer, at the above address.

Sincerely,

W. Michael Rogers
District Director
Kansas City District

Enclosure - Form FDA 483

cc: Jarold L. Kohll, Pharmacy Manager
Pharmacy Corporation of America
12767 Q Street
Omaha, Nebraska 68137

DISTRIBUTION:

Orig. & Enclosure: Addressee
bcc: LF; FF(1933717); HFA-224; HFD-325(Sylvia); HFI-35/DIB(via FOI); HFC-210; Drug Team; O/RP; FLA-DO (HFR-SE250); IBRF;

CRP:blw