



DEPARTMENT OF HEALTH AND HUMAN SERVICE

Public Health Service

HFI-35 (PURGED)

mjg/rp

CFN: 1122156

Food and Drug Administration  
Baltimore District Office  
900 Madison Avenue  
Baltimore, MD 21201-2199  
Telephone: (410) 962-3461 x122  
FAX: (410) 962-2219

November 9, 1998

**WARNING LETTER**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Mr. Thomas S. Petr, President  
Medi-Rents & Sales  
743 South Conkling Street  
Baltimore, Maryland 21224

Dear Mr. Petr:

A Food and Drug Administration (FDA) inspection was conducted October 21 to 27, 1998 at your facility in Baltimore, Maryland. The inspection determined that you manufacture liquid Oxygen U.S.P., a drug product 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) regulations (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, manufacturing, processing, packing, storage, or holding, are not in conformance with the GMP regulations.

The deviations included the following:

1. Failure to adequately retest or reexamine cryogenic vessels after being subject to conditions that might adversely affect them or the liquid Oxygen U.S.P. contained in them (e.g., after repair or maintenance of the vessels). Also, failure of a quality control unit to approve or reject such vessels.
2. Failure to document pre-fill inspections of cryogenic home vessels for conformance to all appropriate specifications.
3. Failure to document the training of all individuals engaged in the manufacture, processing, and packing of liquid Oxygen U.S.P.

4. Failure to establish and follow written procedures for all production and process control operations to assure that the liquid Oxygen U.S.P. has the identity, strength, quality, and purity it is represented to possess.

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.

The specific violations noted in this letter and on the FDA-483 issued to and discussed with you 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, Baltimore District, 900 Madison Avenue, Baltimore, Maryland 21201, to the attention of Thomas C. Knott, Compliance Officer. Mr. Knott can be reached at (410) 962-3461, extension 122.

Sincerely,



Elaine Knowles Cole  
Director, Baltimore District

cc: Maryland Board of Pharmacy  
4201 Patterson Avenue  
Baltimore, MD 21215-2299