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DEPARTMENT OF HEALTH AND HUMAN SERVICE

Public Health Service d1974b

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

August 6, 1998

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. G. Lawrence Hogue, President
Washington Heights Pharmacy, Inc.
205 Washington Heights Medical Center
Westminster, Maryland 21157

Dear Mr. Hogue:

A Food and Drug Administration (FDA) inspection was conducted July 21 to 27, 1998 at your Westminster, Maryland facility. The inspection determined that you manufacture Liquid Oxygen, USP, at that facility. Liquid Oxygen, USP, is a drug products as defined by Section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act).

Your Liquid Oxygen, USP, is misbranded within the meaning of Section 502(o) of the Act, as it was manufactured in a facility that was not duly registered under Section 510 of the Act, and the article has not been listed as required by Section 510(j).

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 perform appropriate testing to assure that the product meets specifications for purity, strength, and quality as follows:
 - a) identity testing of the incoming Liquid Oxygen, USP;
 - b) assaying each batch of filled cryogenic home vessels prior to release for distribution;
 - c) testing cryogenic home vessels before transfilling;
 - d) testing cryogenic home vessels after exposure to conditions that may adversely affect the vessels.

2. Failure to establish scientifically sound and appropriate written operating procedures, specifications, sampling plans, and test procedures designed to assure that components, cryogenic containers, and filled cryogenic home vessels conform to appropriate standards of identity, strength, quality, and purity.
3. Failure to maintain records for: assaying incoming Liquid Oxygen, USP; the examination of cryogenic containers; and the production and control of each batch of filled cryogenic home vessels.
4. Failure to train personnel engaged in the transfilling of cryogenic home vessels in the particular operations they perform and in Current Good Manufacturing Practice.
5. Failure to identify each batch of product with a lot or control number that permits determination of the history of manufacture and control of the batch and facilitates its recall if necessary.
6. Failure to establish and follow written procedures describing the handling of all written and oral complaints regarding the product.

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 Mr. Arthur N. Riley 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.

We acknowledge receipt of Mr. Riley's response, dated July 30, 1998, to the observations recorded on the FDA-483. The response indicates, in general terms, your intention to conform to the provisions of the Act and pertinent regulations. One concern not directly addressed in your response, however, is testing of gas and cryogenic vessels to assure the purity, strength, and quality of the product delivered to patients. The investigator supplied guidance documents to assist you in correcting the noted deficiencies. Corrections will be confirmed during a future inspection.

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.