



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

HF1-35

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Refer to: CFN 1121651

BALTIMORE DISTRICT OFFICE
900 Madison Avenue
Baltimore, Maryland 21201
Telephone: (410) 962-4040

March 27, 1998

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Richard W. Millman, CEO
Medserv Corporation
1337-F Canton Road
Marietta, Georgia 30066

Dear Mr. Millman:

A Food and Drug Administration (FDA) inspection was conducted from February 26 to March 2, 1998 at your Millersville, Maryland Liquid Oxygen, U.S.P., manufacturing facility. Liquid Oxygen is 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) requirements (Title 21, Code of Federal Regulations (CFR), Part 211) were observed. These deviations cause your Liquid Oxygen, U.S.P., 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 GMP regulations.

The deviations included the following:

1. Failure to test or to 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 establish the reliability of the supplier's analyses through appropriate validation of the supplier's test results at appropriate intervals.
3. Failure to adequately calibrate the oxygen analyzer according to written procedures.

Mr. Richard Millman
Page 2
March 27, 1998

4. Failure to follow written procedures for the production and process controls covering testing of Liquid Oxygen, supplier audits, certificates of analyses, and calibration of the oxygen analyzer.
5. 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.

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 the Millersville facility and at all facilities operated by your firm. The specific violations noted in this letter and in the FDA-483 (enclosed) 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 considering the awarding of contracts.

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.

Mr. Richard Millman
Page 3
March 27, 1998

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,


Carl E. Draper
Acting Director, Baltimore District

Enclosure

cc: Christine Ludwiczak,
Corporate Director of Quality Control
Medserv Corporation
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Wisconsin Rapids, Wisconsin 54494

Robert L. Marrs,
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