



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

1/7/96 RB D1071B

Certified/Return Receipt Requested

January 6, 1997

Food and Drug Administration
Kansas City District Office
11630 West 80th Street
Lenexa, Kansas 66214-3340

Telephone: (913) 752-2100

WARNING LETTER

Boyd L. Sullivan, Branch Director
Koley's Home Care, Inc.
8646 F Street
Omaha, Nebraska 68127

Ref.# - KAN-97-007

Dear Mr. Sullivan:

During an inspection of your medical oxygen transfilling operation located at the above address, conducted on December 12 to 16, 1996, 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 assay the incoming liquid oxygen for identity prior to filling the liquid home units, and failure to conduct a USP test (at least once a year) for identity and strength to verify the reliability of your supplier's certificate of analysis [21 CFR 211.165(a)];

failure to retest at least for identity, the contents of cryogenic home vessels sent out for repair or maintenance, prior to redistribution to customers [21 CFR 211.87];

failure to perform adequate prefill operations on cryogenic home vessels prior to filling [21 CFR 211.84(d)(3)];

failure to properly calibrate the Oxygen Analyzer used for the assay of Oxygen, USP, in that your firm is not using a documented certified standard of Oxygen [21 CFR 211.160(b)(4)].

DISTRIBUTION:

Orig.: Addressee
bcc: LF; FF(1931961); HFA-224; HFD-322(Sylvia); HFI-35/DIB(via

Page 2
January 6, 1997
Koley's Home Care, Inc.

At the conclusion of the inspection Form FDA 483, Inspectional Observations, was prepared, issued to and discussed with you.

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. We received and reviewed your letter dated December 18, 1996, concerning the Form FDA 483 observations, prior to the issuance of this letter.

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, in addition to those covered in the letter, that are being taken to correct the noted violations and to prevent their recurrence. If you feel the December 18 letter adequately addresses your corrections we will accept it as your response to this letter.

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

Sincerely,

W. Michael Rogers
District Director
Kansas City District