



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

M230M

Certified/Return Receipt Requested

December 4, 1998

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 LETTERJames E. Helget, President
Helget Gas Products, Inc.
P.O. Box 24246
Omaha, NE 68124

KAN #99-005

Dear Mr. Helget:

Recently an inspection was made of your medical gas transfilling operation located at 2105 Atlantic Street, North Kansas City, Missouri. This inspection was conducted on November 4 through 13, 1998, by a Food and Drug Administration Investigator from this office, and an Inspector with the Missouri State Board of Pharmacy, who documented deviations from the Current Good Manufacturing Practice (CGMP) Regulations (Title 21, Code of Federal Regulations, Part 211). These deviations cause the medical gases transfilled at this location to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (Act).

Significant deviations include, but are not limited to the following:

failure to discontinue the transfilling of compressed oxygen USP, quarantining of filled cylinders, and cessation of filled cylinder distribution, after the breakdown of the vacuum pump and the finding of oil in the "E" manifold on October 16, 1998 [21 CFR 211.165 & 211.192];

failure to validate and document the cleaning process used to remove oil residues from the manifold piping system [21 CFR 211.67 & 211.182];

failure to validate the check valve located between the vacuum pump and manifold on the compressed oxygen USP filling lines [21 CFR 211.68(a)];

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failure to properly calibrate the Servomex 570A Oxygen Analyzer used for the assay of oxygen USP [21 CFR 211.160(b)(4)]. Examples include:

inconsistently performing the daily span as required by the instruction manual;

no documentation of zeroing with nitrogen or checking of the filter;

no certificates of analysis for the calibration gasses;

failure to establish standard operating procedures for, and to document the calibration of gauges and thermometers used during the filling of compressed oxygen USP and nitrous oxide USP;

failure to use lot numbers on compressed medical gasses in such a way that permits determination of the history of the manufacture and control of the batches [21 CFR 211.130(c)];

failure to exercise proper controls regarding the receipt, storage and use of labels for medical gas products [21 CFR 211.122, 211.125 & 211.130];

failure to have a documented training program for employees in CGMP's and the transfilling of medical gasses [21 CFR 211.25(a)];

failure to establish a quality control unit [21 CFR 211.22];

failure to have an adequate complaint handling system in place which captures pertinent information for proper investigation follow-ups [21 CFR 211.198].

This letter is not intended to be an all-inclusive list of deficiencies at your North Kansas City facility. At the conclusion of the inspection you were issued a Form FDA 483 which is a list of the investigator's observations of GMP deviations noted during the inspection. It is your responsibility to ensure adherence to each requirement of the Act and regulations, at each medical gas facility you operate.

You should know that this serious violation of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizure and/or obtaining a court injunction against further marketing of your medical gasses. Also, other Federal agencies are informed about the Warning Letters we issue, such as this one, so that they may consider this information when awarding government contracts.

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It is necessary for you to take action on this matter now. Please let this office know in writing within fifteen (15) working days from the date you received this letter what steps you are taking to correct the problems. We also ask that you explain how you plan to prevent these violations from happening again. If you need more time, let us know why and when you expect to complete your correction.

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

Sincerely,

Janett D. Salmon (for)
W. Michael Rogers
District Director
Kansas City District

CRP:tlw