



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Kansas City District
Southwest Region
P.O. Box 15905
Lenexa, Kansas 66285-5905

Telephone: (913) 752-2100

February 22, 2002

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

WARNING LETTER

Ref. KAN 2002-03

Wayne Schellhammer, President/CEO
InTrust Plus Home Medical Equipment
1212 Pleasant St.
Des Moines, IA 50309-1414

Dear Mr. Schellhammer:

On February 11-14, 2002, an inspection was made of your medical oxygen transfilling operation located at 1206 Mulberry St., Des Moines, Iowa, by Food and Drug Administration Investigators from our office. Significant deviations from the Current Good Manufacturing Practice (CGMP) Regulations (Title 21, Code of Federal Regulations, Part 211) were observed. These deviations cause the Compressed and Liquid Oxygen USP 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 determine the identity and strength of each incoming batch of liquid oxygen [21 CFR 211.165(a)]. Specifically, no testing is performed on your firm's bulk storage tank located at [REDACTED]. Additionally, there is no testing performed of the truck-mounted vessels filled from your bulk storage tank.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that your firm adheres to all current regulations applicable to your operations. We are enclosing a copy of the Form FDA 483 - Inspectional Observations that was issued to Phyllis J. Stadlander, RN, Executive Director Clinical Services, at the conclusion of the inspection.

By copy of this letter, we are advising the Centers for Medicare & Medicaid Services (CMS) that our inspection of your firm 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.

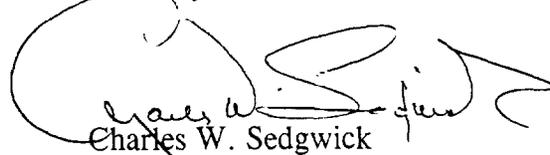
Wayne Schellhammer, President/CEO
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You should know that these serious violations of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizure and/or obtaining a court injunction against further marketing of your medical oxygen. Also, other Federal Agencies are advised of Warning Letters, such as this one, that are issued so they may consider this information when awarding government contracts.

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 this 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 Nadine Nanko Johnson, Compliance Officer, at the above address.

Sincerely,

A handwritten signature in black ink, appearing to read "Charles W. Sedgwick", is written over the typed name below.

Charles W. Sedgwick
District Director
Kansas City District

Enclosure - Form FDA 483

cc: Phyllis J. Stadlander, R.N.
Executive Director, Clinical Services
InTrust Plus Home Medical Equipment
1206 Mulberry St.
Des Moines, IA 50309