



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region d1973b

Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

Telephone (973) 526-6006

August 4, 1998

WARNING LETTER

CERTIFIED MAIL -
RETURN RECEIPT REQUESTED

Mr. Michael Fried, CEO
Community Surgical Supply
163 Route 37 West
Toms River, NJ 08755

FILE: 98-NWJ-32

Dear Mr. Fried:

During an inspection of your firm between July 13 and July 15, 1998, our investigator documented deviations from the Current Good Manufacturing Practice Regulations (Title 21, Code of Federal Regulations, Parts 210 & 211) in conjunction with your firm's transfilling of compressed oxygen USP. These deviations cause your drug product(s) to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act as follows:

1. Your firm cannot assure the identity and strength of your compressed oxygen USP, Lot #07138, which was transfilled on July 13, 1998 and distributed by your firm. For example:
 - A. Oxygen, transfilled on July 13, 1998, was not tested for identity and strength. A purity of [REDACTED] was listed on the batch record for Lot #07138, brake numbers 01, 02, 03, 04, and 05 with each brake number representing a filling sequence. Upon further examination, it was determined that [REDACTED] was the purity of the initial filling sequence when the "H" cylinder was changed, not the purity of each individual brake number (filling sequence) on July 13, 1998.
 - B. Your firm lacks a Certificate of Analysis or a record showing that full USP testing was performed for the incoming five "H" oxygen USP cylinders, Supplier Lot #'s 239-1888-26 (three cylinders), 239-0278-03, and 239-3437-01. These "H" cylinders were used for transfilling oxygen USP on July 13, 1998.

August 4, 1998

2. Your firm cannot assure that the Oxygen Analyzer used, Servomex Model 570A, is properly calibrated. For example:
 - A. It was noted that your firm lacks Certificates of Analysis to establish the known concentrations of your oxygen cylinder labeled with [REDACTED] and your nitrogen cylinder labeled with [REDACTED]. These cylinders are used as reference standards to check(span) the Servomex.
 - B. There is no procedure for how often the Servomex should be calibrated by the factory or internally. Initially, the Servomex was factory calibrated on March 10, 1995 and April 6, 1996 and there were no internal calibration records. There is no documentation to show/justify why the Servomex was not factory calibrated or internally calibrated from April 6, 1996 to April 14, 1998.
 - C. Drying tubes were not used with the Servomex 570A as indicated in the equipment operating manual.
3. Your firm lacks approved written procedures regarding the labeling and release of compressed oxygen, USP. There were also no procedures on the responsibilities of the Quality Control unit.
4. Your firm lacks documentation to show that transfilling records were reviewed.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the good manufacturing practice regulations. Until these violations are corrected, Federal agencies will be informed that Food and Drug Administration recommends against the award of contracts for affected products.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. These include seizure and/or injunction.

Community Surgical Supply
Toms River, NJ 08755

August 4, 1998

Should your firm have additional comments concerning the FDA-483 or the above points, it should notify this office in writing, within 15 working days of receipt of this letter. Your reply should be sent to the Food and Drug Administration, 10 Waterview Blvd., 3rd Floor, Parsippany, New Jersey 07054, Attention: Diane E. Boucher, Compliance Officer.

Very truly yours,


DOUGLAS I. ELLSWORTH
District Director
New Jersey District Office

DEB:np