



June 29, 2000

Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863

WARNING LETTER
CHI-24-00

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

William Thieben, CEO
Kewanee Hospital Association
719 Elliot Street
Kewanee, IL 61443

Dear Mr. Thieben:

An inspection of the Kewanee Hospital Home Medical Equipment's medical gas transfilling facility, located at 125 N. Tremont Street, Kewanee, IL, was conducted on May 25, 2000, by Investigator James L. Finn. At the conclusion of the inspection, a Form FDA 483, List of Observations (FDA 483), was issued to and discussed with Mr. George E. Yatso, Director. A copy of the FDA 483 is enclosed. Medical gases are drug products as defined by Section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act).

Investigator Finn documented deviations from the Good Manufacturing Practice Regulations (cGMP) (Title 21, Code of Federal Regulations, Part 211) in conjunction with your firm's transfilling operation of Oxygen U.S.P, causing this drug product to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act). The deviations reported included:

1. Failure to perform adequate testing on each batch of drug product for conformance with final specification as required by 21 CFR 211.165(a) in that your firm does not always test at least one cylinder per manifold. For example, Investigator Finn reviewed several oxygen transfilling records and observed that the records for lot #803 (filled 1/17/00), lot #853 (filled 3/30/00) and lot #848 (filled 5/1/00) failed to indicate whether any filled cylinders were analyzed.
2. Failure to establish and follow written procedures that assure that filled Oxygen U.S.P. cylinders contain not less than 100 percent of the labeled amount, as required by 21 CFR 211.101(a). The inspection revealed that your firm does not monitor the temperature of the cylinders while they are being filled. Monitoring the temperatures while filling is needed in order to assure that the authorized pressure is not exceeded and the amount filled does not exceed the net content statement listed on the label.

3. Failure to establish and follow standards or specifications, methods of testing, and where indicated, methods of cleaning, sterilizing, and processing to remove pyrogenic properties for drug product containers and closures as required by 21 CFR 211.94(d). During the inspection, Investigator Finn observed that your firm does not calibrate its pressure, vacuum, or temperature measuring devices used to monitor conditions during the transfilling of Oxygen, U.S.P.
4. Failure of the quality control unit to review and approve all drug product production and control records, including those for packaging and labeling as required by 21 CFR 211.192. Investigator Finn reviewed several production records that showed the release of the batch despite the fact that the records failed to contain any analytical results.

We note that Investigator Finn was told that the only employees receiving training in the cGMPs were Mr. Yatso and the driver/technician. Title 21 CFR 211.25(a), requires that any employee involved in the manufacturing, filling, processing, handling, holding, or shipping of a medical drug receive cGMP training.

Neither the above identification of the violations nor the inspectional observations listed on the FDA 483 is intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence with each requirement of the Act and its implementing regulations.

You should take prompt action to correct these violations and establish procedures whereby such violations do not recur. Failure to promptly correct these violations may result in regulatory and/or administrative sanctions without further notice. These include seizure and/or injunction.

You should 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, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which corrections will be completed.

Page 3

Your response should be addressed to Richard Harrison, Compliance Director, at the address provided in the letterhead.

Sincerely,

/s/
Raymond V. Mlecko
District Director

cc: George E. Yatso, Director
Kewanee Hospital
Home Medical Equipment
125 N. Tremont Street
Kewanee, IL 61443