



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

m2363n

EB 2/10/99

Certified/Return Receipt Requested

February 10, 1999

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 LETTER

Larry Higby, President &
Chief Operating Officer
Apria Healthcare, Inc.
3560 Hyland Avenue
Costa Mesa, CA 92636

KAN #99-011

Dear Mr. Higby:

Recently an inspection was made of your medical gas transfilling operation located at 11224 Aurora Avenue, Des Moines, Iowa. This inspection was conducted on January 13, 1999, by a Food and Drug Administration Investigator from this office, 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 establish that the test procedure used to determine the strength and identity of Liquid Oxygen USP received between April 16 & 28, 1998, was equivalent or superior to the official test procedure, in that testing was performed with a [REDACTED] Model [REDACTED] Analyzer, which has an unacceptable accuracy [21 CFR 211.165(e)].
- Failure to establish adequate batch production and control records for each batch of drug product produced, including documentation that each significant step in the manufacture, processing, packing, or holding of the batch was accomplished [21 CFR 211.188(b)]. For example:

Page 2

February 9, 1999

Apria Healthcare, Inc.

- No assay/identity and purity tests performed on at least 19 lots of compressed Oxygen USP, between September 1, 1998 and January 12, 1999.
 - Production records lack data/entries required by your SOP #607-005, Filling High Pressure Cylinders From Stand Tank.
 - No calibration of the [REDACTED] Analyzer prior to performing finished product identity and purity testing on at least 21 lots of compressed Oxygen USP, between September 1, 1998 and January 12, 1999.
 - Second person review of production records between September 1, 1998 and January 12, 1999 failed to identify omissions.
- Failure to calibrate the vacuum gauge annually as required by your SOP #604-017, Measurement Equipment Scheduling of Calibration and Routine Maintenance.

This letter is not intended to be an all-inclusive list of deficiencies at your Des Moines, Iowa facility. At the conclusion of the inspection a Form FDA 483 was issued to Mr. Todd M. Heagle, Branch Manager. This is a list of the investigator's observations of GMP deviations noted during the inspection. A copy is enclosed for your information. It is your responsibility to ensure adherence to each requirement of the Act and regulations, at each medical gas facility you operate.

We have received a faxed letter dated January 15, 1999, from Ms. Catherine Mendoza, Manager Clinical Regulatory Compliance, which represents a response to the Form FDA 483 observations. The letter was taken into consideration prior to the issuance of this letter.

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.

By copy of this letter, we are advising the Health Care Finance Administration (HCFA) 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.

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.

Page 3
February 9, 1999
Apria Healthcare, Inc.

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,

Handwritten signature in cursive script that reads "Barbara Blasser" with "for" written below it.

W. Michael Rogers
District Director
Kansas City District

Enclosure - Form FDA 483

cc: Todd M. Heagle, Branch Manager
Apria Healthcare, Inc.
11224 Aurora Avenue
Des Moines, IA 50332