



U.S. FOOD AND DRUG ADMINISTRATION

NEW YORK DISTRICT

850 THIRD AVENUE, BROOKLYN, NEW YORK 11232

d1691b

Telephone: [718] 965-5300 [Ext 5301]

WARNING LETTER

CERTIFIED MAIL RETURN RECEIPT REQUESTED

Andrew J. Fleming, President
Anthony Home Health Care, Inc.
2373 Hempstead Turnpike
East Meadow, NY 11554

November 21, 1996

Ref: 19-NYK-97

Dear Mr. Fleming.

During an inspection of your home respiratory care facility conducted on October 22, 23 and 29, 1996, our investigator documented deviations from the Current Good Manufacturing Practice Regulations (Title 21, Code of Federal Regulations, Parts 210 and 211) with respect to your filling of liquid oxygen, USP into cryogenic home units. These deviations cause your drug product to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act ("the Act"). These deviations include, but are not limited to, the following:

1. Failure to establish that the test procedure used to determine the strength and identity of liquid oxygen, USP will provide test results that are equivalent or superior to the official test procedure. Your firm does not always receive valid certificates of analysis from your oxygen suppliers. The [REDACTED] oxygen analyzer that you use for the assay of incoming liquid oxygen, USP is a non-official test procedure. You have not documented its accuracy, sensitivity, specificity, and reproducibility compared to those obtained using the official test procedure.
2. Failure to document the assay of each cylinder of incoming bulk liquid oxygen, USP to determine conformance with appropriate specifications for strength and identity prior to release and filling of the liquid oxygen home units.
3. Failure to document on the driver's manifest the performance of adequate prefill inspections on each liquid oxygen home unit prior to filling, such as valves, fittings, labeling, etc.
4. Failure to have adequate written specifications and procedures for the acceptance of incoming bulk liquid oxygen, USP and for its quarantine prior to release.

5. Failure to properly calibrate the [REDACTED] oxygen analyzer used for the assay of liquid oxygen, USP in that the "standard" oxygen cylinder required to calibrate the analyzer was unlabeled and lacked a certificate of analysis from the supplier.

6. Failure to follow established written procedures for receiving and handling any complaints. For example, your firm failed to file the form referenced in its written complaint procedure in response to complaints dated May 8, April 28, and March 23, 1996.

7. Failure to have written procedures for and documentation of the maintenance and calibration of head pressure and flow gauges used in the filling of liquid oxygen home units.

Neither this letter nor the list of observations (Form FDA 483) that was presented to you at the conclusion of the inspection are meant to be an all-inclusive list of deficiencies at your firm. It is your responsibility to ensure adherence with each requirement of the Act and its regulations. Federal agencies are advised of the issuance of all warning letters about drugs so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct these violations. Failure to promptly correct these violations may result in regulatory action without further notice. Possible actions 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 the corrections will be completed.

Your reply should be sent to the Food and Drug Administration, 850 Third Avenue, Brooklyn, NY 11232, Attention: Bruce A. Goldwitz, Compliance Officer.

Sincerely,



Lillian Aveta
Acting District Director

Attachment: FDA 483 dated October 29, 1996