



DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

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Food & Drug Administration  
850 Third Avenue  
Brooklyn, NY 11232

WARNING LETTER

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

William C. Tobia  
Northeast Regional Vice President  
Home Care Supply Holdings  
700 Hicksville Road, Suite 105  
Bethpage, NY 11714

August 24, 1999

Ref: NYK-1999-65

Dear Mr. Tobia:

During an inspection of your medical oxygen filling facility located in Bethpage, New York conducted on June 22, 23, 28 and July 1, 1999, our investigator documented deviations from the Current Good Manufacturing Practice for Finished Pharmaceuticals Regulations (Title 21, Code of Federal Regulations, Parts 210 and 211). These deviations cause your liquid oxygen drug products to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act). The deviations include, but are not limited to, the following:

1. Failure to adequately test each lot of incoming liquid oxygen for both identity and strength prior to filling cryogenic home vessels (CHVs). For example, your firm relies on certificates of analysis (COAs) received from your oxygen supplier for the strength determination. However, there were no COAs available for liquid oxygen received by your firm between January 11 and April 19, 1999. Further, there was no COA available for incoming oxygen lot no. 132B902 used to fill CHVs on May 11, 1999. (For your information, acceptable methods of testing incoming liquid oxygen are discussed in the enclosed "Fresh Air '98" document.) [21 CFR 211.165(a)]
2. Failure to have written specifications for the acceptance of incoming liquid oxygen. [21 CFR 211.160(b)]
3. Failure to have complete written procedures for filling and process control of CHVs that have been reviewed and authorized by the quality control unit or a designated, responsible individual. [21 CFR 211.100]
4. Failure to include complete information relating to the filling and process control of each CHV in the batch production and control records. For example, the liquid transfill

records did not document prefill inspections prior to filling CHVs. These include, but are not limited to, inspections of the external vessel, inlet and outlet connections, volume/contents gauge, and labeling. [21 CFR 211.188]

5. Failure to have all batch production and control records reviewed and approved by a designated person with quality control responsibilities to determine compliance with all established, approved written procedures before liquid oxygen products are released or distributed. [21 CFR 211.192]

6. Failure to have written procedures for the receipt, examination, storage, issuance, and reconciliation of oxygen labels. [21 CFR 211.122 and 211.125]

7. Failure to have a written procedure for assigning distinctive lot numbers to CHVs filled on-site and stored for future delivery. [21 CFR 211.130(c)]

8. Failure to document the periodic calibration of the pressure gauges used to fill CHVs. [21 CFR 211.68(a)]

9. Failure to document the periodic calibration of the oxygen analyzers used to test CHVs filled curbside from your firm's trucks. [21 CFR 211.160(b)(4)]

10. Failure to document that each employee has been trained in current good manufacturing practices as they relate to the employee's functions. [21 CFR 211.25(a)]

11. Failure to document the qualification and acceptance of CHVs prior to release for use. [21 CFR 211.82]

In addition, the cryogenic home vessels of liquid oxygen are misbranded within the meaning of Section 502(b)(2) of the Act in that their labeling fails to contain a statement of the net quantity of contents in commonly used units of measure. [21 CFR 201.51]

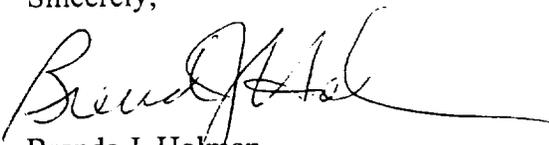
Neither the above identification of violations nor the inspectional observations (Form FDA 483) presented to you at the conclusion of the inspection (copy enclosed) is intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence with each requirement of the Act and its implementing regulations. Federal agencies are advised of the issuance of all warning letters about drug products so that they may take this information into account when considering the award of contracts. Additionally, pending Antibiotic Form 6, NDA, ANDA, or export approval requests may not be approved until the above violations are corrected.

You should take prompt action to correct these violations. Failure to promptly correct these violations may result in regulatory action without further notice. These actions include, but are not limited to, seizure and/or injunction.

You should notify this office in writing, within 15 working days after receipt of this letter, of (1) each step that has been or will be taken to completely correct the current violations and to prevent the recurrence of similar violations; (2) the time within which the corrections will be completed; (3) any reason why the corrections have not been completed within the response time; and (4) any documentation necessary to show the corrections have been achieved.

Your reply should be sent to the attention of Bruce A. Goldwitz, Compliance Officer, Food and Drug Administration, 850 Third Avenue, Brooklyn, NY 11232, Tel. (718) 340-7000 ext. 5507.

Sincerely,



Brenda J. Holman  
District Director

Enclosures: Form FDA 483 dated July 1, 1999  
"Fresh Air '98' A Look at FDA's Medical Gas Requirements"

cc: Todd Christopher, CEO  
Home Care Supply Holdings  
2155 I H Route 10 East  
Beaumont, TX 77701

cc: Judith Berek, Regional Administrator  
Health Care Financing Administration  
26 Federal Plaza, Room 3811H  
New York, NY 10278