



Food & Drug Administration
Olympic Towers, Suite 100
300 Pearl Street
Buffalo, NY 14202

December 11, 1997

WARNING LETTER BUF 98-2

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Jerry M. Jones, CEO
Apria Healthcare, Inc.
3560 Hyland Ave.
Costa Mesa, CA 92626

Dear Mr. Jones:

Inspection of your liquid oxygen manufacturing facility at 1250 Scottsville Rd., Suite 80, Rochester, New York 14624, was performed on 18-24 November 1997 by Food & Drug Administration (FDA) Investigators Russ E. Davis and Gifford Whitehurst, Jr. The inspection revealed serious violations of the Federal Food, Drug and Cosmetic Act (the Act) and regulations promulgated thereunder. At the conclusion of the inspection, George Baumann, Branch Manager, was presented with a written list (FDA-483) of objectionable conditions and practices. A copy is enclosed for your reference.

Medical oxygen processed and distributed by your firm is considered a drug within the meaning of Section 201 (g) of the Act. Your product, Liquid Oxygen USP, is considered adulterated within the meaning of Section 501 (a)(2)(B) of the Act, since the controls used for the manufacture, processing, packing or holding of this product are not in conformance with current Good Manufacturing Practice regulations for Drugs (Title 21, Code of Federal Regulations (CFR), Parts 210 and 211) as follows:

- *Failure to assay incoming liquid oxygen, from (at least) the stand tank or from every truck mounted vessel filled from the stand tank, for identity and strength for release prior to filling liquid home units [21 CFR 211.165 (a)].* Your firm does not perform an assay on a sample taken directly from the stand tank after receipt of a new delivery of bulk liquid oxygen from your supplier and prior to Transfilling Truck Mounted Vessels (TMVs) and liquid home units. Your firm operates two trucks equipped with a combined total of four TMVs and large cryogenic vessels (three of which are in service) and performs an assay on a sample collected from one of these vessels after being filled from the stand tank following a delivery of bulk liquid oxygen by your supplier. This testing addresses only the contents of the truck vessel sampled and the results cannot be correlated to the contents of the stand tank, the other truck vessels or the contents of the vessel initially tested following subsequent fillings.
- *Failure to follow written procedures relative to the collection of a sample directly from the stand tank for assay, prior to filling TMVs, after receipt of a new bulk liquid oxygen delivery [21 CFR*

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211.100 (b)]. Your firm does not perform an assay on a sample taken directly from the stand tank, prior to filling the TMVs, after receipt of a new bulk liquid oxygen delivery as required by your written procedures [REDACTED] Receipt of Medical Oxygen Supply: Stand Tank, and [REDACTED]; Transfilling to a Truck Mounted Vessel (TMV) from a Stand Tank.

-Failure to follow written procedures for assigning Apria lot numbers for liquid oxygen where more than one vessel in a truck is filled from the stand tank [21 CFR 211.130 (c)]. Your written procedure [REDACTED], Apria Assigned Lot Numbers, requires the addition of a [REDACTED] vessel identification number) to the Apria unique lot number assigned to the stand tank where more than one vessel is in a truck. Your Truck [REDACTED] is equipped with TMV [REDACTED] and VGL [REDACTED]. The lot numbers assigned to these vessels have not included the required vessel identification numbers (e.g. Both TMV [REDACTED] and VGL [REDACTED] were assigned lot [REDACTED] for the period 11/10 - 18/97, rather than lot # [REDACTED] and lot # [REDACTED] respectively).

-Failure to follow written procedures for the identification and designation of medical gas "Master Labels" and the sampling and identification of a specimen from subsequent label shipments [21 CFR 211.122 (a)]. Your written procedure [REDACTED], Label Issuance and Control, requires the Quality Control Unit person to initial and date medical gas labels designated as "Master Labels". Medical gas labels (including liquid oxygen labels) designated as "Master Labels" were not initialed and dated. Your written procedure [REDACTED] also requires the collection of a sample from subsequent label shipments for comparison to the "Master Label" for approval/rejection purposes. The sample label is to be initialed and dated by the individual approving or rejecting the shipment. A sample of a liquid oxygen label from a subsequent shipment (9/14/97) was not obtained, dated and initialed to document approval.

-Failure to follow written procedures for maintaining Label Control Log sheets [21 CFR 211.122 (a) & (c)]. Label Control Log sheets for liquid oxygen labels were noted to lack documentation of Master Label sampling and approval/rejection, subsequent shipment sampling and approval/rejection, and identification of individuals issued labels on 6/6/97 as required by your written procedures. Label Control Log sheets for medical gas name/address labels were noted to lack documentation of the date of receipt and Master Label sampling and approval/rejection.

-Inadequate training of personnel engaged in the performance and supervision of liquid oxygen transfilling operations with respect to written procedures contained in the Apria Medical Gases Manual Policies & Procedures (issued/revised 1/20/97) as evidenced by the failure to follow the aforementioned procedures [21 CFR 211.25 (a) & (b)]. Although it is documented that the Service Technicians, Distribution Supervisor (designated Quality Control Unit employee) and Branch Manager received training (3/31/97) with respect to the Apria Medical Gases Manual, it is evident through their failure to follow procedures for liquid oxygen testing, lot number assignment and label control that the training was inadequate.

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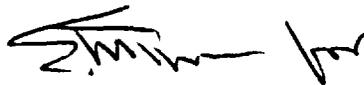
It is your responsibility to insure all drugs manufactured and distributed by your firm meet the requirements of the Act, and regulations promulgated thereunder. You should take prompt action to correct these and all violations existing at your firm. Failure to take such action may result in regulatory action, such as seizure and/or injunction, **without further notice.**

Federal agencies are advised of the issuance of all Warning Letters about drugs and devices so they may take this information into account when considering the awarding of contracts. By copy of this letter, we are specifically advising the Health Care Financing 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.

If, after reviewing this Warning Letter and the COMPRESSED MEDICAL GASES GUIDELINE (copy attached) you still have questions regarding acceptable methods for complying with these requirements, you may contact Joseph H. Erdmann at our Syracuse office (315-448-7601).

Please notify this office, in writing, within 15 days of the specific steps you have taken to correct the noted violations and to prevent a recurrence of similar violations. Your response should be directed to Joseph H. Erdmann, Team Leader, P.O. Box 7197, Syracuse, New York 13261-7197.

Sincerely,



Brenda J. Holman
District Director

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Attachments: -FDA-483
-Compressed Medical Gases Guideline
-Fresh Air '97 - A Look at FDA's Medical Gas Requirements

cc: George Baumann, Branch Manager
Apria Healthcare, Inc.
1250 Scottsville Rd., Suite 80
Rochester, NY 14624