



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

d17296 5/1/98

Food and Drug Administration  
555 Winderley Place, Suite 200  
Maitland, Florida 32751

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-98-41

April 3, 1998

Mr. Carl L. Allison, President  
Baya Home Care, Inc.  
2669 US 90 West  
Lake City, Florida 32055

Dear Mr. Allison:

Inspection of your medical gas filling operation located in St. Augustine, Florida, on March 10 and 12, 1998, by FDA investigator Julie D. Bringer, revealed serious violations of the Federal Food, Drug, and Cosmetic Act (the Act). The investigator documented significant deviations from the Current Good Manufacturing Practice (CGMP) Regulations for drugs [Title 21, Code of Federal Regulations, parts 210 and 211 (21 CFR 210 and 211)] in conjunction with the testing and release for distribution of compressed medical oxygen causing the products to be adulterated within the meaning of Section 501(a)(2)(B) of the Act.

Inspection revealed there is no assurance that your medical oxygen products meet applicable standards of identity, strength, quality, and purity in that you have failed to adequately test filled cylinders of compressed Oxygen USP for purity and identity prior to release for distribution. Testing is inadequate in that the [REDACTED] oxygen analyzer used by your firm is not being calibrated in accordance with the manufacturer's instructions prior to use. For example, industrial oxygen is being used to calibrate the device in lieu of a certified oxygen standard. In addition, purity and identity testing is not being performed on at least one filled cylinder per uninterrupted filling sequence.

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Written procedures are not established for production and process controls designed to assure that your medical oxygen products have the identity, strength, quality, and purity they are represented to possess. For example, no written procedures are established for completion of batch production records, calibration and maintenance of equipment, labeling, quarantine, distribution, and training. No documentation is available to show that personnel have been adequately trained in the duties they perform.

Batch production records are not being completed concurrently with the operations being performed. The investigator observed 15 cylinders of compressed Oxygen USP filled on March 10, 1998, with batch production records that were not completed documenting that each significant step in the manufacturing operation was accomplished, such as all required pre and post fill cylinder inspections and testing of finished product. In addition, no documentation is available to show that batch production records are reviewed and approved by a supervisor prior to release.

We acknowledge receipt of an undated and unsigned letter from your St. Augustine facility submitted to this office in response to the Inspectional Observations (Form FDA 483) issued to and discussed with your branch manager, Brian S. Kaman, at the close of the inspection, addressing the observations and stating corrective actions taken. We consider this response to be inadequate in that examples of new or revised written procedures and other documentation (e.g. receipt of calibration gases, revised calibration and batch record, training record, etc.) to support the stated corrective actions were not provided for review, and no time frames for completion of the stated corrective actions were provided. This response does not alleviate our concerns regarding the violations documented during the inspection.

Other Federal agencies are routinely advised of Warning Letters issued so that they may take this information into account when considering the award of contracts. Additionally, pending application for agency approval (NDA, ANDA, SNDA, etc.) or export approval request may not be approved.

In order to facilitate the Food and Drug Administration (FDA) in making the determination that such corrections have been made and thereby enabling FDA to withdraw its advisory to other Federal agencies concerning the award of government contracts, and to resume review of any pending applications, we request that you notify this office when corrective actions are completed and you believe your facility is in compliance with the CGMP regulations so that a verification inspection can be scheduled.

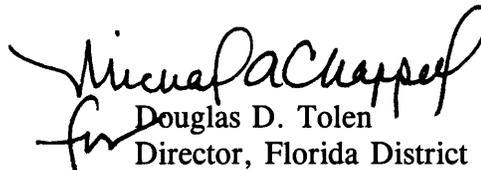
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The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure that all medical gas products you repack and distribute are in compliance with the Act and the requirements of the CGMP Regulations. You should take prompt action to correct these violations. Failure to correct these violations may result in regulatory action, including seizure and/or injunction, without further notice.

We request that you notify this office in writing, within 15 working days of receipt of this letter, of specific steps you have taken to correct these violations. Your response should include appropriate documentation to support the corrective actions taken. If corrections cannot be completed within 15 working days, state the reason for the delay and the time frame within which corrections will be completed.

Your reply should be directed to Jimmy E. Walthall, Compliance Officer, U.S. Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, telephone (407) 475-4731.

Sincerely,

  
Douglas D. Tolen  
Director, Florida District

cc: Mr. Brian L. Kaman  
Baya Home Care, Inc.  
105 Southpark Blvd., A101  
St. Augustine, Florida 32086