



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Atlanta District Office
60 Eighth Street N.E.
Atlanta, GA 30309

Telephone: 404-253-1161
FAX: 404-253-1202

March 7, 2001

VIA FEDERAL EXPRESS

Charles W. Barnes III
Owner
Barnes Health Care Services
200 S. Patterson Street
Valdosta, GA 31601

WARNING LETTER
(01-ATL-29)

Dear Mr. Barnes:

Investigators Jackie M. Douglas and Patricia F. Hudson conducted an inspection of your medical oxygen transfilling facility on 2/12-14/01. Our investigators documented significant deviations from the Current Good Manufacturing Practice Regulations (GMPs) as set forth in Title 21 of the Code of Federal Regulations (21 CFR), Part 211. These deviations cause your transfilled drug product, Oxygen USP, to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act).

You have failed to assure that all medical oxygen transfilled and distributed by your facility conforms to appropriate final specifications prior to release. No purity and identity test results are recorded for transfilled lots 090700H and 120400C. You have failed to always document the calibration of the [REDACTED] analyzer prior to being used to perform testing of lots of Oxygen USP prior to distribution. Transfilling of Oxygen USP took place on the following dates 2/1/01, 1/29/01, 1/12/01, 11/17/00, 10/30/00, 10/26/00, 9/22/00 and 9/20/00; however there is no corresponding record to indicate calibration of the [REDACTED] Analyzer on each of these dates.

You failed to maintain adequate batch production and control records for each batch of Oxygen USP produced, including documentation that each significant step in the manufacture, processing, packing or holding of the batch was accomplished. For example, batch record for 12/19/00 contains only partial entries to indicate production of a lot, but the record fails to show complete production documentation. No explanations were recorded when entries in the batch records were marked through. Batch records for lot numbers 010501E/F contain check marks instead of the actual filling temperatures of the cylinders. Also, batch records for lots 011001E, 110900C, and 09300A fail to include the serial numbers of the Oxygen USP tanks, which were tested for purity and identity. Batch records did not always contain the lot numbers of the "H" tanks used in transfilling, for example on 9/20/00, 9/22/00 and 9/26/00.

All drug production and control records were not being reviewed and approved by a responsible individual prior to batch release. A review by a responsible individual should have detected many of the record keeping deficiencies noted in the batch records and calibration records.

You failed to establish written procedures designed to assure that correct labels and labeling are used, including identification of the drug product with a lot or control number that permits determination of the history of the manufacture and control of the batch. For example, the firm's written prefill procedures for label inspection do not specifically address the removal of old labels and/or lot numbers found on cylinders. Our investigators observed 16 cylinders, which were labeled with the name of more than one responsible firm. Two "D" cylinders were noted labeled with more than one lot number (your firm's lot number and a previous manufacturer's lot number). The presence of old labels and failure to remove the old labels during the required prefill checks was also noted during the previous inspection of your facility.

You failed to exercise strict controls over labeling issued for use in drug labeling operations. For example, your most recent entry on the label control record is dated 9/7/00, but the batch records for lots 121900A/B/C indicate 15 labels were issued and used on 12/19/00.

You failed to maintain training documentation for all employees performing Oxygen USP activities. You do not have written procedures for training. Employees in training reportedly can only perform transfilling operations under direct supervision, however there was no documentation to indicate this is actually being done.

You failed to adequately calibrate the manifold pressure gauge, the vacuum gauge, and the thermometer. Your maintenance procedure requires the yearly replacement of the manifold pressure gauge and the vacuum gauge (in lieu of calibration). Your records indicate these gauges were replaced on 2/7/01. Prior to this date, records indicate that the pressure gauge was last replaced in 1997 and vacuum gauge in 1996. Neither of these gauges is labeled with replacement dates as required by your maintenance procedure. Your firm was unable to produce any purchase records documenting the instrument replacement between 1996/97 and 2001. Your procedure also does not address the calibration and/or replacement of the thermometer or a daily check of the vacuum gauge. Inadequate documentation of instrument calibration/exchange was also cited during our previous inspection.

Your product, Oxygen USP, is misbranded within the meaning of section 503(b)(4)(A) of the Act in that the label on your Oxygen USP cylinders does not bear the statement "Rx only" or equivalent.

At the conclusion of the inspection, our investigators issued the Inspectional Observation (FDA 483), and discussed the findings with Mr. Robert L. Steedley Jr., Chief Operating Officer. A copy of this FDA 483 is enclosed for your review. Neither the above discussion of deficiencies, nor the FDA 483, should be construed as an all-inclusive list of violations that may be in existence at your facility. It is your responsibility to ensure that all requirements of the Act are met at this facility and any other similar operations under your authority.

You should take immediate action to correct these violations. Failure to promptly correct these deviations may result in legal sanctions provided by the law such as product seizure and/or injunction, without further notice to you. Federal agencies are advised of the issuance or warning letters involving drugs so that they may take this information into account when considering the awards on contracts.

You are requested to notify this office within fifteen (15) working days of receipt of this letter of all steps you have taken, or intend to take, 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 corrections will be completed.

We are in receipt of a letter from Ms. Elena K. Sant, Operations Manager dated February 20, 01. We are currently reviewing Ms. Sant's response. You may refer to Ms. Sant's letter in your response to this warning letter.

Your response should also address any proposed actions regarding any oxygen lots currently in distribution, which were not properly documented. Your response should be addressed to Serene A. Kimel, Compliance Officer, at the address noted in the letterhead. You can also contact Compliance Officer Kimel at 404-253-1296 if you have any questions about this letter.

Sincerely,

A handwritten signature in black ink, appearing to read "Ballard H. Graham". The signature is fluid and cursive, with a long horizontal stroke at the end.

Ballard H. Graham, Director
Atlanta District

Enclosure

Cc: Mr. James L. Steedley, Jr.
Chief Operating Officer
Barnes Health Care Services
P.O Box 160
Valdosta, GA 31603