



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Atlanta District Office

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HCI-35

60 8th Street, N.E.
Atlanta, Georgia 30309

December 23, 1996

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Hubert F. Chancy, Jr., President
Chancy Oxygen Service, Inc.
205 1/2 E. Main Street
Mableton, GA 31632

WARNING LETTER

Dear Mr. Chancy:

An inspection of your medical oxygen transfilling facility was conducted on November 19 - 20, 1996, by investigators B. Douglas Brogden and Jackie M. Douglas. Our investigators documented numerous 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).

The following deviations were observed:

1. You have failed to assure that all compressed medical oxygen transfilled and distributed by your facility conforms to appropriate specifications for purity prior to release. Your failure to calibrate the ~~XXXXXXXXXX~~ Oxygen Analyzer renders invalid all % purity results obtained with this instrument. Moreover, you distributed product labeled as Oxygen, USP, which according to your own results, had failed to meet the 99.0% purity limit as established in the current edition of the United States Pharmacopeia.
2. You have failed to establish and/or implement written procedures covering production records, equipment calibration, testing, recalls, and labeling. For example:
 - a) There were no adequate written procedures for the calibration, and operation of the ~~XXXXXXXXXX~~ Oxygen Analyzer.
 - b) Your firm has not calibrated the various measuring equipment used in the transfilling operation such as pressure gauges, the vacuum gauge, and the thermometer used for monitoring the filling temperatures of cylinders.

c) The written procedure for filling out the batch production record is incomplete in that steps 5 through 7 fail to specify how certain portions of the record will be documented, specifically, the use of the unfinished phrase "place a _____ ...". In addition, step 8 of this procedure dealing with the maintenance of a label inventory has not been implemented.

d) A written recall procedure has not been established.

e) Labels containing old lot/batch numbers and/or other non-current information are not always removed from the cylinders, during the prefill inspection, as required by your written prefilling policy.

f) Failure to follow the firm's written labeling policy concerning the assigning of lot numbers to filled cylinders.

3. You have failed to perform certain required tests during the prefill, fill, and postfill operations, as follows:

a) Failure to use a leak-detecting solution to test for leaks during the prefill and postfill operations.

b) Failure to adequately check the hydrostatic test dates to assure the specified time limit has not expired. During the inspection, our investigators found four "E" cylinders in the "full" rack (available for distribution) bearing expired hydrostatic test dates.

4. Your records lack documentation which demonstrates that your employees have received adequate training on the equipment and procedures used in your operation, including training on current good manufacturing practice as it relates to their functions.

In addition, your product is misbranded in accordance with Section 502(o) of the Act, in that the drug was transfilled in an establishment not duly registered under Section 510, and the drug has not been listed as required by Section 510(j). Mr. Bert A. Chancy, Manager, was provided with registration and listing forms by the investigators.

Our investigators observed several Oxygen USP cylinders which were available for distribution, and which lacked required labeling such as a net contents statement and adequate directions for use. These drug products are misbranded in accordance with Section 502(b)(2) and Section 502(f)(1) of the Act.

At the conclusion of the inspection, investigators Douglas and Brogden issued their Inspectional Observations (FDA 483), copy enclosed, to Mr. Bert A. Chancy, Manager & Vice President, and discussed their findings with him and with Mr. Jeffrey Patton. 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 firm. It is your responsibility to ensure that all requirements of the Act are being met at this facility and any other similar operation under your authority.

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

You are requested to notify this office within fifteen (15) days of receipt of this letter of all steps you have taken, or intend to take, to correct these violations. Your response should address any proposed actions regarding any oxygen cylinders currently in distribution which have not been properly tested, and any determination on whether you plan to continue transfilling. We acknowledge Mr. Bert A. Chancy's decision to voluntarily cease transfilling operations until the firm can be brought into compliance. Your response should be addressed to Carlos A. Bonnin, Compliance Officer, at the address noted in the letterhead.

Sincerely yours,

for 
Ballard H. Graham, Director
Atlanta District

Enclosure