



DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

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One Montvale Avenue
Stoneham, Massachusetts 02180
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WARNING LETTER

NWE-28-01

June 22, 2001

Via Fed-EX

Mr. Mark Sheehan
President
Cape Medical Supply, Inc.
28 Jan Sebastian Drive
Sandwich, MA 02563

During an inspection of your medical oxygen filling facility located in Sandwich, MA conducted on May 21, 29 and 31, 2001, our investigator documented significant deviations from the Current Good Manufacturing Practice (cGMP) for Finished Pharmaceuticals Regulations (Title 21, Code of Federal Regulations, Part 210 and 211). These deviations cause your 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 establish adequate batch production and control records of each batch of drug product produced. These records should document that each significant step in the manufacture, processing, packing and holding of the batch was accomplished as required by 21 CFR 211.188 (b). For example:
 - (a) there were no batch production records for the filling of cryogenic home vessels at your firm or curbside at residences.
 - (b) batch production record documentation for the filling of high pressure tanks does not appear to be accurate or reliable in that the identity and purity test results and the temperatures of tanks during filling are not actual observed values recorded from equipment such as the Oxygen analyzer and thermometers.
 - (c) batch production record documentation of the prefill inspections of labeling does not appear to be accurate or reliable in that the FDA investigator made numerous observations of inadequate labeling of Oxygen tanks.

- (2) Failure to properly calibrate the [REDACTED] oxygen analyzer used for the assay of Oxygen, USP as required by 21 CFR 211.160 (b) (4). For example, the analyzer is not calibrated in accordance with the manufacturer's directions. In addition, the nitrogen and oxygen calibration gases used for calibrations are not adequate. The nitrogen calibration gas expired on 12/4/00 according to the certificate of analysis. The concentration of the oxygen calibration gas used by your firm is too low in that according to the certificate of analysis, the assay result of [REDACTED] oxygen and a certified high purity oxygen [REDACTED] is required for calibration.
- (3) Failure to adequately test or take other appropriate measures to assure the quality and potency of Oxygen, U.S.P. as required by 21 CFR 211.165(a) in that your firm does not periodically verify the reliability of the supplier's analysis of incoming product.
- (4) Failure to document that each employee engaged in the manufacture, filling, processing, holding, or shipping of your oxygen products is trained in the particular operations that the employee performs and in current good manufacturing practices as it relates to the employee's functions as required by 21 CFR 211.25 (a).
- (5) Failure to follow your firm's own written procedures as required by 21 CFR 211.100 (b). During the inspection, our investigator observed numerous examples where your personnel did not follow written policies and procedures.
- (6) Failure to establish written procedures addressing a calibration schedule for all equipment used during its operation as required by 21 CFR 211.68(a). During the inspection, the investigator observed that your firm does not calibrate its pressure, vacuum or temperature measuring devices used to monitor conditions during the transfilling of Oxygen, U.S.P.

Your product, Oxygen U.S.P., is misbranded within the meaning of section 503(b)(4)(A) of the Act in that it was noted during the inspection that several high pressure tanks filled by the firm did not bear either the statement "For emergency use only when administered by properly trained personnel for oxygen deficiency and resuscitation. For all other medical applications, RX only" or the statement "Caution: Federal law prohibits dispensing without a prescription." In addition, your product, Oxygen U.S.P., is misbranded within the meaning of section 502(b)(2) of the Act in that its labeling fails to contain a statement of the quantity of the contents.

The June 8, 2001 letter from you responding to the list of inspectional observations (Form FDA 483) has been reviewed. This response is less than fully adequate in that it does not address all of the cGMP deficiencies noted during the inspection, such as your failure to follow written procedures, completion of batch production records and calibration of the oxygen analyzer.

Neither the above identification of CGMP violations nor the inspectional observations (Form FDA 483) presented to you at the conclusion of the inspection 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, 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.

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 injunction.

These deviations from the GMP regulations are significant and concern us greatly. We are therefore scheduling a meeting for June 29, 2001 at 10:00 A.M. at the Food and Drug Administration, One Montvale Avenue, 4th Floor, Stoneham, MA 02180. We are requesting that you attend this meeting to discuss your medical oxygen transfilling operation and what changes you will make to ensure that your medical oxygen is processed in accordance with cGMP regulations. You should be prepared to provide the following information: (1) each step that has been or will be taken to completely correct the current violations and to prevent the recurrence of similar violation; (2) the time within which the corrections will be completed; and (3) any documentation necessary to show the corrections have been achieved.

Please confirm your attendance at this meeting with Patricia Murphy, Compliance Officer, Food and Drug Administration, One Montvale Avenue, 4th Floor, Stoneham, MA. If you have any questions concerning this matter, please contact Mrs. Murphy at 781-279-1675 ext. 1660.

Sincerely,



Gail T. Costello
Director
New England District