



Food and Drug Administration
Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
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WARNING LETTER

WL-CIN-11986-02

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

January 23, 2002

Carl A. Mulberry, President
Columbus Medical Equipment
306 East 5th Avenue
Columbus, OH 43201

Dear Mr. Mulberry:

FDA Investigators conducted an inspection of your home respiratory care facility located at 306 E. 5th Avenue, Columbus, OH on November 8 and December 7, 11 and 12, 2001. During the inspection, our investigators documented serious deviations from current Good Manufacturing Practices found in Title 21 Code of Federal Regulations, Part 211 for the filling of liquid oxygen. These deviations cause your medical oxygen to be adulterated within the meaning of section 501 (a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act).

The specific deviations included the following:

The failure to adequately test the product for identity and strength (21 CFR, Part 211.165(a)). You rely on the Certificate of Analysis provided by your oxygen supplier however you do not witness the testing and you do not perform any purity testing of each load.

Batch production records do not contain complete information relating to the production and control of each batch (21 CFR, Part 211.188). For example, there is no documentation that an external vessel inspection, a gauge inspection, or a label inspection were conducted.

There are no established written procedures documenting the responsibilities of the quality control unit (QCU) (21 CFR, Part 211.22).

There are no established written procedures detailing training required by employees. Also, there is no documentation that employees received training in cGMPs (21 CFR, Part 211.25).

Written procedures for production and process control are not complete (21 CFR, Part 211.100). For example, there are no established written procedures specifying how to perform filling of cryogenic vessels, and how to complete the proper examination and testing of cryogenic vessels.

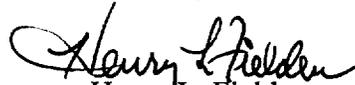
The above-described violations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that you adhere to all current regulations applicable to your operations.

Until these violations are corrected, Federal agencies will be informed that FDA recommends against award of contracts for affected products.

You should take prompt action to correct these violations. Failure to achieve prompt correction may result in regulatory action without further notice. These actions include seizure and/or injunction. Please advise us in writing within fifteen (15) working days of receipt of this letter of the specific actions you are taking to correct these violations. Your response should explain each step you have taken to correct the noted violations, including steps taken to prevent recurrence of similar violations. Include any documentation showing these corrections. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to the U.S. Food and Drug Administration, 6751 Steger Drive, Cincinnati, Ohio 45237-3097, to the attention of Stephen J. Rabe, Compliance Officer. Any questions regarding this letter may be directed to Mr. Rabe at telephone (513) 679-2700, extension 167.

Sincerely,


Henry L. Fielden,
District Director