



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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 Food and Drug Administration
 Cincinnati District Office
 Central Region
 6751 Steger Drive
 Cincinnati, OH 45237-30977
 Telephone: (513) 679-2700
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July 8, 1999

WARNING LETTER
CIN-WL-99-293

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Robert J. Maher, CEO
 Our Lady of Bellefonte Hospital Inc.
 100 St. Christopher Drive
 Ashland, KY 41101

Dear Mr. Maher:

The Food and Drug Administration conducted an inspection of your liquid and gaseous oxygen USP transfilling facility Bellefonte Health Enterprises, Inc., doing business as ABLS Home Medical Supplies, located at 1700 Winchester, Ashland, KY 41101 on June 8, 1999. Our investigator documented significant deviations from the Current Good Manufacturing Practice Regulations for Finished Pharmaceuticals (Title 21 Code of Federal Regulations [CFR] Parts 210 and 211). These deviations cause your 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 deviations documented during the inspection included:

1. The oxygen cylinder and the nitrogen cylinder used to calibrate the oxygen analyzer were not certified standards.
2. Failure to maintain complete and satisfactory liquid and gaseous transfilling records as follows:
 - a. Some batch records were not reviewed and approved by management from one to three months after transfilling.
 - b. Two gaseous batch records showed no product analysis and two had no approval signature.
 - c. Eight liquid oxygen batch records showed the assay was not witnessed after the Vehicle Mounted Vessel was filled at the supplier.
 - d. Seven liquid oxygen batch records which were not signed and approved by management.
3. Standard Operating Procedures are either outdated or do not correctly cover all of the transfill operations as follows:
 - a. The oxygen analyzer calibration Standard Operating Procedure is outdated because it calls for the analyzer zero to be set with ambient air rather than a certified nitrogen standard.
 - b. The Standard Operating Procedures for gaseous Oxygen transfilling does not include the first leak check and step #18 calls for an analysis of the first tank of the fill cycle, which is described as one day's production, rather than from each uninterrupted filling sequence.

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 requirements of the Act and regulations promulgated thereunder are being met.

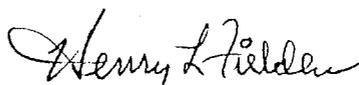
Federal agencies are advised of the issuance of all Warning Letters about drugs so that they may take this into account when considering the award of contracts. By copy of this letter, we are advising the Health Care Facility Administration (HCFA) that our inspection of your firm revealed significant 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 deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by FDA without further notice. These actions include seizure and injunction.

Please notify this office with fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct the noted violations including an explanation of each step being taken to prevent the recurrence of similar violations. If correction action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to The Food and Drug Administration, Compliance Branch, 6751 Steger Drive, Cincinnati, Ohio 45239 to the attention of Lawrence E. Boyd, Compliance Officer.

Sincerely,



Henry L. Fielden
District Director
Cincinnati District

cc: Melissa K. Law
Assistant Director
ABLS Home Medical Supplies
1700 Winchester Avenue
Ashland, KY 41101

Health Care Finance Administration
101 Marietta Tower, Suite 702
Atlanta, GA 30323
Attn: Mr. William Lyons