



DEPARTMENT OF HEALTH AND HUMAN SERVICES

HFD-35

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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 20, 1999

**WARNING LETTER**  
**CIN-WL-99-303**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Mr. Glenn Fisher, President  
BOC Group, Inc.  
575 Mountain Avenue  
Murray Hill, NJ 07974

Dear Mr. Fisher:

On June 8-11, 1999, the Food and Drug Administration conducted an inspection of your Oxygen U.S.P. air and liquid transfilling plant at 4534 Bishop Lane, Louisville, KY.

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 U.S.P. 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. Failure to calibrate the oxygen analyzer to zero each day of production. The analyzer is directly adjacent to the warehouse door. The analyzer would be exposed to temperature fluctuations.
2. On some transfilling records, the review by management is from 2 to 5 days later and would be after the product is released.
3. Failure to record the daily zero check of the vacuum gages.
4. Failure to perform a final odor test on the filled cylinder that is tested from each lot.

We acknowledge receipt of the July 6, 1999 letter and attachments from Debbie Capuano, Manager, FDA Compliance, which was sent in response to the FDA-483, Inspectional Observations issued at the close of the June 8-11, 1999 inspection. We agree with her response to Points #2, #3 and #4. We disagree with her response to Point #1. It is current Center for Drug Evaluation & Research policy that calibration of analyzer zero step at weekly intervals may be appropriate if the transfiller can document that the instrument had not been moved and that the temperature of the area where the analyzer is kept did not fluctuate more than 10°C/18°F. A copy of the Human Drug CGMP Notes (December 1995) with the Policy Question is attached.

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 they may take this into account when considering the award on contracts. By copy of this letter, we are advising the Health Care Finance 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 products 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 corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the correction will be completed.

Your response should be sent to the Food and Drug Administration, Compliance Branch, 6751 Steger Drive, Cincinnati, Ohio 45237 to the attention of Lawrence E. Boyd, Compliance Officer.

Sincerely,

  
Henry L. Fielden  
District Director

cc: Joseph A. Hardman, Plant Manager  
BOC Group, Inc.  
4534 Bishop Lane  
Louisville, KY 40218

Health Care Finance Administration  
101 Marietta Tower  
Suite 702  
Atlanta, GA 30323