



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Public Health Service
Food and Drug Administration
CINCINNATI DISTRICT OFFICE

1141 Central Parkway
Cincinnati, OH 45202-1097

June 4, 1998

WARNING LETTER
CIN-WL-98-297

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Carl C. Barker, President
Carl's Commercial Gases
368 Terry Boulevard
Louisville, KY 40229

Dear Mr. Barker:

The Food and Drug Administration conducted an inspection of your liquid and gas oxygen transfilling facility on May 14 & 15, 1998. Our investigator documented significant deviations from the Current Good Manufacturing Practice Regulations for Finished Pharmaceuticals (Title 21 Code of Federal Regulations [CFR] Parts 210 & 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:

- ▶ Failure to establish and maintain signed, dated & written procedures covering:
 - the establishment of a quality control unit; testing intervals and procedures used for analytical testing; employee training procedures; calibration and maintenance of the pressure gauge, vacuum gauge and thermometer; assignment and determination of lot numbers; and procedures for warehousing/distribution, recalls and complaints.
- ▶ Failure to establish and maintain master production and control records.
- ▶ Failure to perform the following quality control checks prior to filling high pressure cylinders:
 - examination of cylinder markings; external examination of cylinders; odor test during venting; hammer test on steel cylinders; check of valve assembly; cylinders color (green); and vacuum evacuation.
- ▶ Failure to perform the following quarterly control checks prior to filling large cryogenic vessels; external examination of vessel:
 - examination of inlet and outlet connection; volume or contents gage and content - condition of the labels.

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 of 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

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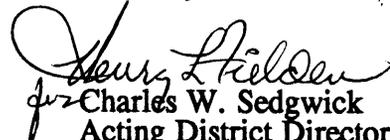
for any health care products in violation of state or federal law.

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 in writing within 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 corrections will be completed.

Your response should be sent to the Food and Drug Administration, Compliance Branch, 1141 Central Parkway, Cincinnati, Ohio 45202 to the attention of Lawrence E. Boyd, Compliance Officer.

Sincerely,


for Charles W. Sedgwick
Acting District Director
Cincinnati District

LEB/jp

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

Enclosure