



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

m49027

Food and Drug Administration
New Orleans District Office
6600 Plaza Drive, Suite 400
New Orleans, LA 70127

December 8, 2000

SENT VIA FEDERAL EXPRESS

Garrett
12/11/00
JWA

Mr. John L. Walsh
President, Tonnage and
Applied Gas Solutions
BOC Gases
575 Mountain Avenue
Murray Hill, NJ 07974

WARNING LETTER - 01-NSV-08

Dear Mr. Walsh:

During an inspection of your liquid carbon dioxide, USP, manufacturing facility located at 1040 Industrial Drive, Cherokee, Alabama on November 13-17, 2000, our investigator documented deviations from the Current Good Manufacturing Practice Regulations (CGMP's), Title 21, Code of Federal Regulations, Part 211, which cause the liquid carbon dioxide manufactured at the facility to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act).

Our inspection revealed: failure to have a baseline on contamination of carbon dioxide feedgas, failure to perform residual content testing on each tanker trailer, failure to perform complete USP testing on each full tanker trailer, no Quality Control Unit, no validation of the autoload transfilling system, inadequate employee training in CGMP's and incomplete Standard Operating Procedures.

The above identification of violations is not intended to be an all-inclusive list of deficiencies. It is your responsibility to ensure adherence to each requirement of the Current Good Manufacturing Practice Regulations. Until the violations are corrected, federal agencies will be informed that FDA recommends against the award of contracts for the affected product.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action, including seizure and/or injunction, without further notice.

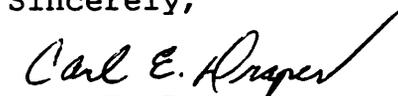
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Please notify this office in writing within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations.

If corrections 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 reply should be directed to the attention of Joseph E. Hayes, Compliance Officer, Food and Drug Administration, 297 Plus Park Boulevard, Nashville, Tennessee 37217.

Sincerely,



Carl E. Draper
Director, New Orleans District

Enclosure: 21 CFR Part 211

Cc: Robert K. Leopard
Process Operations Manager
BOC Gases, Inc.
1040 Industrial Drive
Cherokee, AL 35616