



DEPARTMENT OF HEALTH AND HUMAN SERVICES.

587 HFI-35
(Purgdcww) 12/1/97
FOOD AND DRUG ADMINISTRATION

4298 Elysian Fields Avenue
New Orleans, LA 70122-3896
Telephone (504) 589-7166
Fax (504) 589-4657

November 20, 1997

WARNING LETTER NO. 98-NOL-05

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Jim Doerr, President
MG Industries
3 Great Valley Parkway
Malvern, PA 19355

Dear Mr. Doerr:

During an inspection of your manufacturing facility, located at 2745 Houston River Road, Westlake, Louisiana 70669, on October 8 and 10, 1997, our investigator documented deviations from the Current Good Manufacturing Practices (CGMP) regulations, Title 21, *Code of Federal Regulations*, Parts 210 and 211. These deviations cause your drug products, medical bulk liquid oxygen and nitrogen, to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act.

Our inspection revealed the following CGMP deviations:

- (1) Failure to produce documented evidence to demonstrate the [REDACTED] used to test the purity and identity of the oxygen provides equivalent or greater results to those of the official USP test method.
- (2) Failure to produce documented evidence to demonstrate the [REDACTED] Analyzer used to test nitrogen provides equivalent or greater results to those of the official USP test method.
- (3) Failure to calibrate the [REDACTED] at intervals required by your Standard Operating Procedure (SOP).
- (4) Failure to produce documented evidence to demonstrate the computer controlled/automated system for the manufacturing of liquid oxygen and nitrogen has been validated.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the Current

Good Manufacturing Practices regulations. Federal agencies are advised of the insurance of all warning letters about drugs and devices so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. This may include seizure and/or injunction. This warning letter will serve as official notice that FDA expects all locations to be in compliance with the Federal Food, Drug and Cosmetic Act.

You should notify this office in writing, within 15 working days of receipt of this letter, of the 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 15 working days, state the reason for this delay and the time within which the corrections will be completed.

Your response should be directed to Carolyn W. White, Compliance Officer, U. S. Food and Drug Administration, 4298 Elysian Fields Avenue, New Orleans, Louisiana, 70122-3848, telephone number 504-589-7166. Should you have any questions concerning the contents of this letter, or if you desire a meeting with the agency staff, do not hesitate to contact Ms. White.

Sincerely,



James E. Gamet
District Director
New Orleans District Office

/ker

Enclosure: FDA-483

cc: Mr. Louis A. Neiman
Plant Manager
MG Industries
2745 Houston River Road
Westlake, LA 70669