



HFI-35 744 12/30/97
DEPARTMENT OF HEALTH AND HUMAN SERVICES, FOOD AND DRUG ADMINISTRATION

4298 Elysian Fields Avenue
New Orleans, LA 70122-3896
Telephone (504) 589-7166
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December 18, 1997

WARNING LETTER NO. 98-NOL-10

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Edward Driscoll Shaw III, President
Shaw Oxygen Co., Inc.
2914 DeSiard Street
Monroe, Louisiana 71201

Dear Mr. Shaw:

During an inspection of your manufacturing facility, located at 2914 DeSiard Street, Monroe, Louisiana, conducted on November 20-22, 1997, our investigator documented deviations from the Current Good Manufacturing Practice (CGMP) regulations. These deviations cause your drug products, liquid oxygen and USP compressed oxygen, to be adulterated within the meaning of Section 502(a)(2)(B), in that the controls used for the manufacture, processing, packing, or holding of these products are not in conformance with Current Good Manufacturing Practice regulations (Title 21, *Code of Federal Regulations*, Part 210 and 211).

Our inspection revealed the following CGMP deficiencies:

1. Failure to properly calibrate the Servomex oxygen analyzer used for the assay of oxygen, in that your firm did not follow the manufacturer's instructions nor zero the meter before use;
2. Failure to assay the bulk liquid oxygen, filled cylinders and cryogenic vessels for identity and strength prior to release;
3. Failure to date the oxygen purity test logs with the actual date of review;
4. Failure to attach the firm's approved USP oxygen label on the 41 liter cryogenic vessels before release and distribution;
5. Failure to have a USP oxygen master label on file with a responsible individual's signature and date of approval.

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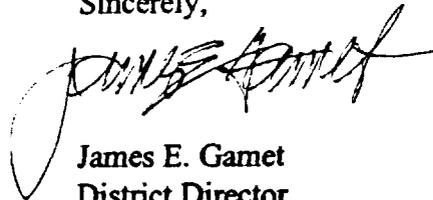
The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the Current Good Manufacturing Practice regulations. Federal agencies are advised of the issuance of all warning 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.

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 can not 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 S. Olsen, Compliance Officer, U.S. Food and Drug Administration, 4298 Elysian Fields Avenue, New Orleans, Louisiana 70122-3896. Should you have any questions concerning the contents of this letter, or if you desire a meeting with the Agency staff, you may contact Ms. Olsen at telephone number (504) 589-7166.

Sincerely,



James E. Gamet
District Director
New Orleans District

Enclosure: FDA-483

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