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DEPARTMENT OF HEALTH & HUMAN SERVICES  
Food and Drug Administration  
New England District

Food and Drug Administration  
One Montvale Avenue  
Stoneham, Massachusetts 02180  
(617)279-1675 FAX: (617)279-1742

June 23, 1997

**WARNING LETTER**

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

NWE-08-97W

Bruce Albiston, Owner & President  
Maine Oxy-Acetylene Supply Co.  
#2 Adams Street  
Auburn, Maine 04210

Dear Mr. Albiston:

During an inspection of Maine Oxy-Acetylene Supply Co., Brewer, Maine, conducted on June 5, 6, and 11, 1997, our Investigator determined that liquid and gaseous oxygen are being transfilled and distributed. Compressed medical gases, including both liquid and gaseous medical oxygen, are drugs as defined by Section 201(g) of the Federal Food, Drug and Cosmetic Act (the Act).

This inspection revealed that the liquid and gaseous medical oxygen being transfilled and distributed by your firm are adulterated within the meaning of Section 501(a)(2)(B) of the Act, in that the controls used for the manufacture, processing, packing or holding of these products are not in conformance with the current good manufacturing practice regulations (cGMPs) Title 21, Code of Federal Regulations (21 CFR), Parts 210 and 211, such as:

1. Failure to assay filled cryogenic vessels of medical liquid oxygen for identity and strength prior to release, in that from January 1, 1997 through May 31, 1997 you only had records for performing this assay for the dates of February 25, 27, and March 3, 1997. Your Standard Operating Procedure (SOP) No. 104 requires every dewar (VGL) to be assayed for purity.
2. Failure to perform adequate prefill, fill and postfill operations on each liquid oxygen cryogenic vessel, in that from January 1, 1997 through May 31, 1997, you only had records for performing these operations for the dates of February 25, 27, and March 3, 1997. Your Standard Operating Procedure (SOP) No. 104 requires you to perform these operations on every dewar (VGL).
3. Failure to perform adequate prefill, fill and postfill operations on each high pressure gas cylinder, in that your records are inaccurate and/or incomplete. Your SOP No. 100 requires you to perform these operations on every cylinder.

4. Failure to adequately calibrate the oxygen analyzer in that there is only one record (April 19, 1997) of: a) zeroing of the oxygen analyzer with nitrogen and b) check of the pressure of the oxygen calibration cylinder. Your SOP No. 110 requires you to perform these steps weekly. Also, there is only one record of the calibration of two thermometers (22407 and 22501) done on February 20, 1997.

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 adherence to each requirement of the Good Manufacturing Practice Regulations. Federal agencies are advised of the issuance of all Warning Letters concerning drugs so that they may take this information into account when considering the award of contracts.

Also, the SOPs at your facility are not signed/approved or dated. You should have the original or copy of the signed/approved and dated Standard Operating Procedures at your facility.

SOP No. 108, "USP Cylinder Gas Labeling" states that an example of current labeling will be kept in a master label file, this is not being followed.

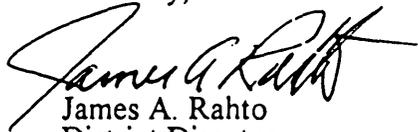
This will serve as official notification to management that FDA expects all locations to be in compliance

You should take prompt action to correct these deviations. Failure to do so may result in regulatory action by FDA without further notice. Possible actions include seizure and/or injunction.

You should 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 corrections will be completed.

Your reply should be sent to Bruce R. Ota, Compliance Officer at the address noted above. If you have any questions concerning this matter, please contact Mr. Ota at (617) 279-1675 x119.

Sincerely,



James A. Rahto  
District Director  
New England District Office

cc: Issac M. Raymond, Branch Manager  
Maine Oxy-Acetylene Supply Co.  
131 Robertson Boulevard  
Brewer, Maine 04412