



DEPARTMENT OF HEALTH & HUMAN SERVICES

m2382n
New York District

Food & Drug Administration
300 Pearl Street, Suite 100
Buffalo, NY 14202

February 16, 1999

WARNING LETTER NYK 1999-31

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

Henry Wakeman, Jr.
Chairman of the Board
Wakeman Industries, Inc.
806 River Road
Charlestown, New Hampshire 03603-4150

Dear Mr. Wakeman:

During an inspection of your medical gas manufacturing facility Merriam-Graves Corp. of NY, 90 Bridge Street, Plattsburgh, New York on December 8 and 9, 1998, our investigator documented a deviation from the Current Good Manufacturing Practice regulations (Title 21, Code of Federal Regulations (CFR), Parts 210 and 211). This deviation causes your drug product, Oxygen, Refrigerated Liquid, USP (ORL), to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act). The deviation noted by the investigator is the following:

--Failure to test incoming bulk ORL for identity prior to filling home units as required per 21 CFR 211.165(a). For example, your firm has not performed identity testing on incoming bulk ORL from at least January 1997 to the present.

We received your firm's letter dated December 21, 1998 to Ms. Brenda Holman, District Director, from Thomas Andrews, Medical Sales Manager, written in response to the FDA 483 issued at the close of the inspection. This letter does not adequately address the aforementioned deviation, however, because it doesn't describe how you plan to correct this deviation.

It is your responsibility to ensure all drugs manufactured and distributed by your firm meet the requirements of the Act, and the regulations promulgated thereunder. Federal agencies are advised of all warning letters regarding drug products so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct this deviation. Failure to correct this deviation may result in regulatory action without further notice. Possible regulatory actions include seizure and/or injunction.

Wakeman Industries, Inc.
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Therefore, 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 violation, 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 the delay and the time within which corrections will be completed. Your response may be directed to Lisa M. Utz, Compliance Officer, at the above address. If you require further information, you may contact Ms. Utz by telephone at (716) 551-4461 extension 3165.

Sincerely,

A handwritten signature in black ink, appearing to read "Brenda J. Holman", with a long horizontal flourish extending to the right.

Brenda J. Holman
District Director

Cc: Wallace N. Pulsifer, Store Supervisor
Merriam-Graves Corp. of NY
90 Bridge Street
Plattsburgh, NY 12901