

HFI-35 Purged/MCL



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

T2093M

Food and Drug Administration
One Montvale Avenue
Stoneham, Massachusetts 02180
Tel 781.279.1675 Fax 781.279.1742

WARNING LETTER

September 30, 1998

NWE-23-98W

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. William Bonk, President
Industrial Safety Supply Co., Inc.
176 Newington Road
West Hartford, CT 06110

Dear Mr. Bonk:

During an inspection of your medical oxygen facility (Industrial Safety Supply Co., Inc., 176 Newington Road, West Hartford, CT) on September 17 and 18, 1998, our investigator determined that compressed gaseous oxygen is being transfilled and distributed. This medical gas is a drug as defined in Section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act). The inspection revealed that this drug is adulterated within the meaning of Section 501(a)(2)(B) of the Act in that the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to Current Good Manufacturing Practice Regulations for drugs specified in Title 21 Code of Federal Regulations, Parts 210 and 211. Deviations documented by our investigator (see enclosed copy of *Form FDA 483*) and presented to Mr. Thomas Manente, Service Manager include:

- ▶ Failure to assay incoming oxygen for identity and strength prior to transfilling using scientifically sound and appropriate test procedures. Your firm currently does not

perform any testing of representative transfilled cylinders for identity and strength prior to distribution.

- ▶ Failure to establish written procedures designed to assure that the drug product (cylinders of compressed medical oxygen) are identified with a lot or control number that permits determination of the history of the manufacture and control of each batch. Our investigator noted that cylinders transfilled on different days may be assigned the same lot number.
- ▶ Failure to establish adequate batch production and control records for each batch of drug product produced, including documentation that each significant step in the manufacture, processing, packing, or holding of the batch was accomplished.
- ▶ Failure to establish written procedures designed to assure that the drug products have the identity and strength they purport or are represented to possess.
- ▶ Failure to establish written procedures for the receiving of any complaints.

Please note that Section 503(b)(4) of the Act was recently amended to require prescription drugs to bear the statement: "**Rx Only or R Only.**" However, if a firm sells Oxygen U.S.P. to emergency medical services, i.e., fire departments, rescue squads, ambulance companies, etc. or for emergency use, then the label is required to contain the statement: "**For emergency use only when administered by properly trained personnel for oxygen deficiency and resuscitation. For all other medical applications, Rx Only or R Only.**" Compliance with this provision of the Act has been extended to February 19, 2003.

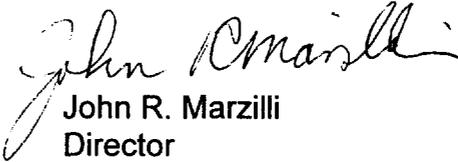
The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Good Manufacturing Practice Regulations. Federal agencies are advised of the issuance of all Warning Letters concerning drugs 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 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 and any documentation necessary to show that the correction has been achieved. 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.

You may direct your reply to Mark Lookabaugh, Compliance Officer, at the address noted above. If you have any questions concerning this matter, please contact Mr. Lookabaugh at 781.279.1675 ext. 118.

Sincerely,



John R. Marzilli
Director
New England District

Enclosure

cc:
Thomas Manente, Service Manager
Industrial Safety Supply Co., Inc.
176 Newington Road
West Hartford, CT 06110