

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

HFI-35
534
8/20/97

Refer to: CFN 1123415

Baltimore District
900 Madison Avenue
Baltimore, Maryland 21201
Telephone: (410) 962-4012

August 13, 1997

WARNING LETTER

97-BLJ-48

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Bradley K. Fountain, President
Welder's Supply Company
701 McCulloh Street
Baltimore, Maryland 21201

Dear Mr. Fountain:

During an inspection of your facility, conducted by the Food and Drug Administration (FDA) from July 24 to July 31, 1997, deviations from the Current Good Manufacturing Practice Regulations (Title 21, Code of Federal Regulations, Parts 210 & 211) were observed in your firm's operation. These deviations cause your compressed medical gas and liquid oxygen products to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). The deviations are as follows:

1. Failure to properly calibrate the oxygen analyzer used for the assay of Oxygen, USP, in that your firm did not have the high purity nitrogen standard required to calibrate the "zero" on the meter.
2. Failure to establish adequate batch production and control records for each batch of drug produced, including documentation that each significant step in the manufacture, processing, packing, or holding of the batch was accomplished, in that the final temperature and pressure of filled compressed gas tanks are not recorded; lot numbers are assigned to an entire's day production rather than each manifold fill; and incoming shipments of bulk oxygen delivered during the day are not assigned lot numbers until the following day.
3. Failure to segregate high-pressure compressed tanks, full or empty, for medical grade oxygen, helium, nitrogen, and carbon dioxide from those for industrial grade gases.

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Additionally, failure to include the statement, "Caution: Federal law prohibits dispensing without a prescription", on labels of leased tanks for compressed medical oxygen causes those articles to be misbranded within the meaning of Section 502(f)(1) of the FD&C Act.

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 Good Manufacturing Practice Regulations. Federal agencies are advised of the issuance of all warning letters about drugs so that they may take this information into account when considering the award of contracts.

By copy of this letter, we are advising the Health Care Financing Administration that our inspection revealed significant deviations from the FD&C Act. They may elect to defer or discontinue payment for any health care product in violation of state or federal law.

You should notify this office in writing, within 15 working days of receipt of this letter, of additional steps you have taken to correct the noted 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 reply should be directed to the Food and Drug Administration, Baltimore District Office, 900 Madison Avenue, Baltimore, Maryland 21201, Attention: Carl R. Nielsen, Compliance Officer.

Sincerely,



William M. Ment
Acting District Director