



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

PURGED *EX*

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

October 10, 1997

cc: HFI-35/FOI Staff
DWA

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 98 - 6

Joy Calkins
President
United Professional Companies, Inc.
3724 West Wisconsin Avenue
Milwaukee, Wisconsin 53208

Dear Ms. Calkins:

During our September 23 and 25, 1997, inspection of your medical gas manufacturing facility, UPC Health Network (UPC)(formerly Stein Medical), located at 2130 S. Memorial Drive, Appleton, WI, our investigator documented numerous, serious violations of the Good Manufacturing Practice Regulations (GMP), Title 21, Code of Federal Regulations, Parts 210 and 211. Your products, medical, compressed oxygen gas and liquid oxygen, are adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food Drug and Cosmetic Act (the Act) in that the controls used for the manufacture, processing, packing, or holding of these products are not in conformance with GMP, such as:

For compressed oxygen gas:

1. UPC does not receive a Certificate of Analysis (C of A) from the supplier of medical oxygen. In lieu of this, UPC does not perform purity or identity tests on the incoming oxygen gas.
2. Oxygen transfilled by UPC is not tested for purity or identity prior to release and distribution.

Page Two

Joy Calkins
October 10, 1997

3. Pumper's logs for oxygen gas are deficient as follows: (a) they contain inaccurate information; (b) the date and lot number are not recorded at the time the lot is transfilled; and (c) they are not verified by a second individual prior to release and distribution of the lot.
4. Inaccurate information on the pumper's log includes: (a) a check indicating the transfilled gas is tested for purity and identity; (b) recording that the [REDACTED] oxygen analyzer has been calibrated; (c) recording incorrect data for the calibration of the [REDACTED] oxygen analyzer; (d) a check indicating the dead ring test has been performed on the empty cylinders; (e) a check indicating that filled cylinder labels have been reviewed, and (f) recording incorrect serial numbers of the filled cylinders.
5. Pressure and vacuum gauges used for cascade transfilling have not been calibrated, and there is no written Standard Operation Procedure (SOP) for calibration of these gauges.
6. There is no written SOP for the transfilling of compressed oxygen gas.
7. There is no written SOP for control of labels, and the firm does not have any cylinder labels on hand to replace damaged labels.

For liquid oxygen:

8. [REDACTED] oxygen analyzer filters are not tested according to the manufacturer's instructions or schedule.
9. There is no documentation that the [REDACTED] oxygen analyzer has been calibrated.
10. There is no C of A for the nitrogen standard used to zero the oxygen analyzer.

Compressed oxygen gas cylinders located at the inspected facility were observed to be misbranded within the meaning Section 502(f)(1), 502(b)(1), or 502(a) of the Act in that labels:

Page Three

Joy Calkins
October 10, 1997

(a) lack the required caution statement, "For emergency use only when administered by properly trained personnel for oxygen deficiency and resuscitation. For all other medical applications, Caution: Federal Law prohibits dispensing without prescription"; (b) fail to bear the name and address for UPC Health Network or bear the name and address of other manufacturers; (c) bear two different lot numbers.

At the conclusion of our inspection form FDA-483 was issued to Ms. Linda M. Baker, Branch Manager, UPC, Appleton, WI. The violations of the GMPs cited on that form and in this Warning Letter are serious and require immediate attention and correction. A copy of the FDA-483 issued to Ms. Baker is enclosed.

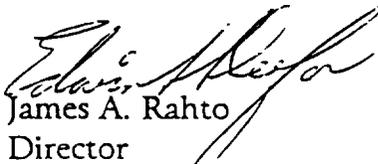
This identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence with each requirement of the GMPs. Federal agencies are advised of the issuance of all Warning Letters about drugs so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Such action includes seizure and/or injunction.

Please notify this office within 15 working days of receipt of this letter of the specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to Compliance Officer Lawrence R. Murphy at the address indicated on the letterhead.

Sincerely,


James A. Rahto
Director
Minneapolis District

LRM/ccl

Enclosure: FDA-483, 9/25/97

xc: Linda M. Baker
Branch Manager
UPC Health Network
2130 S. Memorial Drive
Appleton, WI 54915