



Purged by G. Davis 9/3/99

Food and Drug Administration
Detroit District
1560 East Jefferson Avenue
Detroit, MI 48207-3179
Telephone: 313-226-6260

CERTIFIED MAIL

RETURN RECEIPT REQUESTED

WARNING LETTER
99-DT-13

August 31, 1999

James E. Binson
President
Binson's Hospital Supplies, Inc.
26834 Lawrence
Center Line, MI 48015

Dear Mr. Binson:

An inspection of your medical oxygen manufacturing operation was conducted on May 20 – June 2, 1999 by Investigator Miah I. Schneider. The medical oxygen sold by your firm is adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act), and is misbranded within the meaning of Sections 503(f)(1) and 503(b)(4) of the Act.

The medical oxygen is adulterated based on inspectional evidence which revealed serious deviations from Current Good Manufacturing Practice for Finished Pharmaceuticals, Part 211 (21CFR211), as follows:

1. Failure to implement written procedures for some aspects of your operation, in that there are no written procedures for preventive maintenance on the ~~Analyzer~~ Analyzer nor for the calibration of thermometers.
2. Failure to perform adequate pre-fill operations on each high pressure cylinder prior to filling in that:
 - a. No pre-fill odor check test was done on each empty cylinder.
 - b. Previous lot number stickers were not removed prior to refilling the cylinders.
 - c. The batch filling record, Gasous Oxygen Transfill Log, does not provide sufficient space or columns to fully document the performance of all necessary pre-fill tests such as the vent or blow-down step, and the odor or sniff test.

3. Failure to calibrate the digital thermometer used to monitor cylinder filling temperature.
4. Failure to check the vacuum gauge, on a daily basis when in use, that the gauge returns to "zero" with no vacuum present.
5. Failure to maintain a file of Certificates of Analysis of [REDACTED] tanks of bulk liquid oxygen.
6. Failure to properly calibrate the [REDACTED] Oxygen analyzer used for the assay of Oxygen U.S.P., in that the required high purity nitrogen (zero) gas and oxygen (span) gas are not used for calibration of the instrument.
7. Failure to include a check of the heat of compression during the gas to gas (cascading) procedure for cylinder filling.
8. The batch filling record, Gasous Oxygen Transfill Log, fails to provide for:
 - a. A dated signature of a second responsible management individual who has checked the records prior to release of the drug for distribution.
 - b. The recording of the batch filling temperature and final pressure.
9. Failure to implement a lot numbering system that can identify each separate manifold load of cylinders filled on a single day.
10. Failure to maintain a master label file.

The compressed medical oxygen is misbranded for the following reasons:

- 503(f)(1) The article, Oxygen U. S. P., is a prescription drug and the label fails to bear adequate direction for use in accordance with 21 Code of Federal Regulations (CFR) 201.100(c).
- 503(b)(4) The article, Oxygen U.S.P., is a prescription drug and the label fails to bear the statement: "Rx ONLY"

The above is not intended to be an all-inclusive list of deviations which may exist at your firm. It is your responsibility to ensure that your firm is in full compliance with the Act and regulations promulgated thereunder. Other 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.

We request that you take prompt action to correct these deviations. Failure to make prompt corrections may result in regulatory action without further notice, such as seizure and/or injunction.

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

Your response should be directed to this office to the attention of Mr. Melvin O. Robinson, Acting Compliance Officer. (313) 226-6260 Extension 128

Sincerely yours,


for Raymond V. Mlecko
District Director
Detroit District

cc: EF (Binson's)
~~HFI-35 (purged)~~
HFA-224 (CF # 1828884)
HFC-210
HFD-322 (Sylvia)
HFC-240
HFC-120
Warning Letter Book (99-DT-13)
Warning Letter Jacket (99-DT-13)

J.A.
MIS