



DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Food and Drug Administration
CENTRAL REGION

112233n

Detroit District Office
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Detroit, MI 48207-3179
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CERTIFIED MAIL

RETURN RECEIPT REQUESTED

WARNING LETTER
99-DT-05

December 9, 1998

Irving Sparage, President
Smith Welding Supply
644 Selden
Detroit, Michigan 48201

Dear Mr. Sparage:

An inspection of your facility was conducted on November 8 – 20, 1998 by the Food and Drug Administration. The inspection revealed significant deviations from Current Good Manufacturing Practice Regulations for Finished Pharmaceuticals, Title 21, Code of Federal Regulations, Part 210 and 211 (21 CFR 210 and 211). These deviations cause your product, Oxygen, USP, to be adulterated within the meaning of the Federal Food, Drug, and Cosmetic Act (the Act), Section 501(a)(2)(B), as follows:

1. Failure to properly calibrate the [REDACTED] Oxygen Analyzer used for the assay of Oxygen USP, in that the required high purity nitrogen standard and oxygen standard or "span" gas are not used for calibration of the instrument [21 CFR 211.160(b)(4)].
2. Failure to establish written procedures to assure that the drug products have the identity and strength they purport or are represented to possess to include when cylinders are tested, acceptance criteria for test results, and corrective actions for out of specification test data [21 CFR 211.100(a)].

3. Failure to follow written procedures for removal of expired hydrostatic test dates for high pressure cylinders in that at least six out of date cylinders were observed as having been filled and ready for distribution with expired test dates [21 CFR 211.80 (a)].
4. Failure to perform adequate pre-fill operations on each high pressure cylinder and/or large cryogenic vessel prior to filling [21 CFR 211.84(d)(3)].
5. 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 [21 CFR 211.188(b)]
6. Failure to establish adequate written production and control procedures to assure that the drug products produced have the identity, strength, quality, and purity they purport or are represented to possess, to include filled cylinder temperature and pressure, heat of compression, and leak test [21 CFR 211.101(a)].
7. Failure to establish and/or follow adequate written procedures to assure that correct labels and labeling are used, including identification of the drug product with a lot or control number that permits determination of the history of the manufacture and control of the batch [21 CFR 211.130(b)].
8. Failure to establish adequate training for employees performing filling or delivery of Oxygen, USP high pressure cylinders or cryogenic vessels [21 CFR 211.25(a)].

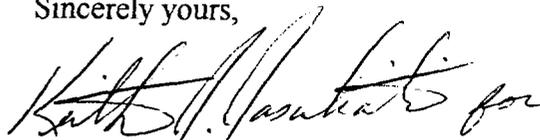
The above is not intended to be an all-inclusive list of deviations which may exist at your firm. It is your responsibility to ensure that your firm is in full compliance with the Act and regulations promulgated thereunder.

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 Mrs. Kathleen M. Lewis, Compliance Officer.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Raymond V. Mlecko for". The signature is written in a cursive style with a large, sweeping initial "R".

Raymond V. Mlecko
Acting District Director
Detroit District