

U.S. FOOD AND DRUG ADMINISTRATION

NEW YORK DISTRICT
850 THIRD AVENUE, BROOKLYN, NEW YORK 11232

12/8
D1077B

Telephone: [718] 965-5300 [Ext 5053]

January 8, 1997

WARNING LETTER

CERTIFIED MAIL RETURN RECEIPT REQUESTED

James P. Ruddy
Chairman of the Board
T. W. Smith Corp.
885 Meeker Avenue
Brooklyn, New York 11222

Ref: 27-NYK-97

Dear Mr. Ruddy:

An inspection of your oxygen transfilling facility was conducted by our investigators between December 2 and 17, 1996. This inspection documented deviations from the Current Good Manufacturing Practice Regulations for Finished Pharmaceuticals [Title 21, Code of Federal Regulations (CFR), Part 211] in conjunction with your firm's transfilling of liquid and compressed medical oxygen which cause these drugs to be adulterated within the meaning of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act).

At the conclusion of the inspection, our investigators presented and discussed the attached list of inspectional observations (Form FDA 483) with you and your management staff. The following deviations were found:

- 1) The filling and testing records fail to document that a visual inspection was conducted on any liquid oxygen GP-45 vessels to assure that these vessels have the proper Compressed Gas Association (C.G.A.) fittings.

- 2) Failure to document the reconciliation of quantities of labels issued, used, and returned, such that evaluation of discrepancies found between the quantity of drug products finished and the quantity of labeling issued can be determined, in that your filling and testing records for liquid and compressed medical oxygen have a medical label section which indicates labels issued, applied, discarded and returned. However, review of approximately 60 filling and testing records, for the period September to November 1996, revealed that this labeling section has not been completed. In addition, there were no reconciliation records for the U.S.P. liquid oxygen labels.
- 3) Failure to have filling and testing records that include complete information relating to the production and control of each lot. For example, the records for 9/3, 9/4, 10/9, 11/13, 11/18, 11/20, and 11/26/96 lack the result of the bulk liquid oxygen assay, review of approximately 60 filling and testing records covering September to December 1996, revealed that none of these U.S.P. liquid oxygen records contain the bulk supplier's lot number(s), and the reviewer's signature as required by your SOP.
- 4) Failure to have written procedures describing the handling of all written and oral complaints regarding a drug product.
- 5) Failure to have established written calibration procedures specifying at what time intervals the ~~oxygen~~ Oxygen analyzer, filling gauge, scales and thermometers should be calibrated. In addition the Servomex Certificate indicates that the Servomex was to be sent out for calibration on 9/1/96. However, the firm has no documentation to show that the Servomex was calibrated.
- 6) Failure to have adequate separation between stored medical oxygen and commercial grade gases. For example, compressed medical oxygen in E size cylinders were observed stored next to cylinders of compressed carbon dioxide. Further, liquid medical oxygen GP-45 Vessels were stored along a railed walkway located on the outside of the building. This area is not identified for the storage of U.S.P. liquid oxygen.
- 7) Failure to have an area on the inside or the outside of the building that is identified as a quarantine area as required by your Standard Operating Procedure (SOP).
- 8) Failure to provide documentation that each person engaged in the manufacture, processing, packing, or holding of a drug product has the education, training, and experience, or any combination thereof, to enable that person to perform the assigned functions. There is no documentation that the employees who deliver and handle medical oxygen have been trained in the handling of medical oxygen as required by your Standard Operational Procedures. Specifically, the drivers are required per the SOP to record the lot numbers of all medical oxygen cylinders and vessels delivered. The delivery ticket dated 11/27/96 for New York

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Foundling Hospital indicates that four (4) GP-45 liquid medical oxygen vessels were delivered to the hospital. However, only three (3) GP-45 liquid medical oxygen vessels were delivered and the driver recorded the wrong lot number for one of the GP-45's and a partial lot number for a second GP-45.

- 9) Failure to thoroughly investigate any unexplained discrepancy or failure of a batch or any of its components to meet any of its specifications. For example, your investigation of a GP-45 liquid medical oxygen vessel, lot number 110390 which had improper C. G. A. fitting did not include a review of the filling and testing record.

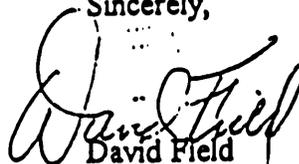
The above identification of violations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with requirements of the Good Manufacturing Practice Regulations. This letter serves as official notification that the Food and Drug Administration expects your transfilling facility to be in compliance. Federal agencies are advised of the issuance of all warning letters about 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 promptly correct these deviations may result in regulatory action being initiated by this Agency without further notice. These include seizure and/or injunction.

You should notify this office in writing, within 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. If corrective action cannot be completed within 15 days, state the reasons for the delay and the time within which the corrections will be completed.

Your reply should be sent to the U. S. Food and Drug Administration, New York District Office, 850 Third Avenue, Brooklyn, New York 11232, attention: Anita Fenty, Compliance Officer.

Sincerely,



David Field

Acting District Director

Attachment
Form FDA 483