



DEPARTMENT OF HEALTH & HUMAN SERVICES

634
8/20/97
Public Health Service
Food and Drug Administration

San Francisco District
1431 Harbor Bay Parkway
Alameda, California 94502-7070
Telephone: (510) 337-6700

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Our reference: CFN 29-38538

July 16, 1997

Mr. Timothy Waits, President
John Davis Company
3412 Auburn Blvd.
Sacramento, CA 95821

WARNING LETTER

Dear Mr. Waits:

During a June 3, 17, and 18, 1997, inspection of your home respiratory care company located at 3412 Auburn Boulevard, Sacramento, California 95821, FDA Investigators Darlene B. Almogela and Karen G. Hirshfield documented deviations from the Good Manufacturing Practice Regulations (Title 21, Code of Federal Regulations, Part 211) in conjunction with your firm's repacking of compressed medical gases which cause these drugs to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act, as follows:

1. Failure to adequately test Oxygen, USP, for identity and purity [21 CFR 211.165 (a)]. You must either test the oxygen yourself by an appropriate method OR you must obtain an acceptable certificate of analysis (COA) from your supplier. Your firm does not routinely test the oxygen and relies on a COA from the supplier. These COA's are not acceptable for the following reasons:
 - a. There is no assurance that the supplier's analytical method is equivalent to the official USP test methods [(21 CFR 211.165(e)].
 - b. The certificates of analysis from your supplier sometimes lack required information such as the purity of the product, the identity of the product or the test method.

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c. There is no documentation that the drivers receiving the liquid oxygen witness the identity and purity testing by your supplier (21 CFR 211.188).

d. You have failed to establish the reliability of the supplier's analyses through validation of the supplier's test results at appropriate intervals (21 CFR 211.84(d)(2)).

For your information, You cannot use your firm's [REDACTED] in lieu of receiving a COA for your supplier because the [REDACTED] is not sufficiently accurate. Testing must be by a method that is equivalent to the official USP method. The USP method has an accuracy of + or - 0.1 % whereas the [REDACTED] has an accuracy of + or - 1.0 to 3.0 %.

2. Failure to follow written procedures to assure the oxygen cylinders bear the correct label (21 CFR 211.130). The labels of eight out of forty-eight tanks did not list the distributor or manufacturer of the Compressed Oxygen, USP, and the label of one tank was missing its lot number.
3. There is no documentation that each significant step of the pre-fill checks and all significant steps performed during the filling operations were completed. (21 CFR 211.188 (b)).
4. There is no documentation that daily batch records or analytical results (COA's) are reviewed to assure that product is approved by the firm's quality control unit prior to distribution (21 CFR 192).

The drug product, Oxygen USP, is misbranded within the meaning of Section 503(b)(4) of the FD & C Act in that it is regarded as a prescription drug and its labeling fails to bear the statement, "Caution: Federal law prohibits the dispensing without a prescription." (21 CFR 201.100(b)(1)).

Your refusal to allow Investigator Almogela to conduct her inspection from June 4 through June 17, 1997 is a prohibited act with the meaning of Section 301 (f) of the Food, Drug and Cosmetic Act (the Act). Section 301 (f) prohibits the refusal to permit entry or inspection as authorized by section 704. Section 704 authorizes FDA Investigators upon showing of credentials and issuing a written notice to enter at reasonable times, any factory in which drugs, such as Oxygen USP, are manufactured and to inspect within reasonable limits such factory. Your plant was operating between June 4 and 17, 1997, so inspection during that time period would have been reasonable within the meaning of the law.

The above enumeration of deficiencies, as well as the Form FDA-483 (Inspectional Observations) which was presented to you, should not be construed as a complete list of deficiencies at the Sacramento facility. As President, it is your responsibility to insure that all of your facilities are in complete compliance with all aspects of the law.

Timothy Waits, President, John Davis Company

I am enclosing a copy of the Food and Drug Administration's booklet entitled the Compressed Medical Gases Guideline; a copy of a speech by Mr. Duane Sylvia of FDA's Office of Compliance, Division of Manufacturing and Product Quality, CDER; and 21 CFR parts 201 and 211.

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.

Failure to promptly correct these deviations may result in enforcement action being initiated without further notice. The Act provides for seizure of illegal products (Section 304) and for an injunction (Section 302) against the manufacturer and/or distributor of illegal products.

Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 days, state the reason for the delay and the time needed to complete the corrections.

Please submit your response to the Food and Drug Administration, San Francisco District Office, 1431 Harbor Bay Parkway, Alameda, CA 94502-7070, attention: Marie Kinkaid, Drug Team Leader.

Sincerely,



Patricia C. Ziobro, District Director
San Francisco District

Enclosures:
FDA 483
21 CFR parts 201 and 211
Speech by Mr. Duane Sylvia
Compressed Medical Gases Guideline