



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION

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D1213B

PHILADELPHIA DISTRICT

97-PHI-16

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2nd and Chestnut Streets  
Philadelphia, PA. 19106

Telephone: 215-597-4390

WARNING LETTER

February 21, 1997

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Guy Smith, C.E.O.  
UPC Health Network  
3724 West Wisconsin Avenue  
Milwaukee, WI 53208

GEN.	SPEC.
RELEASE	
F# _____	DATE 2/24/97
Reviewed by: <i>Cheryl M. Rappell</i>	

Dear Mr. Smith:

From January 23 through 28, 1997, Philadelphia District Investigator Gladys B. Casper conducted an inspection of your liquid oxygen manufacturing facility located at 1001 Parkway View Drive, Pittsburgh, PA. The liquid oxygen manufactured by your company is a drug within the meaning of Section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act) and, as such, is subject to the requirements of Title 21 Code of Federal Regulations (21 CFR).

During this inspection, Investigator Casper documented deviations from labeling requirements for prescription drugs as well as deviations from Current Good Manufacturing Practice (CGMP) regulations for finished pharmaceuticals as codified at 21 CFR Parts 210 and 211. At the conclusion of the inspection, she issued form FDA-483, Inspectional Observations, to Carlton L. Clark, Warehouse Manager, and discussed those observations with him. A copy of the FDA-483 is enclosed for your perusal.

Consequently, the liquid oxygen you manufacture is misbranded within the meaning of Section 502(f)(1) in that it is a prescription drug and its labeling fails to bear adequate directions for use. A prescription drug is exempt from these requirements if it meets the conditions discussed at 21 CFR 201.100. Your product does not meet all of the conditions of the exemption in that its labeling does not bear the "Caution: Federal law prohibits dispensing without prescription" statement as discussed in Section 503(b)(4) of the Act. Please be advised that, on September 19, 1996, FDA informed the Compressed Gas Association that a final decision had been reached on its citizen petition. As a result, labels for medical oxygen should bear the 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."

Page 2  
February 21, 1997  
Guy Smith

Your product is also misbranded within the meaning of Section 502(g) in that it purports to be a drug whose name is recognized in an official compendium, namely, the *United States Pharmacopeia* (USP), and it does not meet the requirements of the USP. Specifically, the USP requires that labeling for Oxygen, USP contain a statement as to whether or not it was produced by air liquefaction. We note that the Certificate of Analysis you obtain from your liquid oxygen supplier indicates that the bulk liquid oxygen is, in fact, produced by air liquefaction. Therefore, your product's labeling must contain a statement to that effect.

Furthermore, your product is adulterated within the meaning of Section 501(a)(2)(B) of the Act in that the controls used for the manufacture, processing, packing, or holding of this product are not in conformance with Current Good Manufacturing Practice regulations as follows:

1.) Failure to periodically verify the reliability of the supplier's analysis of Oxygen, USP for identity and purity [21 CFR 211.84(d)(2)].

Aside from the CGMP requirement cited above, this verification is also found in your company's SOP 12-09 (Effective Date: 2/13/95), Procedure 12, which calls for [REDACTED] on-site visit by an appropriate company representative to your company's liquid oxygen supplier.

2.) Failure to have written procedures for handling, sampling, and testing, and for the approval or rejection of components and drug product containers and closures [21 CFR 211.80(a)].

Written procedures -- for example, SOP 12-06 which describes liquid oxygen transfilling procedures -- do not include instructions regarding pre-fill checks to assure that the drug product containers are appropriate for use.

Additionally, your firm's transfilling logs do not include a specific area that identifies the pre-fill checks to be done so that employees can document that each pre-fill check has been performed [21 CFR 211.188(b)(5)].

3.) Failure to routinely calibrate, inspect, or check such equipment according to a written program designed to assure proper performance [21 CFR 211.68(a)].

The inspection revealed that your firm fails to follow SOP 12-11 (Effective Date: 2/13/95), Scale Calibration, in that the scales used to weigh liquid oxygen cryogenic home vessels are not calibrated.

Page 3  
February 21, 1997  
Guy Smith

4.) Failure to maintain complete records of the periodic calibration of laboratory instruments, apparatus, gauges, and recording devices [21 CFR 211.194(d)].

The records documenting calibration of the hand held oxygen analyzer do not consistently include the reviewer's signature and date as required by SOP 12-08 (Effective Date: 2/13/95), Calibration of Hand-Held Oxygen Analyzer.

5.) Failure to establish written procedures describing the distribution of drug products [21 CFR 211.150].

There are no written procedures regarding the receipt and distribution of your firm's compressed medical oxygen USP cylinders.

We have one final comment concerning the unorganized condition of your firm's transfilling logs. Investigator Casper expressed her concern regarding the state of these logs to Mr. Clark during the inspection; to his credit, Mr. Clark did make an attempt to organize the records, and he produced logs from December 1996 and January 1997 for Investigator Casper's review. The state in which records are kept is important. First, you are required by law to keep these records and to make them available to FDA investigators during inspections; our investigators cannot determine whether or not your firm is in compliance with CGMP requirements if the records are not readily available and organized for review. Second, properly organized records could prove crucial in saving time and effort if your company were faced with a problem warranting a recall or some other type of customer notification.

The above is not intended to be an all-inclusive list of deficiencies at your firm. As top management, it is your responsibility to assure that all of your company's operations are in compliance with the Act and its associated regulations.

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.

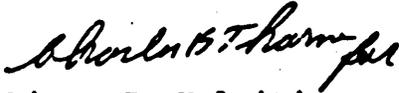
You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. These actions include, but are not limited to, seizure and/or injunction.

We acknowledge the fact that, during the discussion of the deviations with Investigator Casper, Mr. Clark verbally described the corrective actions that he plans to accomplish in order to bring the operation into compliance.

Page 4  
February 21, 1997  
Guy Smith

Please notify this office in writing within fifteen (15) working days of receipt of this letter as to the specific steps you have taken to correct these violations. 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 the attention of Karyn M. Campbell, Compliance Officer, at the address noted in the letterhead.

Sincerely,

  
Diana J. Kolzitis  
District Director  
Philadelphia District

Enclosure

cc: Carlton L. Clark, Warehouse Manager  
UPC Health Network  
1001 Parkway View Drive  
Pittsburgh, PA 15205

Robert E. Bastian, Director  
Division of Primary Care and Home Health Services  
PA Department of Health  
132 Kline Plaza, Suite A  
Harrisburg, PA 17104