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DEPARTMENT OF HEALTH & HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

PHILADELPHIA DISTRICT

800 U.S. Customhouse
3rd and Chestnut Streets
Philadelphia, PA 19106

Telephone: 215-897-4390

WARNING LETTER

October 5, 1998

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Charles Zullo, Owner
CGI International, LLC
1215 Henderson Avenue
Washington, PA 15301

Dear Mr. Zullo:

On September 16 and 21, 1998, Food and Drug Administration (FDA) investigator James M. O'Donnell conducted an inspection of your firm CGI International, LLC, located at 1215 Henderson Avenue, Washington, Pennsylvania, regarding the business aspect relating to the repacking and distribution of compressed oxygen USP, for medical use. At the conclusion of this inspection, a Form FDA 483 (copy attached) was issued to and discussed with Stephen J. Anderl, Operations Manager. This form lists serious deviations from Current Good Manufacturing Practice (CGMP) regulations for finished pharmaceuticals as outlined in Title 21 Code of Federal Regulations (CFR) Part 211. Consequently, your product, compressed oxygen USP, is adulterated under Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) in that the methods used in or the facility used for its manufacture do not conform to CGMP regulations as follows:

1. Failure to perform purity tests on each batch of finished product compressed medical oxygen USP prior to release for product manufactured between April 6, 1998 and July 30, 1998 [21 CFR 211.165(a)].
2. Failure to document purity tests results for each fill of finished product compressed medical oxygen USP manufactured during the period between April 6, 1998 and July 30, 1998 [21 CFR 211.165(a)].
3. Failure to calibrate the ~~XXXXXXXXXX~~ Oxygen Analyzer used for testing compressed medical oxygen USP for purity and identity [21 CFR 211.160(b)(4)].

Your firm has no documentation indicating that your ~~XXXXXXXXXX~~ Oxygen Analyzer was calibrated during the period between April 6, 1998 and July 30, 1998.

4. Failure to perform prefill and post fill inspections on cryogenic cylinders during the period between April 6, 1998 and July 30, 1998 [21 CFR 211.84(d)(3)].
5. Failure to have adequate batch production and control records for each batch of compressed medical oxygen USP produced, including documentation that each significant step in the manufacture of the batch was accomplished [21 CFR 211.188(b)].

Batch records for compressed medical oxygen USP manufactured on September 8 and 13, 1998 fail to document the results of purity testing, final temperature and pressure readings, and the signature of the individual (plant supervisor) responsible for reviewing the entries for completeness and accuracy.

6. Failure to identify each manifold fill of compressed medical oxygen USP with a traceable, unique lot number. [21 CFR 211.130(c) and 211.150(b)]. For example, twelve (12) "E" cylinders of compressed medical oxygen USP manufactured on September 8, 1998 and one (1) "B" cylinder and eleven (11) "E" cylinders of compressed medical oxygen USP manufactured on September 13, 1998 all possess the same lot number, ~~XXXXXXXXXX~~.

With respect to the manufacture of compressed medical gases the agency considers each manifold filling sequence a new lot requiring a unique lot number.

7. Failure to have detailed written procedures regarding all aspects of your compressed medical oxygen USP manufacturing operation [21 CFR 211.100(a)(b)].

Your firm must have in place written procedures regarding, prefill, fill and post fill operations; analytical testing; calibration and maintenance of equipment; distribution; and complaint handling. You should also implement written procedures for employee training and conducting recalls.

The above is not intended to be an all-inclusive list of violations which may exist at your firm. As top management, it is your responsibility to ensure that all requirements of the CGMP

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regulations are being met as well as all other requirements of the Act.

We are providing you with copies of the Compressed Medical Gas Guideline, Fresh Air "98", and 21 CFR Part 211 for your information and review.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. This includes seizure and/or injunction.

Federal agencies are advised of the issuance of all Warning Letters regarding drugs and devices so that they may take this information into account when considering the award of contracts.

Please advise this office in writing within fifteen (15) days of receipt of this letter as to the specific actions you have taken or intend to take to correct these violations. Your reply should be sent to the attention of James C. Illuminati, Compliance Officer, at the address noted in the letterhead.

Sincerely,



Roberta F. Wagner
Acting District Director
Philadelphia District

jci

Enclosures:

- (1) FDA-483 dated 2/21/98
- (2) Compressed Medical Gases Guideline
- (3) Fresh Air "98"
- (4) 21 CFR Part 211

cc: PA Department of Health
Health and Welfare Building
7th and Forster Streets
P.O. Box 90
Harrisburg, PA 17120
Attn: Division of Primary Care and Home Health Services
Robert E. Bastian, Director