



DEPARTMENT OF HEALTH AND HUMAN SERVICES

MAY 20 1999

Food and Drug Administration
 Cincinnati District Office
 Central Region
 6751 Steger Drive
 Cincinnati, OH 45237-30977
 Telephone: (513) 679-2700
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May 28, 1999

WARNING LETTER
CIN-WL-99-254

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Mark A. Witchey
 President
 Columbus Prescription Pharmacy
 6330 Proprietors Road, Suite B
 Worthington, Ohio 43085

Dear Mr. Witchey:

The Food and Drug Administration conducted an inspection of your liquid and gas Oxygen USP transfilling facility April 14-15 & 26, 1999. Our investigator documented significant deviations from the Current Good Manufacturing Practice Regulations for Finished Pharmaceuticals (Title 21 Code of Federal Regulations [CFR] Parts 210 and 211). These deviations cause your drug product, Oxygen USP to be adulterated with the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act).

The deviations documented during the inspection included:

- A) Gaseous Oxygen U.S.P. was distributed after testing results below the U.S.P. minimum of 99.0% (on four of about 200 batch production records for the period of January 1997 to the present). This included readings of 97.5%, 95.5%, 95.3% and 97.6%.
- B) Failure to maintain complete transfilling and testing records for gas and liquid oxygen as follows:
 1. Review of the Oxygen Gas from Gas Transfilling records showed 21 occasions from January 1997 to the present (200 records) where the purity assay was blank and the transfilled cylinders were distributed. There were 20 additional occasions where the blank was checked but an actual reading was not recorded.
 2. Review of the Liquid Oxygen To Liquid Oxygen Transfilling Records showed no finished product testing has been documented as an actual percent purity amount from May 1, 1998 to present.
 3. Sixteen of about 200 transfill records of gaseous oxygen do not contain documentation as the performance of pre-fill, fill and post-fill cylinder inspection or testing. None of the transfill records of gaseous oxygen contain documentation that a visual check was made of the cylinders, that hammer tests were done on steel cylinders and that a pre-fill odor test was being performed on the cylinders prior to filling.
 4. None of the transfill records for liquid oxygen contain documentation for the performance of any inspection of the cryogenic tank, tank labeling and purging of the dispensing line.

5. Thirty of approximately one hundred thirty lots or manifold sequences of gaseous Oxygen U.S.P. were not assigned a unique lot number.
 6. None of the liquid or gas transfill records show the date of review by management prior to distribution.
- C) Calibration of the [REDACTED] Oxygen Analyzer [REDACTED] was done once per week prior to June 1, 1998. Review of transfill records since that time showed that calibration was not conducted prior to testing of each lot gaseous and liquid Oxygen U.S.P.
- D) Calibration of the [REDACTED] Oxygen Analyzer [REDACTED] was being conducted using calibration gases which were not of sufficient strength or purity. For example the Oxygen U.S.P. was labeled as both U.S.P. and as specialty gas and the Nitrogen Gas was not identified as a laboratory grade reference or equivalent.
- E) There was no documentation that the [REDACTED] Oxygen Analyzer [REDACTED] had the manufacturers recommended weekly filter check from March 1997 till present.

A number of cryogenic home tank units were observed during the inspection. These units had labels of different types from the tank manufacturer, a tank refurbisher and your transfiller identification label. Some tanks lacked quantity of product, some lacked the Air Liquefaction statement and some lacked the prescription statement. There should be only one accurate label on a cylinder or cryogenic vessel.

The article of drug, Oxygen U.S.P. in cryogenic home vessels is misbranded under the Act, 21 U.S.C. 502(b)(1) in that the label fails to bear the name and place of business of the filler; 502(b)(2) in that the label fails to bear an accurate statement of the quantity of contents; 502(f)(1) in that the article label fails to bear adequate directions for use; 503(b)(4) in that it's label fails to bear the statement "Rx only"; and 502(c) in that the label fails to bear that the liquid oxygen is produced by air liquefaction method.

We acknowledge your letter dated May 11, 1999 which was sent in response to the FDA-483 Inspectional Observations issued on April 26, 1999. We acknowledge the corrections made as a follow-up to the FDA-483. Please add any labeling corrections made or additional control corrections that you might have made.

The above identification of violations is not intended to be an all inclusive list of deficiencies at your facility. It is your responsibility to ensure that all requirements of the Act and regulations promulgated thereunder are being met.

Federal agencies are advised of the issuance of all Warning Letters about drugs so they may take this into account when considering the award on contracts. By copy of this letter, we are advising the HealthCare Finance Administration (HCFA) that our inspection of your firm revealed significant deviations from the Act. They may elect to defer or discontinue payment for any health care products in violation of state or federal law.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by FDA without further notice. These actions include seizure and injunction.

Please notify this office within fifteen (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 fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to the Food and Drug Administration, Compliance Branch, 6751 Steger Drive, Cincinnati, Ohio 45237 to the attention of Lawrence E. Boyd, Compliance Officer.

Sincerely,

A handwritten signature in black ink, appearing to read "Charles W. Sedgwick". The signature is fluid and cursive, with a large initial "C" and "S".

Charles W. Sedgwick
Acting District Director
Cincinnati District

cc: Health Care Finance Administration
Chief Carrier Operations Branch
105 West Adams, 15th Floor
Chicago, IL 60603-6201

LEB/jp