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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

Refer to: CFN 1111563

Baltimore District  
900 Madison Avenue  
Baltimore, Maryland 21201  
Telephone: (410) 962-4099

May 22, 1997

WARNING LETTER

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Mr. J. Robert Danley, Manger, Regulatory Control  
Nellcor Puritan Bennett, Inc.  
9101 Bond Street  
Overland Park, Kansas 66214-1726

Dear Mr. Danley:

During a Food and Drug Administration (FDA) inspection of your firm located in Linthicum Heights, Maryland on April 29 through May 2, 1997, our investigators documented deviations from the current Good Manufacturing Practice Regulations (Title 21, Code of Federal Regulations (CFR), Parts 210 and 211) during the oxygen manufacturing operation. These deviations cause your firm's Oxygen, U.S.P. to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (Act).

Deviations documented during the inspection include:

1. Failure to calibrate the oxygen analyzer used to assay Oxygen, U.S.P. Your firm did not calibrate and/or document the calibration of the laboratory [REDACTED] Oxygen analyzer on at least two days where transfilling occurred.
2. Failure to properly calibrate the [REDACTED] Oxygen analyzer used for the assay of Oxygen, U.S.P., in that the laboratory analyzer had a loose connection in a frayed electrical cord that caused the reading to fluctuate.
3. Failure to establish adequate written procedures designed to assure that correct labels and labeling are used, including identification of the oxygen, by applying a lot or control number that permits the determination of the history of the manufacture and control of the batch. Your cylinders are assigned one lot number for an entire day's processing.

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4. Failure to establish batch production records for each batch of Oxygen, U.S.P. to document that each significant step in the manufacture, processing, packing, or holding of the batch was accomplished at the time of performance. Your batch production records do not indicate specific tests and examinations performed during the pre-fill operation.
5. Failure to follow written procedures in the execution of the various production and process control functions. For example, on May 29, 1997, labels were observed being placed on compressed gas cylinders after transfilling, rather than before or during, as stated in the Gas Production Manual (GPM) Section 331.
6. Failure to establish adequate written procedures describing in sufficient detail, the control procedures for the issuance and reconciliation of medical gas labels.
7. Failure to assure that each person, engaged in the filling of oxygen, has the education, training, or experience to enable that person to perform the assigned function. Your employee failed to observe the results of a leak test done on Lot AD29E49 or take corrective measures, even though some of the tanks were leaking.
8. Failure to document that each person responsible for supervising the manufacture of Oxygen, U.S.P. has the education, training, and experience to provide assurance that the Oxygen, U.S.P. has the safety, identity, strength, quality, and purity that it purports to possess. There is no documentation to assure that managers who approve batches of Oxygen, U.S.P. for distribution and who provide training to production employees are qualified to perform such duties.

Additionally, it was observed during the inspection that your cylinders failed to bear the statement, "Caution: Federal law prohibits dispensing without a prescription," as per 21 CFR 201.100(b)(1). We acknowledge that during the inspection your employees corrected this violation by attaching a separate label to the product cylinders in-house.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA 483 issued at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective action.

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

We acknowledge that you have submitted to this office a response dated May 15, 1997, concerning our investigator's observations noted on the form FDA 483. Your responses to Observations 1(a), 1(b), 1(d), 2, 3, 4(a), 4(b), 6, and 7 appear adequate. A follow-up inspection will be required, however, to assure that the corrections have been made.

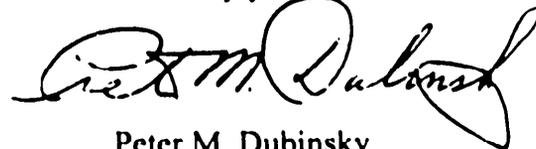
Your response does not adequately address those violations relating to Observations 1(c), 4(c), 5, and 8. Detailed comments on your response are enclosed.

You should take prompt action to correct these deviations. Failure to do so may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please 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 identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective actions cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be directed to the Food and Drug Administration, 900 Madison Avenue, Baltimore, Maryland 21201, Attention Jennifer A. Thomas, Compliance Officer.

Sincerely yours,



Peter M. Dubinsky  
Acting Director  
Baltimore District

Enclosure

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cc: Earl M. Bane, Branch Manager  
Nelcor Puritan Bennett, Inc .  
608 Nursery Road  
Linthicum Heights, Maryland 21090