

Lincoln Medical Supply
Atlantic City, New Jersey 08401
Warning Letter #98-NWJ-03

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documented, nor calibrated with a standard source of oxygen. Your firm also lacked a written procedure to describe this calibration process.

4) Failure to test each lot of bulk liquid oxygen to confirm identity. Additionally, periodic testing to confirm your supplier's certificate of analysis regarding identity and strength, was not performed.

5) Failure to establish adequate batch production and control records, including documentation that each significant step in the manufacture, processing, packing or holding of the batch was accomplished. For example, batch records for liquid oxygen were not reviewed for accuracy, dated and signed. Additionally, there was no documentation to indicate that identity testing was performed on liquid home reservoirs. Deficiencies were also noted on numerous batch records of gaseous oxygen, specifically lacking entries for temperature and pressure during filling and testing for purity, identity and leaks.

6) Your firm's procedure manual, covering all aspects of medical oxygen repacking operations, was found to be deficient in that it was not signed, dated or reviewed by responsible individuals. It also lacks examples of approved product labeling.

The above list is not intended to be all inclusive of deficiencies at your facility. It is your responsibility to ensure that your medical gas repacking operations are in compliance with the FD&C Act and the regulations promulgated under it. You should take prompt action to implement corrections. Failure to take corrective action may result in regulatory action without further notice. These regulatory actions include seizure and/or injunction.

We are in receipt of your written response to the inspectional observations, dated September 26, 1997. We are unable to comment on the adequacy of your response, since the revised procedures you reference were not included with your response. A reinspection will be needed to verify your corrective actions and evaluate your firm's compliance with cGMPs. We offer the following comments to your written response, as they correlate to the FDA483 observations:

FDA 483 Item 3) Your response relates the failure to utilize the high purity nitrogen standard as a lack of training. While we

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agree that training is needed to reinforce established procedures, the observation made during the inspection indicated that the nitrogen cylinder was available but not used since it did not have the proper fitting for use with the [REDACTED]

FDA483 Item 4) The manufacturing guidelines for the hand-held analyzer, referenced in your response, was not available during the inspection. Since calibration of this unit is based on these guidelines, the manual must be maintained on site.

FDA483 Item 6) Your response references that the hand-held oxygen analyzers will be calibrated with 21% oxygen, but is unclear if a standard oxygen tank will be used to ensure this percentage.

FDA483 Item 11) Your response contains the documentation of your supplier's certified experienced trainer, who provided recent training. However this observation related to the experience and qualification of your consultant, who has previously been responsible for training and recently revised all policies and procedures related to your operations.

You should notify this office in writing, within 15 working days of receipt of this letter, of the additional steps you have taken to ensure compliance. Your reply should be sent to the Food & Drug Administration, New Jersey District Office, 10 Waterview Blvd., 3rd Floor, Parsippany, NJ 07054, Attn: Mercedes B. Mota, Compliance Officer.

Sincerely,



DOUGLAS ELLSWORTH
District Director
New Jersey District

CERTIFIED MAIL -
RETURN RECEIPT REQUESTED