



DEPARTMENT OF HEALTH & HUMAN SERVICES  
Food and Drug Administration  
New England District

Original  
Purged  
AFI-35  
M2472n

Food and Drug Administration  
One Montvale Avenue  
Stoneham, Massachusetts 02180  
Tel 781.279.1675 Fax 781.279.1742

WARNING LETTER — PURGED ML 3/19/99 —

March 16, 1999

NWE-13-99W

VIA CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Ms. Cheryl C. Terry, President  
Boston Home Infusion, Inc.  
110 Stergis Way  
Dedham, MA 02026

Dear Ms. Terry:

During an inspection of your medical oxygen facility (Boston Home Infusion, Inc., 110 Stergis Way, Dedham, MA 02026) on March 1, 3, and 4, 1999, our investigator determined that oxygen is being transfilled and distributed. This medical gas is a drug as defined in Section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act). The inspection revealed that this drug is adulterated within the meaning of Section 501(a)(2)(B) of the Act in that the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to Current Good Manufacturing Practice Regulations for drugs specified in Title 21 Code of Federal Regulations, Parts 210 and 211. Deviations documented by our investigator include:

- ▶ Failure to properly assay the incoming liquid oxygen for identity and strength prior to filling the cryogenic home units [21 CFR § 211.165].

The need for testing cryogenic home units is obviated **only under certain conditions**—liquid oxygen must be the only liquefied gas being filled on site; the

incoming liquid oxygen must have been **adequately** tested for identity and strength; and the home units must be filled and retained by your firm.

Adequate testing of the large cryogenic vessels of incoming liquid oxygen can be demonstrated in one of the following ways:

a. if a **trained** representative of your firm **witnesses** your supplier's testing (for identity *and* strength), receives a **valid** certificate of analysis (COA), and **documents** that the testing has been witnessed. The minimum information that should be provided in a valid COA is as follows:

1. supplier's name
2. name of product
3. air-liquefaction statement
4. lot number or other unique identification number
5. actual analytical results for identity and strength
6. test method used (letter on file from supplier is acceptable)
7. supplier's signature and date

The training received by your firm's representative must be documented.

b. if, for those instances when the testing is **not witnessed**, a valid COA is obtained and an identity test is performed on each large cryogenic vessel received or filled. The reliability of the supplier's analysis must be verified periodically—preferably annually—by:

1. full USP testing of a recently delivered vessel by a third party, or
2. verifying the supplier's analysis by:
  - i. confirming that the supplier is registered with FDA
  - ii. confirming that the supplier is following appropriate written procedures
  - iii. witnessing the testing, including any calibration, and
  - iv. documenting these steps

c. If your firm neither witnesses the testing nor obtains a valid COA, full USP testing is required for each cryogenic vessel delivered by your supplier.

Your firm does not document that testing of liquid oxygen by your supplier is witnessed by an appropriately trained employee. Your supplier's Certificates of Analysis are also not routinely kept on file.

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 adherence to each requirement of the Good Manufacturing Practice Regulations. Federal agencies are advised of the issuance of all Warning Letters concerning drugs and devices so that they may take this information into account when considering the award of contracts.

Please note that Section 503(b)(4) of the Act was recently amended to require prescription drugs to bear the statement: "**Rx Only or R Only.**" However, if a firm sells Oxygen U.S.P. to emergency medical services, i.e., fire departments, rescue squads, ambulance companies, etc. or for emergency use, then the label is required to contain the statement: "**For emergency use only when administered by properly trained personnel for oxygen deficiency and resuscitation. For all other medical applications, Rx Only or R Only.**" Compliance with this provision of the Act has been extended to February 19, 2003.

You should take prompt action to correct these deviations. Failure to do so may result in regulatory action by FDA without further notice. Possible actions include seizure and/or injunction.

You should notify this office in writing, 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 and any documentation necessary to show that the correction has been achieved. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which corrections will be completed.

You may direct your reply to Mark Lookabaugh, Compliance Officer, at the address noted above. If you have any questions concerning this matter, please contact Mr. Lookabaugh at **781.279.1675 ext 118**.

Sincerely,



John R. Marzilli  
Director  
New England District

cc:

Robert Simmons, Vice President  
Boston Home Infusion, Inc.  
110 Stergis Way  
Dedham, MA 02026