INSPECTION GUIDELINES

The following areas will be reviewed when performing the inspection of the wholesaler:

1. Responsibility for Operation
   - Check for posting of license
   - Names of officers
   - Ownership information
   - Administration – Who is responsible for operations?

2. Policies and Procedures
   - Review written policies and procedures - these should cover the following (minimums):
     - Receipt of product
     - Inventory and distribution
     - Inspection of incoming and outgoing shipments of legend drug, device, and/or medical gas products
     - Identification, recording, and correction of inventory variances and adjustments for legend drug, device, and/or medical gas products
     - Assure the legend drug, device, and/or medical gas product is shipped only to authorized recipients (e.g., pharmacies, hospitals, physicians, dentists, veterinarians, other wholesale distributors)
       - Check for valid licensure
     - Product stock rotation
     - Excess or unusual purchases of legend drug, device, and/or medical gas product
     - Security
       - Security system
     - Storage
       - Temperature monitoring and logs (when required)
       - Facility sanitation and pest control
     - Handling of recalls and withdrawals of legend drug, device, and/or medical gas products
     - Handling of outdated, damaged, deteriorated, misbranded or adulterated drug, device, and/or medical gas product
       - Product segregation
     - Handling of returned legend drug, device, and/or medical gas product
       - Product destruction
     - Reporting losses, theft, contraband, misbranded, or counterfeit product
     - Crisis handling
     - Recordkeeping
     - Personnel qualification/training and responsibility

3. Suspicious and Excessive Purchases and Sales (Sales personnel should provide input)
   - What criteria is used?
   - To whom do they report?

4. Record Keeping
   - Records readily available
   - Inventories and transactions current
   - Sales and receipts records
   - Temperature monitoring logs current (not required of licenses who distribute medical gas product only)
   - Customer licenses
     - Customer list - must include customer name, address, authorizing license, permit, certificate number and expiration date
     - Copies of valid authorizing license, permit, certificate for each customer must be on file
     - Cross-check records - select some records for verification of customer license
• Suppliers/vendors are verified as current, valid LBWDD licensees
• Check on excess returned legend drug, device, and/or medical gas product
• Maintenance of records for a minimum of three years.

5. Recalls
• Where are recalled legend drugs, devices, and/or medical gases stored?
• Are they in a signed and separated (quarantined) location?

6. Returned Goods
• How are returned products from the customer handled?
• Where are returned items stored?
• How are outdated products checked?
• How is it determined which returned items may be resold?

7. Facilities
• Is the facility suitable for wholesale/distribution operations
  o Suitable size and construction
  o Clean and orderly
  o Free of infestation from insects, rodents, birds, etc.

8. Storage Area
• Adequate lighting
• Ventilation
• Product stored at appropriate temperature and humidity conditions in accordance with USP or labeled requirements
• Sanitary
• Spacious
• Properly equipped
• Secure
• Has a designated and marked quarantine area
• Product stored away from poisons or harmful substances such as cleaning solutions, vermin repellant, and chemicals.

9. Security
• Working monitored alarm system; or for licensees who distribute medical gas product only, product is stored under lock and key in Board approved facility and/or working monitored alarm system on open dock area
• Working security system against theft or diversion
  o How does security system operate?
  o Are legend drugs, devices, and/or medical gases stored in secure area? Is the shipping/receiving area secure?
  o Who has access to legend drugs, devices, and/or medical gases?
  o Is access to legend drugs, devices, and/or medical gases restricted?
  o Who has access to facility after operating hours?
  o Has there ever been any lost or stolen legend drug, device, and/or medical gas product at the facility.
ARE YOU READY FOR INSPECTION?

TEST INSPECTION - CHECKLIST

☐ Current LBWDD license displayed    [46:XCI.301.E] (not for initial (new) applications)
☐ Has off-site storage facility(s)    [46:XCI.301.J] ☐ Not Applicable
☐ Facility is of suitable size and construction    [46:XCI.309.A.1.a]
☐ Facility is clean and orderly    [46:XCI.309.1.d]
☐ Facility is free from infestation by insects, rodents, birds, etc.    [46:XCI.309.1.e]
☐ Storage area provides adequate:
  ☐ Lighting
  ☐ Ventilation
  ☐ Temperature
  ☐ Sanitation
  ☐ Humidity
  ☐ Space
  ☐ Equipment
  ☐ Security
☐ Storage area has a designated and clearly marked quarantine area    [46:XCI.309.1.c]
☐ Storage facility has working monitored alarm system OR (medical gas only) is a Board-approved facility kept under lock and key    [46:XCI.309.2.b/c]
☐ Medical gases stored on open dock area has a working monitored alarm system    [46:XCI.309.2.d]
☐ Facility is equipped with working security system suitable for protection against theft or diversion of product and tampering with computer or electronic records    [46:XCI.309.2.e]
☐ Drug or Device products are stored at appropriate temperature    [46:XCI.309.3]
☐ Inventory records readily available for inspection    [46:XCI.311.B/C]
☐ Perpetual inventories and records of all transactions for all drugs, devices, and/or medical gases are current    [46:XCI.311.A]
☐ Temperature monitoring logs are maintained and current (excluding medical gases only)    [46:XCI.309.A.3.b]
☐ Copies of customer licenses verifying authority to purchase drug products on file and current    [46:XCI.311.D]
☐ Has verified all suppliers are licensed by LBWDD    [46:XCI.311.F]
☐ Has established and maintains policies and procedures covering:    [46:XCI.313]
  ☐ Receipt of drug, devices, and/or medical gases
  ☐ Storage
  ☐ Inventory and distribution
  ☐ Correction of inventory errors and inaccuracy
  ☐ Inspection of all incoming & outgoing shipments    [45:XCI.309.A.4]
  ☐ Product rotation
  ☐ Recalls and withdrawals
  ☐ Out-dated product segregation
  ☐ Product returns or destruction    [45:XCI.309.A.5]
  ☐ Reporting of loss and theft
  ☐ Security and crisis handling
  ☐ Validation of customer licenses    [46:XCI.311.D]
  ☐ Notification of theft & diversions; findings of contraband, counterfeit or misbranded drugs
  ☐ Review of excessive or suspicious purchases
  ☐ Monitoring & recording of storage temperatures    [45:XCI.309.A.3]
  ☐ Verification of suppliers    [46:XCI.311.F]
☐ Has current list of responsible persons – owners, officers, directors, and responsible party    [46:XCI.315]
  ☐ List of employees with access to product
  ☐ List of employees with access to building after hours
☐ Facilities handling controlled substances =    [46:XCI.317.2]
  ☐ Has current CDS registration    ☐ Not Applicable
  ☐ Has current DEA registration    ☐ Not Applicable