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Department: Distribution Operations	SOP #:010
Title: Controlled Substance Handling	

1.0 Scope

The directives contained in this SOP apply to all Anda and Anda Pharmaceuticals employees that have or may have contact or involvement in the activities associated with controlled substances. This is to include, but not be limited to:
* Distribution Center personnel
* Compliance personnel

2.0 Purpose

The purpose of this SOP is to document the procedures to be used in the handling of controlled substances to ensure compliance with DEA and State controlled substance regulations.

3.0 Procedure

I.   Receiving
    A.   LTL/TL Shipments
        1.   When a driver presents the receiving department with a freight bill, the receiving department must review the bill and determine the shipper's box count.
        2.   The pallets that are off-loaded must have the shrink-wrap cut off of them and the piece count determined while the driver is here.
        3.   If there are any discrepancies between the freight bill box count and the actual box count, the discrepancy must be noted on the freight bill. The driver must then provide his full signature and printed name on the freight bill acknowledging the discrepancy. Once this is provided, have him call the O, S, and D department of his company and get us the specific # assigned to the discrepancy.
        4.   Print checklist and verify that the DEA matches the checklist to the packing slip
              *Print PO and choose the correct DEA
              *Checklist will print and you must verify address matches between checklist and packing slip
              *In the event the DEA does not match between the packing slip and checklist, nothing will be received. The packing slip will be sent to purchasing for addition of needed DEA information.

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5. For controlled substance receipt discrepancies, the Inbound Operations Manager will immediately inform the DEA Compliance Manager of the discrepancy and have them verify the discrepancy.

6. The Inbound Operations Manager will then fill out the receiving discrepancy report and call the vendor to report the discrepancy.

7. When receiving controlled substances and completing the receipt checklist, every sealed case or box must be opened, inspected, and double-checked for concealed shortages by the receiving department. The cage operations people will go to receiving, verify the receipts, and take the product to the cage to be put away.

8. If there are any variances between the actual quantity received and the quantity on the packing list, receiving contacts vendor.

9. A designated cage employee will physically check product and sign checklist.

10. Once any variances have been resolved or reported to the vendor, the Inbound Operations Manager keys the quantities received into the receiving screen for the particular purchase order and generates the put away report and labels.

11. The receipt checklist, packing list, and freight bill must be given to the Inbound Operations Manager who will forward them to Accounts Payable for invoice processing.

B. Parcel Shipments

1. Count parcels received for the particular carrier delivering (UPS, FedEx, etc). Each box needs to be counted prior to FedEx/UPS leaving or signing

2. Ensure that the count matches the manifest from the driver.

3. If the counts do not match, determine the source of the discrepancy.

4. Follow the steps in A.3 – A.5.

5. Generate receipt checklists for purchase orders associated with the parcels.

6. Check-in the products contained in the parcels.

7. For controlled substances, follow A.6 – A.9.

II. Put away

A. Once the put away report and labels have been generated and the cage personnel have verified the receipts, the product will be taken to the cage for put away.

B. Once in the cage, the cage operations personnel will split the product by put away zone and then put the product into the location designated on the put away label, ensuring that for:

1. Unit picks

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a. The product is rotated so that the oldest expiration date is in the front of the location and the newest is in the rear and bottom of the location.

b. The product is stocked so that it is in a pick-ready status (the top of the case is cut off and any plastic wrap is cut so that a person picking the product can easily remove the quantity for the order that they are picking).

2. Case picks

a. The cases are rotated so that the oldest expiration date is on the top of the product in the location and the newest is on the bottom.

C. The person putting away the product will then initial the line on the put away report indicating that the product has been put into the location noted on the report.

D. If any information on the put away report changes (location will not fit product designated to go there and product is moved to an open location that will fit the product, etc), the put away person must get approval from the cage lead person or manager to make the change (Initial put away document signifying approval). Once this approval has been received, the change needs to be noted on the put away report and the cage lead or manager must make the manual inventory movement to ensure inventory integrity.

E. The completed put away report is then filed with the put away documentation for that day.

III. Picking
Unit Picks

1. Separate the pick tickets coming off of the printer into 4 different stacks

a. Cage Flow (CF) only

b. Cage Handstack (CG) only

c. Cage Flow (CF) and Cage Handstack (CG)

d. Refrigerated (RF)

2. Select the ticket to be picked.

3. Go to the first location designated on the pick ticket and select the quantity listed on the pick ticket. When picking the product verify the following:

a. The NDC number on the pick ticket matches the NDC number of the product being picked.

b. The unit of measure on the pick ticket matches the unit of measure of the product being picked.

c. The product has at least 6 months before it expires (with the exception of items with "S/D" in the description or special

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handling customers that require more than the standard dating).

4. Circle the quantity picked.
5. Go to the remaining locations on the pick ticket in the same manner as step 3 and 4.
6. When all of the items on the ticket have been picked, write your picker number at the bottom of the pick document, go to the confirmation area and put the product into the designated box (size based on description in upper right hand corner of pick ticket).
7. Take the box to the confirmation area for processing.
8. Go to Step 2.

Case Picks
1. The case labels for the cage will print on the label printer at the beginning of the PM Rack.
2. When the PM picker sees case labels for the cage (with locations having a zone of "CA" or "CC"), they will immediately take the labels to the cage lead person.
3. The cage lead person will assign a picker to these labels.
4. The picker will proceed to the designated location and do the following
   a. Verify that the location they are pulling from is the same as the location on the case pick label.
   b. Verify that the case quantity printed on the label matches the actual case quantity of the product being picked.
   c. Ensure that the NDC number listed on the case pick label is the same as the actual NDC number on the product.
   d. If there are problems during a-c, contact the cage lead person and inform them of the problem encountered.
5. Go to the next location to be picked and perform steps 4a-4d.
6. Once all of the tickets have been picked or the pallet is full, go to the designated confirmation station and give the cases to the checker.

IV. Order Confirmation/Packing
   A. Unit picks
      1. The order checker takes the pick ticket out of the box to be confirmed.
      2. They scan the invoice-page barcode on the pick ticket label to tell the system which box they are working on.
      3. They then scan every piece of product in the box checking the screen after each scan for any ERROR messages that may occur. If an ERROR message appears on the screen,
         a. Read the associated Error Message carefully.
         b. If it is the wrong item,

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c. F-12 and scan any shortages, then F9
1) Note the error and the picker number on the Error tracking log.
2) Give the ticket to the picker who made the error. Have them put back the incorrect product and pick the correct product.
3) If the picker discovers a stocking error at the correct location, they will report the error to the cage lead person who will discover the cause of the error and hold the appropriate people accountable.
4) When the picker brings the correct product, rescan the invoice-page barcode and scan the item.

d. If the message is that the scanned quantity is greater than the quantity on the order, manually check the product in question to see if there are more units than what were ordered.
1) If so, record the overage and the picker number on the Error tracking log.
2) Have the picker who made the error put back the overage to the location from which it came.
3) Rescan the correct number of units and place in the box (the counter for that item resets to zero when this error occurs, so every piece of that product must be rescanned).
4) If the actual number of pieces equals the ordered quantity or is less than the quantity, apiece or pieces have been scanned more than once. Rescan the pieces for that product.

e. If no ERROR messages appear through the time when all units of the box have been scanned or since the last error message, press the F9 key (Done).

f. Three things can happen at this point:
1) A product description can be displayed showing a shortage of one of the products on the order. In this case,
a) Record the shortage and the picker number on the Error tracking log.
b) Have the picker who made the error take the pick ticket to the location and pick the shortage and return it to you.
c) Key in the actual quantity (should be the ordered quantity) and hit "Enter" and then F5 to accept the line.

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      d)   If another item comes up, perform steps a) – c) for that item, etc.

      e)   If the initial checking screen comes up, that means that the box is completed, but it is not the last box on the invoice.

    2)   The initial checking screen comes up. The box is completed, but it is not the last box on the invoice. Give the completed box to the packer.

    3)   The initial checking screen comes up with an "Invoice Printed" message on it. The invoice and stickers (if the customer is designated as such) print on the laser printer. Put them into the box with the product and give the box to the packer.

  4.   The packer then counts the number of units in the box and checks for a match with the number of units on the pick ticket. If any problems, during that check, the packer informs the cage lead person.

  5.   The void in the box is then filled with dunnage; the box is sealed and put on the conveyor.

B.   Case Picks

  1.   The scanner needs to verify that the case quantity on the box as well as the case quantity on the pick ticket match

  2.   The checker must scan the case label invoice-page barcode to tell the system which case they are confirming.

  3.   The checker then scans the barcode on the actual product. If the barcode is incorrect, either

    a.   The wrong item was picked. In this case, find the correct item in the given location and report the discrepancy to the Inventory Control Manager and the cage lead person.

    b.   The incorrect scan code was entered for the item number in question. Inform the Inventory Control Manager and Outbound Operations Manager of the problem so they can resolve.

  4.   If there is no barcode on the case of the product, attempt scanning a unit of the product. If this does not work, attempt keying in the NDC number of the product. Only as a last resort and with the Outbound Operations Manager's permission, key in the item number of the product to confirm the order.

  5.   Three things can happen at this point:

    a. A product description can be displayed showing a shortage of one of the products on the order. In this case,

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       1) Record the shortage and the picker number on the Error tracking log.
       2) Have the picker who made the error take the pick ticket to the location and pick the shortage and return it to you.
       3) F12 and scan any shortages, then F9
       4) Key in the actual quantity (should be the ordered quantity) and hit "Enter" and then F5 to accept the line.
       5) If another item comes up, perform steps a) – c) for that item, etc.
       6) If the initial checking screen comes up, that means that the box is completed, but it is not the last box on the invoice.

   b. The initial checking screen comes up. The box is completed, but it is not the last box on the invoice. Give the completed box to the packer.
   c. The initial checking screen comes up with an "Invoice Printed" message on it. The invoice and stickers (if the customer is designated as such) print on the laser printer.
   d. If shipping the case via a parcel carrier (Airborne, UPS, OTD, FedEx), over pack the case into an appropriate sized Anda box, place the invoice and stickers in the box, fill the air void in the box with dunnage, and seal the box.
   e. If shipping the case via Less than Trailer Load/Trailer Load on a pallet,
       1) Seal each case being shipped.
       2) All cases must be repacked and stacked on pallet
       3) Place the invoice and stickers into a packing slip envelope.
  f. Pallets and paperwork are given to the shipping supervisor for the case pick employees to complete.
       4) Affix the packing slip envelope to a box on the top of one of the pallets.
       5) Have the driver count the number of pieces on the shipment so that he can sign for them in step 8.
       6) Shrink-wrap the pallets.
       7) Put an "Invoice Enclosed" label on the pallet that has the invoice on it.
       8) Print 2 Customer Address Forms and attach to each pallet (one for each fork side of the pallet).

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9) Fill out the bill of lading for the shipment and have the driver sign for the number of pieces shipped.
10) Load the pallets for the order onto the truck.

V. Shipping
    A.   Due to the fact that the controls leave the cage sealed, they are sent through confirmation and into shipping with no changes being made to the product in the box. Doing this almost eliminates the chance of the product being lost or damaged on the conveyor.
    B.   Once the box arrives in shipping, it is scanned by FedEx or processed for another carrier in the same manner as non-controlled products so as not to identify the control orders to carrier personnel.
    C.   Once the carrier scans the package it can be tracked in their system if any problems arise during the delivery process.

VI. Replenishment
    A.   Log in to the TPS Distrack system.
    B.   Proceed to the Warehouse Functions screen (2, 4, 1)
    C.   Select Option 20 – Restocking instructions.
    D.   Select the zone that needs to be replenished by keying in the appropriate Zone/Aisle combination (From CF-01 To CG-03 for instance) and press "Enter".
    E.   Print the spool file(s) for the replenishment (report and labels).
    F.   The report and labels will print in backstock location travel sequence.
    G.   Begin picking the replenishment (full cases). If there are any problems that arise during the picking of the replenishment, note them on the report and inform the Cage Lead Person.
    H.   When complete or a pallet is full, take the replenishment to the designated zone.
    I.   Using the information on the replenishment labels put the product into the designated location.
        1. The product is stocked so that it is in a pick-ready status (the top of the case is cut off and any plastic wrap is cut so that a person picking the product can easily remove the quantity for the order that they are picking).
        2. If there are any problems that arise during the put away of the replenishment, note them on the report and inform the Cage Lead Person.
        3. It is crucial that the replenished stock be put away in the most effective manner because once the replenishment report is generated, the system thinks that the product is already in the primary location. The system will begin allocating orders from these locations. If the product is not put away when a person comes to pick an order, there will be a lot of confusion about where the product is.

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J.   Once all replenishment is put away, turn the completed report into the cage lead person for their review.

K.   The lead person will make all of the corrections noted on the replenishment report and turn the report into the DEA Compliance Manager for their review

VII.   Customer Returns

A.   Prior to Customer Service processing a pick-up for controlled substances, they are to confer with the DEA Compliance Manager on the nature and reason for the return and ensure that the return is being done in accordance with the DEA Regulations.

B.   Once Customer Service and DEA Compliance concur on the return, customer service will issue the pickup for the product being returned.

C.   When the product comes back, it will be coming in with other returns, both non-controlled and controlled. The customer returns personnel will open all boxes to inspect for controlled substances. Any controlled substances that they find need to be processed immediately and then brought directly to the cage.

D.   While processing the controlled substances, there can be several different dispositions for the products.

    1.   The product is saleable and can be returned to stock.

    2.   The product is not saleable, but is within our returns policy. This product will be moved systematically to _V and physically to the morgue/quarantine area of the cage.

    3.   The product is not saleable and is outside our returns policy (partial returns, expired returns, etc). This product will be returned to the customer with a letter explaining why it is being returned to them. **The DEA Compliance Manager will approve these instances.**

E.   When the customer returns personnel bring the product to the cage, they will have the person receiving them into the cage sign for the controls.

F.   The products will be labeled with the disposition on them so that the cage personnel will know where to put the products (either in cage _V or into a location for sale).

G.   The cage personnel will put the product into the directed location as follows:

    1. Unit picks

        a. The product is rotated so that the oldest expiration date is in the front of the location and the newest is in the rear and bottom of the location.

        b. The product is stocked so that it is in a pick-ready status (the top of the case is cut off and any plastic wrap is cut so that a person picking the product can easily remove the quantity for the order that they are picking).

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2. Case picks
   a. The cases are rotated so that the oldest expiration date is on the top of the product in the location and the newest is on the bottom.
3. If the product is going to the cage _V, the cage personnel will put it in the quarantined area. The box containing the product will be labeled with the item number, lot number(s), and quantities contained within it. This will make for an easier count when taking an inventory on _V.
4. When the product has been put into its proper location, the paper work   associated with the return will be filed with the controlled substance inventory control files.

VIII. Vendor Returns
   A. When the Vendor Returns personnel (VRP) are processing returns to a given vendor, they will review the list of items in _V for that vendor, including controlled substances.
   B. The VRP will verify that the product is within the returned goods policy of the given vendor.
   C. The VRP will fill out a Return Goods Authorization form for the given vendor. This form will include:
      1. The item number
      2. The lot number
      3. The quantity for the given item and lot number combination
      4. The NDC number
      5. The expiration date
      6. Anda's internal RGA number for reference
   D. The VRP (or other designated personnel) will call the vendor contact to inform them of the need for a return and a vendor Returned Goods Authorization (RGA).
   E. When the vendor furnishes them with the Vendor RGA, the VRP makes 2 copies – 1 goes to Accounts Receivable, 1 to the VRP files, and the original goes into the box with the product.
      1. The product being returned is boxed, the air void filled with dunnage, and sealed with a copy of the Vendor RGA inside the box.
      2. Create a shipping label for the Vendor using the Access program.
      3. Ship the return in the most cost-effective manner (generally UPS Ground).
      4. Record the carrier tracking information on the VRP copy of the Vendor RGA (or the internal RGA if the vendor does not provide (as in F below)) to facilitate providing a POD to the vendor if needed.

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F.   If the vendor uses a third party to process returns, the VRP needs to get a fax from the vendor acknowledging the return. If the vendor refuses to give a paper authorization, a contact name, position, and telephone number is required to be noted on the paperwork that the VRP retains for that return. Follow Steps in E above.

G.   The VRP will file the RGA's by vendor and then by internal RGA number.

H.   Do a C- adjustment for all of the product contained in the return to vendor including the Vendor RA number in the comment field of the adjustment screen.

IX.   Inventory
   A.   Vault

      1. Every morning before receipt or shipment of product a manual inventory must be done on all schedule 2 products located in the vault.
      2. At the completion of the day another inventory will be done.

   B.   Cage

      1. At the end of each business day a manual inventory must be done on all schedules 3, 4 and 5 controls located in the cage.
      2. At beginning of next working day and reconciliation will be completed prior to any product being shipped.

X.   Reporting Loss
   A. All controlled substance losses and thefts are considered significant and reported immediately upon discovery to the DEA on form 106.

4.0 Revision History
SOP will be reviewed annually, each February, by management

Effective Date	Version	Author	Change Description
August 20, 2004	010	Patrick Cochrane	Original Issue
September 26, 2008	010.01	Michael Cochrane	Change Management where applicable
May 21, 2010	010.02	Michael Cochrane	Review
February 2, 2011	010.03	Michael Cochrane	Review
April 5, 2012	010.04	Michael Cochrnae	Review

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