From: Cochrane, Michael <Michael.Cochrane@Andanet.com>
Sent: Thursday, March 25, 2010 12:21 PM
To: Cochrane, Patrick; Spellman, Jay; Esteves, Alberto
Subject: FW:
Attachments: OPS 40- Anda- SOP SOM.doc

Please take a look at the attachment. IS is working on the programming and someone in my group will take care of the review and release process when necessary. It will be very similar to the CSOS order releasing functionality and I am having her include the reason codes for release. When she is done, I will test to make sure it works. There are no definitions in the CFR regarding suspicious orders, but we can change the formula if necessary. Our limit review process and current allocations will not change. Let me know if you think we should add or change anything. I don't think there is anyone else in our organization that will understand or have any valuable input. If you do let me know and we can have them review as well. We are listed on all our SOP's as the reviewers and approvers along with Al3. I wanted everyone to be on the same page before I test and this goes into production so I can make any changes or modifications prior.

Thanks
Mike

From: Michael Cochrane
Sent: Thursday, March 25, 2010 8:14 AM
To: Deanne Lykins
Subject:

Attached is the SOP we discussed. Please see the reason codes towards the bottom I would like to use when releasing an order.

Thanks
Mike

PLAINTIFF TRIAL EXHIBIT
P-16462_00001

SOP Number: OPS-040-00	**Department: DISTRIBUTION OPERATIONS**
Supersedes: NEW	**Title: Suspicious Order Monitoring/ Order Monitoring System**
ORIGINATOR **Signed By: Patrick Cochrane** **Title: Vice President, Logistics & Operations** **Date:** **Role: Preparer/Originator** **Signature Meaning: Approval**	**Executive Management** **Signed By: Patrick Cochrane** **Title: Vice President, Logistics & Operations** **Date:** **Role: Reviewer** **Signature Meaning: Approval**
DC Management **Signed By: Jay Spellman** **Title: FL Director, Logistics** **Date:** **Role: Reviewer** **Signature Meaning: Approval**	**Executive Management** **Signed By: Al Paonnessa III** **Title: Executive Vice President & COO** **Date:** **Role: Reviewer** **Signature Meaning: Approval**
DC Management **Signed By: Alberto Esteves** **Title: OH Director, Logistics** **Date:** **Role: Reviewer** **Signature Meaning: Approval**	**Compliance Management** **Signed By: Michael Cochrane** **Title: Director, Logistics Compliance** **Date:** **Role: Reviewer** **Signature Meaning: Approval**

REVISION HISTORY

Effective Date	Document Number	Author	Change Description
December 2009	OPS-040-00	Michael Cochrane	

1.0 Scope

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

* Distribution Operations
* Compliance

2.0 Purpose

To document the procedures involved in reviewing Held and/or Suspicious Orders.

3.0 Procedure

3.1 System Formula:

1. Add quantity purchased over last 12 months for all customers.
2. Add the number of total customer months purchased that do not equal 0
3. Divide the quantity purchased by the total customer months.
4. Multiply the quantity by a factor of 3.
5. If customer order quantity exceeds this number order is to be held for review.

3.2 Review all held orders and determine the reason for additional product ordered. The following are release reasons for held orders

1. Increased supply to new or existing customer/patient
2. Increased supply to new facility
3. Consistent with customer order pattern and/or within CS increase granted
4. Increasing stock due to promotion or pricing change
5. First time order of product
6. Consistent with customer class order pattern
7. Administration release. Customer call not required.
8. Released unchanged with DEA concurrence

3.3 Orders that exceed the above criteria and cannot be released with an appropriate reason listed above will be reported to the local DEA office for the applicable distribution center.