From: Cochrane, Michael <Michael.Cochrane@Andanet.com>
Sent: Wednesday, September 10, 2014 11:05 PM
To: Schultz, Emily
Subject: Fwd: Follow Up Items

Sent from my iPhone

Begin forwarded message:

From: "Cochrane, Michael" <Michael.Cochrane@Andanet.com>
To: "Mitchell, Valerie D. (Dawn.V.Mitchell@usdoj.gov)" <Dawn.V.Mitchell@usdoj.gov>
Cc: "brittany.m.freeman@usdoj.gov" <brittany.m.freeman@usdoj.gov>, "duane.h.stickles@usdoj.gov" <duane.h.stickles@usdoj.gov>, "brice.d.burchard@usdoj.gov" <brice.d.burchard@usdoj.gov>, "Brown, Robert" <robert.brown@andanet.com>, "Alberto Esteves (Alberto.Esteves@Andanet.com)" <Alberto.Esteves@Andanet.com>, "Paonessa, Albert" <Al.Paonessa3@Andanet.com>
Subject: Follow Up Items

Ms. Mitchell,

We would like to first start by thanking you for hosting us and the meeting at your office. We appreciate your time as well as DI Freeman, DI Burchard, and Supervisory Special Agent Unit Chief Stickles.

Attached, please find the breakdown of distribution for Anda, Inc. overall as well as by each individual Anda facility. In addition to that, I am attaching the Standard Operating Procedures(SOP's) we discussed the pertain to some of the slides and the flow charts we reviewed. Going forward we will not co-mingle our customers cut off or refused with any suspicious orders. Rather than an email containing all the information from Emily Schultz, you will receive a separate email from Robert Brown as well as a phone call in the event there is a suspicious order to report. We will include all the specifics regarding the order in our email transmission as well as a verbal via phone call to you or a designee. Thank you again for your time.

Michael Cochrane
Anda, Inc.
954-217-4325

PLAINTIFF TRIAL EXHIBIT
P-16468_00001

Department: Distribution Operations	SOP #:028
Title: Information Needed to Set-up a New Account	

1.0 Scope

The 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, Information Needed to Set up a New Account. This is to include, but not be limited to:
* Sales
* Customer Service
* Regulatory Compliance

2.0 Purpose

To provide the licensing requirements to establish pharmacy, physician and wholesaler/distributor ("Customer") accounts with Anda, Inc.

3.0 Procedure

1. Before a new pharmacy, physician, or wholesaler/distributor account is established, Anda must receive copies of the following regulatory licensing requirements:

   (a) Pharmacy licenses, physician's licenses, or wholesaler/distributor licenses in order to ship **non-controlled substances**. The address on the license must match exactly to the "Ship To" address for a pharmacy or wholesaler/distributor. The address may differ in a situation where we have a physician's license as doctors may practice at multiple locations. Our software system tracks expiration dates and prevents shipments from being processed accordingly.

   (b) For Customers wishing to purchase controlled substances, the above information is needed, as well as a valid copy of the Customer's DEA registration. The "Ship To Address" must **match exactly** the address listed on the license, including the zip code. **NO EXCEPTIONS**. Our software system tracks expiration dates and prevents shipments from being processed accordingly.
   - All new and reactivated customers that wish to purchase controlled substances are required to complete our due diligence documents which include our customer questionnaire.

- In most cases we also require the submission of a dispensing log of controlled and non-controlled substances dispensed by the pharmacy.
    - The allocation of all controlled substance chemical families to 1000 dosage units for new/reactivated customers and have excluded Oxycodone and Methadone products from availability until we can confirm that the customer is acting in accordance with the Controlled Substances Act.
    - Physicians and wholesale distributor accounts are not eligible to purchase any controlled substances.

(c) Prior to license expiration we request the customer to provide a copy of their updated license.

(d) A retired Registrant Listing is compared to our sales database to identify any customers that no longer hold a valid DEA registration

(e) For chains of stores a spreadsheet would suffice as long as it includes the store number, address, license number (both DEA registration number and Pharmacy Permit number) and the expiration of above licenses. It is then the requirement of Anda Inc. that we check the validity of these licenses.

(1.) For chains greater than 50 stores, a spreadsheet containing the same information described in paragraph (d) will be sufficient under theses two circumstances:

a. The list is provided by the chain's legal department and/or regulatory department and the department(s) attest to Anda that the data is true and correct.
b. The provided list is compared and matched, by DEA registration number, to the "DEA Registration File" residing on Anda's systems that is updated every month via CD sent by the Department of Justice. This check is performed to ensure that the registrations are active and in good standing and that the street addresses are correct.

2. In addition to the regulatory documentation described in the preceding section, all customers requesting the ability to purchase controls must complete a Customer Questionnaire, a copy of which is attached hereto. Further, all customers desiring to purchase controlled substances must provide a dispensing log that contains a list of all pharmaceutical products dispensed by the customer during the 3 months immediately preceding the date that the account is established which includes the quantities and number of prescriptions filled for each dispensed product. The dispensing log should be organized by the largest dispensed products in descending order.

3. Criteria for denying business
    a. Not properly licensed

b. Failure to submit renewed permits
c. Undesirable quantities and/or combinations of dispensed controlled substances
d. Suspicious controlled substance purchases
e. Compliance decision based on review of due diligence materials

4. Report to the appropriate federal and state agencies within 2 business days

5. A hardcopy file is maintained for each customer. Contents of the file include all previous state and federal licensing.

4.0 Revision History

SOP will be reviewed annually, each February, by management

Effective Date	Version	Author	Change Description
August 20, 2004	028	Patrick Cochrane	Original Issue
March 9, 2007	028.01	Patrick Cochrane	Addition of 3.0-1.-(d)-(1)
September 26, 2008	028.02	Michael Cochrane	Change Management where Applicable
May 21,2010	028.02	Michael Cochrane	Review
February 2, 2011	028.02	Michael Cochrane	Review
August 2011	028.03	Michael Cochrane	Include CQ and DD requests
April 5, 2012	028.03	Michael Cochrane	Review
June 10, 2013	028.03	Emily Schultz	Review
June 2, 2014	028.03	Emily Schultz	Review
August 26, 2014	028.03	Emily Schultz	Review

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Author:	easchultz
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Number of Characters:	4,464 (approx.)

Department: Distribution Operations	SOP #:040
Title: Orders of Interest Monitoring System/Suspicious Order Monitoring	

1.0 SCOPE

The directives contained in this SOP apply to all Anda DEA Compliance Analysts who are involved in the review of a sales order deemed to be of "interest". Orders of Interest are captured using historical sales information with a user defined time frame by looking at past averages of the following using a user defined multiplier:

- DEA Registrant's average dosage units ordered per month of a specific chemical family
- DEA Registrant's average dosage units per order of a specific chemical family
- The average dosage units per order by that class of trade for a specific chemical family
- Order frequency per rolling 30 day period

2.0 PURPOSE

To document the procedures involved in reviewing Held Orders of Interest/Suspicious Orders.

3.0 PROCEDURE

I. Determine the type of hold an order has been stopped for

- DEA Registrant's average dosage units ordered per month of a specific chemical family
- DEA Registrant's average dosage units per order of a specific chemical family
- The average dosage units per order by that class of trade for a specific chemical family
- Order frequency per rolling 30 day period

II. **Refer to TPS – Customer Maintenance License Info (TPS 2.2.4.1)**

- Pay particular attention to City/State of request
- Determine if a Customer Questionnaire is on file (customer flagged "Y")

III. **Review Customer Compliance Notes (TPS 2.2.4.1/Shift+F4&F8)**

- Determine if customer had previously been reviewed or grandfathered in to control eligibility
- Review Compliance notes regarding: historical requests, trends, approvals or denials
- Review any comments regarding changes to account, ownership, licensure

IV. **Review Customer Questionnaire**

- Open Customer Questionnaire on shared drive if already saved. (O:\Florida\Anda\Warehouse\Compliance\Customer Questionnaire)
- Determine type of pharmacy reviewing: volume, location, age, etc.
- Determine types of customers serviced by pharmacy, including review of identified physicians submitting controlled substance prescriptions, pharmacy proximity to healthcare facilities and physician practices and pharmacy procedures for ensuring that products are being dispensed for legitimate medical purposes by physicians who are in good standing with no history of regulatory violations or suspicious professional practices.

V. **Review Summarized Dispensing Data from Pharmacy if on file**

- Determine the way in which data is summarized: patient & script, descending pill quantity dispensed (by product or NDC), alphabetical, number of RX's
- Determine the level of control volume for time frame
- Determine ratio of controls versus non-controls
- Evaluate top products dispensed
- Determine particular products or NDC's dispensed most frequently

VI. **Review TPS- Controlled Substance Inquiry (2.4.3.12)**

- Determine if Anda will be a primary source of controls, etc.
- Review purchasing trends on a monthly basis by product & product family
- Evaluate percentage of control business on a monthly basis (average)

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/State Authority concurrence

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

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4.0 REVISION HISTORY

SOP will be reviewed annually, each February, by management

Effective Date	Version	Author	Change Description
December 2011	040	Michael Cochrane	Original Issue
April 5, 2012	040.01	Michael Cochrane	Review
June 10, 2013	040.01	Emily Schultz	Review
June 2, 2014	040.01	Emily Schultz	Review
August 26, 2014	040.01	Emily Schultz	Review

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