From: Cochrane, Patrick <Patrick.Cochrane@Andanet.com>
Sent: Thursday, July 22, 2010 10:11 PM
To: Paonessa, Albert
Subject: Draft 2 - DEA Summary
Attachments: DEA Summary.docx

Here is the whole document. Attached as a Word document and pasted below.

Summary of time spent on-site at Anda, Inc

Friday July 9, 2010	230pm-500pm	Security Walkthrough/ Alarm Test/ Initial request for information
Monday July 12,2010	1030am-330pm	Inventory Count
Tuesday July 13, 2010	1000am-500pm	Inventory Reconciliation/audit roll/review materials
Wednesday July 14, 2010	230pm-500pm	Inventory audit discussion/Review of previous audit materials
Thursday July 15, 2010	1015am-230pm	Review of previous audit materials /Business practice discussion
Tuesday July 20, 2010	1000am-445pm	Business practice discussion

Friday July 9th – Thursday July 15th AM
Scope of audit until just after noon on Thursday July 15th was routine. We covered all of the requirements related to inventory accountability, security, employees, licensure by other regulatory departments, Operations SOPs, etc. We also provided the investigators with the documentation requested on day 1 related to the Watson/Andrx/Anda corporate structure and officer/director listing. A complete listing of all materials and reports provided to the investigators has been maintained.

Thursday July 15th PM
We had a brief question/answer period about customer setup processes. There was a question asked about whether or not we were aware that we sold to locations that had multiple doctors at the same physical address. A follow up question was asked about whether we visited these customers.
The investigator stated that one of the DEA's concerns was about the amounts of controlled substances sent to locations with multiple doctors. She stated that she would bring specific examples the following week to review. She asked that we prepare and review sales to doctors at the same location, a list of accounts that had increases granted above our 5000 dosage unit baseline limit, the dates and sizes of any of these increases, and who approved the increases and why.
She gave us a specific example to review related to Dr Bertman. She stated that this doctor had 2 DEA licenses at the same address and that we shipped him controlled substances against both registrations. She was in fact incorrect on this. The doctor did have 2 DEA registrations, but they were at different addresses in different cities at the time we shipped.
She then stated that our record keeping was impeccable, that the normal audit was not a focus of this visit, and that their focus for the duration of their time with us would be on customer setup practices, sales training related to controlled substance sales, and large amounts of controls shipped to doctors and pain clinics.
She then commented that she didn't know if they were going to hold a closing discussion with us related to the audit and then continue the conversations or wait until all questions were answered to hold the closing discussion then. She stated that she would need to review that with her boss.

Tuesday July 20th

The investigators started the day's discussion by requesting the details of the requests that she had made previously related to physician customers and related increases. She then gave us 7 specific DEA registration #s for physicians that she wanted us to compile data on. Five of these were at one address and she stated that the other 2 were at another address. The 2 were actually at separate addresses.
Investigator Hamilton provided a copy of a DEA letter regarding Suspicious Orders dated December 2007. She asked if it looked familiar and if we had a copy. We stated that it did not look familiar to any of us.
The investigators stated that they were going to take some time to further review documentation previously provided and that we would continue our discussion at about 1130am.
When we resumed the discussion, Investigator Hamilton again asked about the suspicious orders letter and we confirmed that we did not have the letter.
Investigator Hamilton asked why we had separated Oxycodone products and Oxycodone APAP combo products into two separate families. We responded that they were prescribed for two different severities of pain much like the difference between the other families of pain chemicals.
We then discussed the details of the Dr Bertman request from earlier. We did resolve that Dr Bertman was licensed at two different addresses when we shipped. Jan made a copy of an Invoice and Form detailing such.
Jan stated that in a one year period, Anda shipped approximately 142,000 dosage units to the 5 physicians previously mentioned. She further commented that had we visited this location, we wouldn't have sold them controlled substances. She noted that they perform surveillance of these types of locations and that they regularly "see people in the parking lots throwing up" and "sitting in the parking lot." She asked again if we visited the location in question and we reconfirmed that we had not. We asked her if DEA realized that they had 5 licenses at the same location. She then stated that "registrants have a responsibility to know their customers separate and apart from an active registration." She added "a distributor should visit a customer at least once – at the very least, initially, prior to starting distributions. Thereafter, look at locations that are meeting thresholds. Visit those locations as a follow up. That is DEA's stance."
We then provided the details regarding purchases made by the 6 physician locations that were granted increases over the 5000 dosage baseline. Investigator Hamilton then asked for the same report for all customers nationwide and the specific details leading us to grant increases to the 6 physician locations.
Investigator Hamilton then stated that she was going to perform a closing discussion but that she did not know if it was going to be on Wednesday July 21st, Friday July 23nd or Monday July 26th.
She then chose 7 pharmacy customers from the summary list of customers granted increases. She requested the same details for these as she requested for the doctors. (Why we granted increase, how much increased, how much of each family purchased).
We then broke for lunch.
When we resumed the conversation after lunch, we reviewed the nature and reasoning of the increases to the customers. All of the customers increased had the non-controlled vs. controlled product mix analyzed and all of the customers were taking advantage of our CSOS (Controlled Substance Ordering System) technology. Investigator Hamilton asked if any of these 7 customers were visited. We confirmed that they had not.
Investigator Hamilton then stated that they had what they needed and that they wanted to now schedule the closing discussion for Thursday July 22nd at 230pm.
She thanked us for our time and information provided and added that she may need to reach out to us in the coming days for additional support.

Wednesday July 21st
Investigator Hamilton informed us by email that they would need to reschedule the closing meeting for next week.

Thursday July 22nd
Investigator Hamilton informed us by email that they would be performing the closing discussion on Monday afternoon at 230pm.

Summary of time spent on-site at Anda, Inc

Friday July 9, 2010	230pm-500pm	Security Walkthrough/ Alarm Test/ Initial request for information
Monday July 12,2010	1030am-330pm	Inventory Count
Tuesday July 13, 2010	1000am-500pm	Inventory Reconciliation/audit roll/review materials
Wednesday July 14, 2010	230pm-500pm	Inventory audit discussion/Review of previous audit materials
Thursday July 15, 2010	1015am-230pm	Review of previous audit materials /Business practice discussion
Tuesday July 20, 2010	1000am-445pm	Business practice discussion

Friday July 9th – Thursday July 15th AM

Scope of audit until just after noon on Thursday July 15th was routine. We covered all of the requirements related to inventory accountability, security, employees, licensure by other regulatory departments, Operations SOPs, etc. We also provided the investigators with the documentation requested on day 1 related to the Watson/Andrx/Anda corporate structure and officer/director listing. A complete listing of all materials and reports provided to the investigators has been maintained.

Thursday July 15th PM

We had a brief question/answer period about customer setup processes. There was a question asked about whether or not we were aware that we sold to locations that had multiple doctors at the same physical address. A follow up question was asked about whether we visited these customers.

The investigator stated that one of the DEA's concerns was about the amounts of controlled substances sent to locations with multiple doctors. She stated that she would bring specific examples the following week to review. She asked that we prepare and review sales to doctors at the same location, a list of accounts that had increases granted above our 5000 dosage unit baseline limit, the dates and sizes of any of these increases, and who approved the increases and why. She gave us a specific example to review related to Dr Bertman. She stated that this doctor had 2 DEA licenses at the same address and that we shipped him controlled substances against both registrations. She was in fact incorrect on this. The doctor did have 2 DEA registrations, but they were at different addresses in different cities at the time we shipped.

She then stated that our record keeping was impeccable, that the normal audit was not a focus of this visit, and that their focus for the duration of their time with us would be on customer setup practices, sales training related to controlled substance sales, and large amounts of controls shipped to doctors and pain clinics.

She then commented that she didn't know if they were going to hold a closing discussion with us related to the audit and then continue the conversations or wait until all questions were answered to hold the closing discussion then. She stated that she would need to review that with her boss.

Tuesday July 20th

The investigators started the day's discussion by requesting the details of the requests that she had made previously related to physician customers and related increases. She then gave us 7 specific DEA registration #s for physicians that she wanted us to compile data on. Five of these were at one address and she stated that the other 2 were at another address. The 2 were actually at separate addresses.

Investigator Hamilton provided a copy of a DEA letter regarding Suspicious Orders dated December 2007. She asked if it looked familiar and if we had a copy. We stated that it did not look familiar to any of us.

The investigators stated that they were going to take some time to further review documentation previously provided and that we would continue our discussion at about 1130am.

When we resumed the discussion, Investigator Hamilton again asked about the suspicious orders letter and we confirmed that we did not have the letter.

Investigator Hamilton asked why we had separated Oxycodone products and Oxycodone APAP combo products into two separate families. We responded that they were prescribed for two different severities of pain much like the difference between the other families of pain chemicals.

We then discussed the details of the Dr Bertman request from earlier. We did resolve that Dr Bertman was licensed at two different addresses when we shipped. Jan made a copy of an Invoice and Form detailing such.

Jan stated that in a one year period, Anda shipped approximately 142,000 dosage units to the 5 physicians previously mentioned. She further commented that had we visited this location, we wouldn't have sold them controlled substances. She noted that they perform surveillance of these types of locations and that they regularly "see people in the parking lots throwing up" and "sitting in the parking lot." She asked again if we visited the location in question and we reconfirmed that we had not. We asked her if DEA realized that they had 5 licenses at the same location. She then stated that "registrants have a responsibility to know their customers separate and apart from an active registration." She added "a distributor should visit a customer at least once – at the very least, initially, prior to starting distributions. Thereafter, look at locations that are meeting thresholds. Visit those locations as a follow up. That is DEA's stance."

We then provided the details regarding purchases made by the 6 physician locations that were granted increases over the 5000 dosage baseline. Investigator Hamilton then asked for the same report for all customers nationwide and the specific details leading us to grant increases to the 6 physician locations.

Investigator Hamilton then stated that she was going to perform a closing discussion but that she did not know if it was going to be on Wednesday July 21st, Friday July 23nd or Monday July 26th.

She then chose 7 pharmacy customers from the summary list of customers granted increases. She requested the same details for these as she requested for the doctors. (Why we granted increase, how much increased, how much of each family purchased).

We then broke for lunch.

When we resumed the conversation after lunch, we reviewed the nature and reasoning of the increases to the customers. All of the customers increased had the non-controlled vs. controlled product mix analyzed and all of the customers were taking advantage of our CSOS (Controlled Substance Ordering System) technology. Investigator Hamilton asked if any of these 7 customers were visited. We confirmed that they had not.

Investigator Hamilton then stated that they had what they needed and that they wanted to now schedule the closing discussion for Thursday July 22nd at 230pm.

She thanked us for our time and information provided and added that she may need to reach out to us in the coming days for additional support.

Wednesday July 21st

Investigator Hamilton informed us by email that they would need to reschedule the closing meeting for next week.

Thursday July 22nd

Investigator Hamilton informed us by email that they would be performing the closing discussion on Monday afternoon at 230pm.