Walgreens
INTERNAL AUDIT

Internal Audit Report

Date December 22, 2008

Subject DEA Compliance – Perrysburg Distribution Center

From L. Dettmer – Internal Audit
B. Kowalski – Internal Audit
J. VanOverbake – Internal Audit
B. Yarbrough – Internal Audit

To Steve Kneller, Manager – Perrysburg Distribution Center
Dan Coughlin, Regional Vice President – Distribution Centers and Logistics

cc K. Amos, D. Boyajian, D. Brandt, R. Delaney, D. Doyle, T. Gorman, G. Hodge, B. Leander, R. Lewis, M. Linden, S. Malusa, G. Peters, D. Pinon, B. Rogan, T. Steffen, T. Trumbull, K. Wilson, C. Young

Conclusion

In our opinion, internal controls that ensure compliance with DEA regulations at the Perrysburg DC require improvement. In addition, some of these issues pertain to all company DCs and should be addressed to avoid potential DEA sanctions. Specifically, our review found four issues previously cited in the DEA's May 2006 inspection report that are still open. In addition, four issues noted in our previous audit (report dated July 2005) remain un-remediated. Areas requiring the greatest level of improvement are as follows:

DC-wide:

- pseudoephedrine reporting requirements and inventory maintenance
- suspicious controlled drug order processing and reporting
- controlled drug reporting, specifically receiving record information
- lack of formalized CII controlled substance policies and procedures

Perrysburg DC:

- significant concern regarding the growing in-transit controlled drug losses
- controlled drug security procedures
- employee background screening documentation
- controlled drug receiving procedures

Areas noted for improvement were reported to Management with suggestions for improved compliance. Management has corrected or is in the process of taking appropriate action to resolve our noted concerns.

Background
Internal Audit's (IA) examination for compliance with DEA regulations and Company policies for the distribution of controlled drugs was conducted November 17 - 21, 2008. Company policies and procedures regarding controlled drugs are communicated to the DCs via the online Compliance Manual.

The Perrysburg DC is licensed to handle Schedule II through V controlled drugs and was last visited by the DEA in May 2006. A subsequent meeting with the DEA was held in January 2008 to address their growing concern regarding in-transit losses the DC has been experiencing.

Objective
The purpose of our review was to ascertain if the Perrysburg DC is in compliance with DEA regulations and Walgreens policies relating to controlled drug distribution, handling, and reporting. In addition, our review verified whether any previously noted deficiencies have been corrected or are in the process of remediation.

Scope
The review focused on the internal controls established by Walgreens DCs to ensure compliance with DEA regulation Section 1300 found in Title 21 of the Federal Code of Regulations. To substantiate compliance with Section 1300, we conducted interviews with DC management, documented the movement of controlled drugs from the receiving dock to the shipping dock, and used an audit testing program that encompasses Section 1300 requirements.

Findings
Our review found compliance within the following areas:

- The Pseudoephedrine receiving and shipping reports were generated in a timely fashion.
- The retention of primary controlled substance records is being maintained properly.
- The controlled substance shipping policies and procedures were properly being followed.

Our review disclosed opportunities for improvement of compliance controls in the areas specified below. Management has addressed our concerns and corrective action has either been performed or is in the process of remediation. Detailed descriptions of our findings and recommendations, along with management responses, are included in Attachment A as indicated.

We would like to thank the Perrysburg Team for their cooperation and hospitality during our review.

CII Distribution Center Observation Summary **Attachment C**
DEA Compliance Review

Observations Noted	DC with CIIs		
	Perrysburg Q1 - FY09	Jupiter Q4 - FY07	Woodland Q2 - FY07
Closed Stores with DEA Form 222s On-hand: Our review of a sample of closed stores serviced by the DC disclosed the DC had a moderate percentage of closed stores with DEA Forms 222 on-hand.	x	x	x
CII Vault Combination Change Process: DC did not have an effective CII vault combination change process.	x	x	
DEA 222 Form Series Accountability A small percentage of sampled stores disclose the DC had voided DEA Form 222s in the unexecuted file that were not identified in the system as voided.		x	
DEA Form 222 Completeness: Our review of a sample of DEA Form 222s disclosed a small percentage were not completely filled out. The line item was not filled out due to the product not being received.	x		
CII ARCOS Monthly Transaction Report Review: Per the Online Compliance Manual, DCs are required to print off the monthly transaction reports that have been submitted to the DEA to ensure completeness and accuracy of transactions. Discussions with the CII Function Manager disclosed the monthly transaction review is not being performed.	x		

5/4/2009

Exit...eeting Outline
DEA Review - Perrysburg DC
Date of Review: 11/17 - 11/21/08

Point	Discussion	Risk	Recommendation	Mgmt Response	Completion Date	Driver
1	Pseudoephedrine (PSE) Reporting Requirements: 1. IA noted that the PSE item selected to perform an inventory audit on was short 7 SKUs compared to SIMS on-hand count. 2. IA could not perform an inventory on one PSE inventory taken on 11/17/08 due to lack of a clear Beginning Balance from the Audit Trail. The Audit Trail does not keep the daily balances for non-controlled substances. 3. The PSE Receiving Report was missing the Vendor's DEA number, which is DEA required information.	Inadequate monitoring of PSE items can lead to non-compliance with DEA regulations relating to PSE security.	1. DC should move all PSE items into the Rx Area to increase security and camera coverage. 2. The Corporate Information Systems Engineer (ISE) Department should provide all DCs with the same PSE data retrieval as Controlled Substances (i.e. on-hand counts).	**(1) DC will look at the possibility of moving PSE items into RX. This will depend on space both back and s/c pick locations. Will also depend on whether or not this is able to be mixed with the regular RX items. (2) If we can't move to RX Room DC will implament a plan to increase count frequency. (Items 2 and 3 James will follow-up with ISE)**	**12/12/2008**	**Dan VanDyk**
2	Walgreens is submitting the Monthly Suspicious Control Drug Orders Report (SCDOR) to the DEA with numerous instances of filled suspicious controlled substance orders. Also, there is no monitoring process in place to stop a suspicious order to assess if the order is suspicious or not.	Walgreens is filling orders that have been deemed suspicious without performing any research to ascertain the legitimacy of the order, which could lead to non-compliance with DEA Regulation Section 1301.74.	We recommend Walgreens develop a cross-functional team consisting of the Logistics, Corporate and Regulatory Law and Loss Prevention Departments to assess what is considered a suspicious controlled drug order and revisit the report parameters to reduce the report size to a manageable level. Discussions should also include how to effectively train DC employees to monitor and manage the report.	**Corporate & Regulatory Law is currently in process of addressing this issue.**	**???? James will keep DC informed of his progress on this item.**	**James VanOverbake**
3	Receiving Report for sampled controlled substances did not have the Vendor's Shipping Address, DEA Required Info - Note: Non-DC issue.	The DC may not be able to substantiate where receipts are coming from, which could lead to non-compliance with DEA regulation Section 1304.22 (b).	Issue addressed to Jason Elliot, Logistics Systems Manager.	**Corporate issue**	**???? James will keep DC informed of his progress on this item.**	**James VanOverbake**
4	During the Alarm Testing, IA noticed an unattended pallet of CIII-V controlled substances that were not locked up in the transport cage, waiting to be lifted to the CIII-V Cage.	Unattended controlled substances are susceptible to diversion and against Company policy.	Please reiterate the policy and procedures to the Transported and Rx Manager/Supervisor regarding the handling of controlled substances from the receiving dock to the controlled substance cage.	**Controlled Drug Transport Process will be reviewed with all Transport Drivers and RX, Receiving and FCS Function Managers**	**12/1/2008**	**Dan VanDyk**
5	Camera Coverage in the Controlled Drug Cages: C III-V: • Cage - Not all audit stations covered by camera/s C II Cage: • Camera for Pick-To-Lane Area too low • Need camera coverage at back end of PTL area	Unable to effectively monitor/document diversion.	Work with Corp. AP to ensure adequate camera coverage in all Rx Cage Areas. A decision should be made to add an additional camera for middle lane.	**Dave will follow-up with IA. The camera placement was approved by the DEA. Dave will talk with IA and if cameras are needed he will work with outside vender to schedule the work to be completed.**	**12/20/2008**	**Dave Brandt**
6	Alarm Testing Results: Internal: CII - Zones 134 and 46 did not activate. External: C II - Zones 39, 46, 60, 61, 62, 69, 70, 71, 72, and 136 were found on Perrysburg's test results but not found on F. E. Moran's test results.	1. Inactive motion detectors limit the effectiveness of the cage security system. 2. The Alarm Company can not effectively monitor the DC's alarm system if they do not have the correct alarm point assignments.	The DC should work with the central monitoring station to address the points that did not activate on their side.	**Jeremy Willis (PBAPFM) will work with FE Moran to resolve these issues.**	**12/3/2008**	**Dave Brandt / Jeremy Willis**
7	Controlled Cage and Vault Layouts: Our review indicated the cage and vault layouts do not represent the current layout of the cages and vault accurately. In addition, the layouts do not match AP's Alarm Point Data Sheets.	There is no assurance that AP can monitor and test all alarm points in the cages and vault.	Please update documentation to 100% accuracy on alarm points and camera coverage.	**Dave and Jeremy will work with DC IE to ensure that the alarm points are correct to the drawing.**	**12/3/2008**	**Dave Brandt / Jeremy Willis**

Exit-meeting Outline
DEA Review - Perrysburg DC
Date of Review: 11/17 - 11/21/08

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8	Asset Protection Monthly Security and Safety Audit: 1. IA noted that the Asset Protection Monthly Security and Safety Audit is outdated, with multiple questions relating to the Traccess System, a trailer security system not used at the DCs for a significant period of time. 2. The DC Manager did not provide an approval signature indicating his review and acceptance of the audit results from October & September.	1. An outdated Monthly Safety and Security Audit limits its effectiveness to ensure all areas have been adequately covered. 2. If the DC Manager does not provide an approval signature, there is less assurance that Safety and Security issues noted in the audit will be adequately addressed.	1. Corporate Asset Protection should review the Asset Protection Monthly Security and Safety Audits for all DCs to ensure they are current and reflect the actual DC security environment. 2. The DC Manager should sign the Asset Protection Monthly Safety and Security Audit to document their review and approval. Any issues noted in the audit should be addressed and documented in the commentary section.	**Jeremy and Dave are working to create a new montly recap that will be placed into affect by the first of the year. November and December reports will be submitted to Steve Kneller for review.**	1/2/2008	Dave Brandt / Jeremy Willis
9	Threshold Permanent Access: Currently, the DC does not keep records for request for changes to permanent access to the controlled drug cages.	Unnecessary access may be granted to the controlled drug cage without the approval of DC management.	No changes should be made to Threshold permanent access unless Function Manager or above approval email is obtained which should be filed for a reasonable period of time in an electronic folder.	**Jeremy has created a log for both permanent and temp access for the controlled cage. AP will call IO, MO, HRM, or DCM to get approval to grant access to controlled cage to also include C2 access as well. If IO or above is not in the building then FM who is in the building may grant temp access. AP will keep an e-mail on all permanent changes to access.**	11/24/2008	Jeremy Willis
10	Threshold Temporary Access: AP Office does not utilize the Card Access Log for temporary access to the Cages, per the AP Instruction Manual.	AP may not be able to effectively monitor who is entering the Cage and time period.	Ensure the Card Access Log for temporary access is being utilized, per the AP Instruction Manual.	**See above..**	11/24/2008	Jeremy Willis
11	DC does not utilize the CIII-V Controlled Cage Sign In/Out Log, tracking individuals who do not have permanent badge permission into the cage.	AP may not be able to effectively monitor who is entering the Cage and time period.	The DC should utilize a sign in/out sheet for team members entering the Controlled Drug Cage with out Card Access. AP should monitor the sign in/out sheet on a weekly basis to ensure there is no unauthorized access to the Controlled Drug Cage.	**A clipboard will be added to the C3-5 cage door. We will post a sign that instructs anyone entering the cage to sign in / out on the log. We do have the sign in place but we need to re-train the RX FM's on this requirement**	12/3/2008	Dan VanDyk
12	AP Incident Reports are not being performed for CIII-V controlled substance issues	Lack of Asset Protection Incident Reports may indicate issues are not fully resolved or handled appropriately (i.e. noting a spillage, but not filing a DEA Form 41). In addition, there is less assurance trends can be identified regarding controlled substance incidents without the incident being documented completely.	Work with Corp. AP to obtain the MS Access Database to track Incident Reports commonly used at other DCs.	**Dave Brandt will need to check with James VanOverbake. We currently have the database in place that track all C3-5 inciednts.**	12/3/2008	Dave Brandt
13	Lack of AP Daily Security Walk-through Check List: The Perrysburg AP Office does not utilize an AP Daily Security Walk-through Check List, which allows the AP Office to ensure all activities have been performed for the day. Note: Discussions with the AP Office indicated one was being developed.	Daily AP responsibilities may be unknown and not performed adequately.	The Perrysburg AP Office should continue efforts to develop a AP Daily Security Walk-through Check List. The checklist should be reviewed by the AP Manager and retained for a reasonable period of time.	**Jeremy has re-created a new daily sheet that is filled out per shift regarding C3-5 walk throughs to include checking cages on the shipping dock.**	11/24/2008	Jeremy Willis

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14	HR Process Improvement - Employee Background Checks: Excluding DCM from the sample of 25 employees tested, the following was not completed: 2 TMs - DEA Employee Screening Questionnaire 1 TM - National Criminal Records Check 11 Management - Local Criminal Records Check	Failure to perform the required background checks and screening tests may result in the hire of individuals that may be considered unemployable had the checks been performed timely. In addition, Walgreens could be found in non-compliance with Section 1301.93 regarding employee background checks.	1) Take the necessary actions to update the employee personnel files for the missing documentation. 2) Develop a binder containing the four documents for all employees in (1) above that would be immediately available for review by the DEA or other entities. 3) On a quarterly basis, review and update the HR Binder containing DEA required documentation of all employees having regular access to controlled substances to ensure that all screening tests for all required employees have been executed.	**Currently creating a binder of copies of all 4 employee checks. Dave us checking with Christine M. on getting all the items that we are currently missing.**	12/15/2008	Lisa Obbish
15	Closed Stores with DEA Form 222s On-hand: Our review of 15 closed stores serviced by the DC disclosed the DC had 15 closed stores with DEA Forms 222 on-hand.	The potential use of an inactive DEA Form 222 could lead to inadequate shipping documentation, creating potential non-compliance with DEA Regulation Section 1305.18.	1. The Perrysburg DC should follow the guidance provided by the Corporate and Regulatory Law Department to have the DEA Form 222s returned to Corporate. 2. The DC should develop a quarterly review process to compare stores with unused DEA 222 Forms against stores the DC services.	**DC will run a query the first of each month that id's all closed stores that have 222's in the file. Once these are identified they will be sent back to the reginal DEA Office (Columbus, Ohio) to be destroyed.**	11/24/2008	Deb Bish
16	DEA Form 222 Completeness: Our review of 10 DEA Form 222s for DC receipts disclosed 1 form was not completely filled out. The line item was not filled out due to the product not being received.	The DC may not be including all DEA required information on DEA Form 222s.	If receipts do not arrive on the scheduled date, the DEA Form 222 should be noted accordingly that zero packages were received with a slash to document if the control substances are received at later date.	**DC will place a (0) zero in each item that is listed on a 222 but no quantity is received for. This process began on 11/18 and all C2 receiver checkers have been trained.**	11/24/2008	Deb Bish
17	CII ARCOS Monthly Transaction Report Review: Per the CM, DCs are required to print off the monthly transaction reports that have been submitted to the DEA to ensure completeness and accuracy of transactions. Discussions with the CII Function Manager disclosed the monthly transaction review is not being performed.	Less assurance all transactions have been completely and accurately been transmitted to the DEA, in addition to non-compliance with Company policy.	Each month, ARCOS transactions reported to the DEA should be verified to the DC's ARCOS spreadsheet, per Company policy.	**Deb will be working with James VanOverbake to create a solution to this problem. This is an 1,800 page report that requires each line item to be checked off on. This is the report that is sent monthly to Marsha Park that is forwarded to the DEA.**	12/15/2008	Deb Bish
18	DEA 106 Follow-up: To limit the loss in-transits for the DC, the DEA recommended in January 2008: 1. DC to removed the CII Manager's name from the shipping label, and 2. Remove the "CII" label on the tamper proof bag. Our review disclosed the above is still present.	CII controlled substances could be easily identified and may be susceptible to diversion.	DC should remove the CII Manager's name from the shipping labels, in addition to removing "CII" from the tamper proof bags.	**(1) Deb will check with ISE and UPS to see if we can have Deb's name removed from the label. (2) Deb is working with Corp. Purchasing to see if we can get the C2 removed from the tamper proof bags.**	12/15/2008	Deb Bish

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19	CII Vault Combination Change Process: Discussions with the CII Manager indicated that the Perrysburg DC could not recall the last time the CII vault combination was changed.	Non-Compliance with DEA Regulations	The Perrysburg DC should develop a policy to change the CII vault combination periodically and when there is employee turnover. Furthermore, the Perrysburg DC should develop a log to monitor/track when the lock combination is changed.	**Deb has checked with the vender and the vender does not recommend that we change the combination without a lock smith. DC will develop a plan (change 2x per year on the time changes)and get the directions to change the combination and work with Maint / AP to see if we can change without a lock smith.**	**12/8/2008**	**Deb Bish**
20	Pending Observation - CII Receipt: IA could not observe a CII receipt due to the DC's inability to process the CII receipt. Discussions disclosed the inability was due to Corporate not sending the required DEA 222 Form and Purchase Order timely.	Store orders can not be filled timely which could lead to more Cardinal orders at a premium cost.	IA to follow-up with Corporate Purchasing to address why the documentation was not sent timely.	**Corp Issue. Deb will e-mail James when this happens over the course of the next month so James can address with Corp. Purchasing.**		**James VanOverbake**

Calendar Entry

Meeting Invitation Steve Kneller has invited you to a meeting

Subject	Internal Audit DEA Review
When	Date: Thursday 12/04/2008 Time: 01:00 PM - 02:00 PM (1 hour)
Chair	Steve Kneller/LOG/Walgreens
Invitees	
Required (to)	Darlene Gallaher/LOG/Walgreens, David
Optional (cc)	Dan VanDyk/LOG/Walgreens, Justin

Please be prepared to to update those items that you are responsible for on Thursday. I have the meeting scheduled for 1 hour but we should be able to get through much sooner if all come prepared. Dave we will make it available via the web. The number is as follows:

http://www.genesys.com/

7991121093

(See attached file: PB Responses.xls)

Thanks,

Steve

- PB Responses.xls