

U.S. Department of Justice
Drug Enforcement Administration

REPORT OF INVESTIGATION

Page 1 of 27

1. Program Code	2. Cross File <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Related Files	3. File No. [REDACTED]	4. G-DEP Identifier
5. By: DI Jacqueline Honoway At: Detroit, MI			6. File Title WALGREEN CO. 28727 Oregon Rd. Perrysburg, OH 43551	
7. <input type="checkbox"/> Closed <input type="checkbox"/> Requested Action Completed <input type="checkbox"/> Action Requested By:			8. Date Prepared 05/18/09	
9. Other Officers: DI Paula Albert				
10. Report Re: In-depth regulatory investigation of WALGREEN CO., 28727 Oregon Rd., Perrysburg, OH 43551, DEA #RW0294493 [REDACTED]				

SYNOPSIS:

On April 28, 2009, DI's Jackie Honoway and Paula Albert initiated an in-depth regulatory investigation at WALGREEN COMPANY, 28727 Oregon Road, Perrysburg, Ohio, 43551, DEA Registration #RW0294493. This investigation was initiated in accordance with the Detroit Divisional Office Fiscal Year Regulatory Work Plan for 2009.

WALGREEN COMPANY, 28727 Oregon Road, Perrysburg, Ohio, 43551, holds DEA Registration #RW0294493 as a Distributor of Schedule II-V controlled substances.

The results of the accountability did not identify any discrepancies however the following recordkeeping and security violations were noted:

- 21 CFR 1305.13(b): DEA 222 Order Forms not completed for items not received. The date items were shipped was not accurately identified on DEA 222 Order forms.
- 21 CFR 1301.72(a) (3) (iii): Failure to provide adequate security required for storage of Schedule II controlled substances.

The following violations pertaining to List 1 chemicals were cited on previous inspection and have not been corrected:

- 21 CFR 1310.04(d): Failure to maintain readily retrievable reports of regulated transactions.
- 21 CFR 1309.71(b) (8): Failure to identify suspicious orders.

11. Distribution: Division	12. Signature (Agent) Jacqueline Honoway	13. Date 05/18/2009
District	14. Approved (Name and Title) Angela R. Francis Group Supervisor	15. Date Error! Reference source not
Other [REDACTED]		

DEA Form - 6
(Jul. 1996)

DEA SENSITIVE
Drug Enforcement Administration

JH: Regulatory

This report is the property of the Drug Enforcement Administration.
Neither it nor its contents may be disseminated outside the agency to which loaned.

Previous edition dated 8/94 may be used.

CCSF v. Purdue Pharma,
et al. 3:18-CV-7591
WAG-MDL-00121
Admitted: 06/08/2022

REPORT OF INVESTIGATION <i>(Continuation)</i>	1. File No. [REDACTED]	2. G-DEP Identifier
	3. File Title WALGREEN CO. 28727 Oregon Rd. Perrysburg, OH 43551	
4. Page 2 of 27		
5. Program Code	6. Date Prepared 05/18/09	

- 21 CFR 1310.04(f): Failure to be able to identify regulated transactions.
- 21 CFR 1310.06(a) (3): Failure to maintain required reports of regulated transactions to include the name, quantity and form of packaging of the listed chemical.

Additionally, the investigators advised WALGREEN management of the following recordkeeping and security issues which had been corrected prior to initiation of the investigation:

- 21 CFR 1305.13(b): Order forms were not completely filled out to indicate the quantity/date of controlled substances received.
- 21 CFR 1301.74(e): Must provide more effective measures to thefts/losses during shipping through common carrier.

In response to the investigation, the Detroit DO issued a letter to Walgreen approving an exception to their requirement to close the "conveyor belt day-gate" situated in the Schedule II vault.

A Letter of Admonition will be prepared to be forwarded to WALGREEN CO.

REPORT OF INVESTIGATION <i>(Continuation)</i>	1. File No. [REDACTED]	2. G-DEP Identifier
	3. File Title WALGREEN CO. 28727 Oregon Rd. Perrysburg, OH 43551	
4. Page 3 of 27		
5. Program Code	6. Date Prepared 05/18/09	

ENCLOSURE PAGE

1. List of states serviced
2. Letter of Admonition dated May 2006
3. Response to Letter of Admonition
4. DEA - 82 Notice of Inspection
5. Request for central recordkeeping
6. Power of Attorney
7. List of List 1 Chemicals
8. Report of List 1 products received from L. PERRIGO
9. DEA 12 Receipt for Cash of Other Items
10. Summary of Theft and Losses
11. List of Controlled substance suppliers
12. List of List 1 suppliers
13. Brochure from CustomVault
14. "Day-gate" exemption letter
15. 1st floor layout
16. Employee access list
17. Alarm test results on vault
18. Layout of Schedule III-V cage

REPORT OF INVESTIGATION <i>(Continuation)</i>	1. File No. [REDACTED]	2. G-DEP Identifier
	3. File Title WALGREEN CO. 28727 Oregon Rd. Perrysburg, OH 43551	
4. Page 4 of 27		
5. Program Code	6. Date Prepared 05/18/09	

BASIS FOR INVESTIGATION:

This investigation was initiated in accordance with the Detroit Divisional Office Fiscal Year Workplan for 2009.

SUBJECT FIRM'S BACKGROUND:

1. WALGREEN COMPANY is located at 28727 Oregon Road, Perrysburg, Ohio, 43551. The firm is a Distributor registered to handle Schedules II-V controlled substances. WALGREEN COMPANY was founded in 1901 and incorporated in the State of Illinois on February 15, 1909, under the name C.R. Walgreen and Company. The name WALGREEN COMPANY was adopted on April 13, 1916. The purpose of the corporation is to manufacture, compound, buy, sell, and generally deal in drugs, medicines, chemicals, and druggists' sundries of all kinds at wholesale and retail together with all goods, wares, and merchandise. The firm's corporate offices are located at 200 Wilmot Road, Deerfield, Illinois, 60015. WALGREEN COMPANY is a publicly held company listed on the New York Stock Exchange, and its shares are widely held by individuals, corporations, and other. No individual, to their knowledge, owns as much as 5% of corporate stock.
2. WALGREEN COMPANY is a retail pharmacy wholesale chain that is known nationwide. The Perrysburg, Ohio distribution center is one of WALGREENS' three distribution centers which distribute Schedule II controlled substances. The Perrysburg distribution center currently distributes Schedule II-V controlled substances to six states and Schedule II controlled substances to another 22 states (Enclosure #1). WALGREEN COMPANY distributes solely to all company owned pharmacies. Controlled substances account for less than 5% of the company's total sales. WALGREEN COMPANY does not distribute controlled substances samples.
3. The following individuals are WALGREEN's principal officers:

Greg Wasson	-	Chairman/CEO
Mark Wagner	-	Executive Vice President
Randy Lewis	-	Senior Vice President
Don Boyajian	-	Regional Vice President

REPORT OF INVESTIGATION <i>(Continuation)</i>	1. File No. [REDACTED]	2. G-DEP Identifier
	3. File Title WALGREEN CO. 28727 Oregon Rd. Perrysburg, OH 43551	
4. Page 5 of 27		
5. Program Code	6. Date Prepared 05/18/09	

4. WALGREEN COMPANY employs approximately 800 employees. The WALGREEN COMPANY in Perrysburg, Ohio, occupies approximately 1.5 million square feet. The warehouse is open for limited activity 24 hours a day from Sunday 11pm through "Friday night". Controlled substance picking and deliveries are usually always limited to "day shift" hours approximately 6:00am - 4:00pm.

5. WALGREEN COMPANY maintains the following registrations:

- DEA #RW0294493, Distributor in Schedules II-V expiring 5/31/2010.
- State of Ohio, Board of Pharmacy, License #W-2101, as a Distributor of Controlled Substances, expiration date 6/30/09.
- State of Ohio, Board of Pharmacy, License #01-1347450, as a Wholesale Distributor of Dangerous Drugs, expiration date 6/30/09.

FIRM'S HISTORY WITH DEA:

1. A check of M204 Systems revealed WALGREEN COMPANY is of record with DEA under NADDIS numbers [REDACTED] and [REDACTED] as follows:

NADDIS [REDACTED]:

06/03: Approval of application

02/06: Pseudoephedrine supplier for Toledo NWO Food Bank

08/06: received lot numbers of pseudoephedrine found at meth lab

08/08: customer of Sun Pharmaceutical Industries

03/09: Target of excessive thefts and losses of Schedule II controlled substances

NADDIS [REDACTED]:

05/05: excessive purchase of Tussionex suspension pints

02/07: modification of registration

01/08: shipper of controlled substances to Waukesha, WI which reported lost in transit

2. The following events pertaining to WALGREEN have not been identified in NADDIS:

[REDACTED]: Theft of Schedule II controlled substances shipped via common carrier.

REPORT OF INVESTIGATION <i>(Continuation)</i>	1. File No. [REDACTED]	2. G-DEP Identifier
	3. File Title WALGREEN CO. 28727 Oregon Rd. Perrysburg, OH 43551	
4. Page 6 of 27		
5. Program Code	6. Date Prepared 05/18/09	

[REDACTED]: In-depth regulatory investigation completed in February 2006. This investigation resulted in a Letter of Admonition citing the following violations:

Controlled substances:

- 21 CFR 1304.74(b): suspicious ordering system inadequate.
- 21 CFR 1301.74(e): failure to provide effect controls against theft or loss when using common carriers.
- 21 CFR 1304.04(a): failure to maintain required records at the registered location.
- 21 CFR 1304.11(a): failure to indicate if inventories were taken at the close or beginning of business.
- 21 CFR 1304.21(d): failure to record the proper date of distribution
- 21 CFR 1304.22(b): failure to maintain adequate records of receipt of controlled substances.

List 1 chemicals:

- 21 CFR 1309.71(8): failure to identify List 1 chemical products
- 21 CFR 1310.03(a): failure to provide a system for determining threshold quantities.
- 21 CFR 1310.05(a) (1): failure to report regulated transactions
- 21 CFR 1310.05(b): suspicious ordering system was inadequate
- 21 CFR 1310.06(a) (3): failure to adequately identify sales of List 1 chemical products.

3. In May 2006, a Letter of Admonition was issued for the afore-mentioned violations (Attachment #2). In a letter dated July 28, 2006, WALGREEN responded to the noted violations and advised that corrective measures would be taken (Attachment #3).

PERSONS INTERVIEWED AND INDIVIDUALS RESPONSIBILITY:

On April 28, 2009, DI's Honoway and Albert presented their credentials and a Notice of Inspection to Distribution Center Manager, Steve KNELLER. KNELLER was advised of the conditions under which a Notice of Inspection is issued, at which time he read and signed the notice (Enclosure #4).

REPORT OF INVESTIGATION <i>(Continuation)</i>	1. File No. [REDACTED]	2. G-DEP Identifier
	3. File Title WALGREEN CO. 28727 Oregon Rd. Perrysburg, OH 43551	
4. Page 7 of 27		
5. Program Code	6. Date Prepared 05/18/09	

SCOPE OF INVESTIGATION:

The investigation began on April 28, 2009 and was completed on April 30, 2009. Management discussion was completed on May 7, 2009. An accountability audit was performed from Close of Business (COB) September 25, 2008 through Close of Business (COB) April 28, 2009. The audit spanned approximately a six (6) month period and included 17 Schedule II controlled substances and 22 Schedule III-V controlled substances. The investigators audited the following controlled substances due to the frequency of their sales by the registrant, the frequency of their abuse, and the large number of thefts and losses involving these controlled substances:

Schedule II:

<u>Product</u>	<u>Strength</u>	<u>Size</u>	<u>Walgreen Item #</u>
Oxycodone ER	80mg	100	512014
Oxycodone ER	40mg	100	512045
Oxycodone ER	20mg	100	512089
Oxycodone HCL	30mg	100	682971
Oxycodone HCL	15mg	100	682972
Oxycontin	80mg	100	684285
Oxycontin	60mg	100	535303
Oxycontin	40mg	100	684278
Oxycontin	30mg	100	535305
Oxycontin	20mg	100	684277
Oxycontin	10mg	100	684276
Morphine Sulfate	30mg	100	514718
Morphine Sulfate CR	30mg	100	564861
Morphine Sulfate	60mg	100	N/A
Oxycodone/Apap	10/325mg	100	652294
Oxycodone/Apap	10/650mg	100	684145
Oxycodone/Apap	7.5/325mg	100	645920
Oxycodone/Apap	7.5/500mg	100	684147

REPORT OF INVESTIGATION <i>(Continuation)</i>	1. File No. [REDACTED]	2. G-DEP Identifier
	3. File Title WALGREEN CO. 28727 Oregon Rd. Perrysburg, OH 43551	
4. Page 8 of 27		
5. Program Code	6. Date Prepared 05/18/09	

Schedule III:

Hydrocodone/Apap	10/325mg	500	563756
Hydrocodone/Apap	10/650mg	100	627664
Hydrocodone/Apap	10/500mg	500	674756
Hydrocodone/Apap	7.5/650mg	100	564863
Hydrocodone/Apap	7.5/750mg	500	675772
Hydrocodone/Apap	7.5/500mg	500	675773
Hydrocodone/Apap	5/500mg	500	672663

Schedule IV:

Diazepam	5mg	500	676041
Diazepam	10mg	500	676052
Alprazolam	1mg	500	673036
Alprazolam XR	1mg	500	594173
Alprazolam	2mg	100	673037
Alprazolam XR	2mg	60	594167

Schedule V:

Cheratussin AC	16oz.	675584
Cheratussin DAC	16oz.	674485

RECORDKEEPING:

Pursuant to the 2006 in-depth regulatory investigation, WALGREEN COMPANY submitted a request for central recordkeeping. The request was approved but upon review it was determined that WALGREEN did not include all schedules of controlled substances and List 1 chemicals in their request. A letter dated April 29, 2009 was provided to amend the central recordkeeping request to include all controlled substances and List 1 chemicals (Enclosure #5).

Initial Inventory:

4. WALGREEN COMPANY maintains a perpetual inventory. Every Wednesday an inventory is taken at the Close of Business for all Schedule III-V controlled substances. This inventory is then verified against the perpetual inventory. Every Thursday, an inventory is taken of all Schedule II controlled substances at the Close of Business (COB). This inventory is also verified against the perpetual inventory.

REPORT OF INVESTIGATION <i>(Continuation)</i>	1. File No. [REDACTED]	2. G-DEP Identifier
	3. File Title WALGREEN CO. 28727 Oregon Rd. Perrysburg, OH 43551	
4. Page 9 of 27		
5. Program Code	6. Date Prepared 05/18/09	

5. For audit purposes, the inventory for Schedule III-V controlled substances taken September 24, 2008, COB was used as the initial inventory and the inventory for Schedule II controlled substances taken September 25, 2008 COB was used as the initial inventory.

Closing Inventory:

The closing inventory was taken at the closing of business on April 28, 2009 by DI's Honoway and Albert. Steve KNELLER Distribution Center Manager (DCM) concurred with this inventory.

Biennial Inventory:

WALGREEN COMPANY presented biennial inventories taken COB 12/31/08 for Schedule II and Schedule III-V controlled substances. The Schedule III-V inventory failed to indicate if it was taken at the opening or close of business, in violation of Title 21 U.S.C. CFR Section 1304.11(a). KNELLER stated that the inventories are always taken on 12/31/08 unless that date falls on a weekend day. Inventories are always taken by two individuals and the lack of a second signature on the Schedule III-V inventory was an oversight.

Receiving Records:

Schedule II:

1. Power of Attorney has been granted to several individuals at WALGREEN COMPANY - Perrysburg center to execute DEA 222 Order forms (Enclosure #6)
2. The investigators reviewed DEA 222 Order Forms for random dates within the audit period. Upon review, it was noted that the DEA 222 Order Forms were not filled out completely in violation of Title 21 CFR 1305.13(b). Upon receipt of an order, the quantity and date received were completed on the right hand side of the Order Form, however, if an ordered Schedule II controlled substance was not received, the quantity section was left blank. KNELLER stated that this procedure had been corrected in December 2008, pursuant to a WALGREEN internal audit however DEA Order Forms reviewed in March 2009 still were not completely filled out. The following DEA 222 Order Forms were not properly completed:

REPORT OF INVESTIGATION <i>(Continuation)</i>	1. File No. [REDACTED]	2. G-DEP Identifier
	3. File Title WALGREEN CO. 28727 Oregon Rd. Perrysburg, OH 43551	
4. Page 10 of 27		
5. Program Code	6. Date Prepared 05/18/09	

10/06/08: #075813941, 075813945
11/03/08: #071729869
12/08/08: 071729971, 071729956, 071729970
01/22/09: 075813563
02/12/09: 086243489, 086243506, 086243489
03/10/09: 086243558, 086243540, 086243558, 086243556

Schedule III-V:

1. WALGREEN is authorized for central recordkeeping to maintain required records at their corporate office in Deerfield, Illinois. The primary purchase record provided to the investigators was Walgreen Company Report Number REPB309, which lists receipts solely by specific item number. This report identifies all information required to be retained for the receipt of controlled substances, to include date received, quantity, name and strength of controlled substance, and form; supplier's information to include name, DEA Registration number and address. WALGREEN'S provided a similar printout for all controlled substances received during the audit period.
2. All controlled substance purchases are coordinated through WALGREEN'S corporate office based on inventory levels.

List 1 chemicals:

1. Enclosure #7 is a list of List 1 chemical products distributed by WALGREEN COMPANY. WALGREEN COMPANY failed to identify the amount of pseudoephedrine in the products received resulting in the following violations:
 - CFR 310.04(f): Failure to record amount of List 1 chemical in transaction;
 - 21 CFR 1310.04(d): Failure to maintain readily retrievable reports of regulated transactions;
 - 21 CFR 1310.06(a) (3).
2. At the request of DI Honoway, WALGREEN provided a list of List 1 chemicals purchased between October 2008 and March 2009 from L. PERRIGO COMPANY. Although the strength of the products was not listed on the report, the number of SKU's received would make these regulated transactions (Enclosure #8). During management discussion, DI Honoway

REPORT OF INVESTIGATION <i>(Continuation)</i>	1. File No. [REDACTED]	2. G-DEP Identifier
	3. File Title WALGREEN CO. 28727 Oregon Rd. Perrysburg, OH 43551	
4. Page 11 of 27	6. Date Prepared 05/18/09	
5. Program Code		

and GS Francis were advised that all the required information is maintained in their computer records however this information has not been provided to DI Honoway.

Distribution Records:

Shipments are only made to other Walgreen pharmacies.

Schedule II:

A review of random dates in the audit period revealed that some of the DEA 222 Order Forms did not identify the date the product was shipped, in violation of Title 21 CFR 1305.13(b). The DEA 222 Order Forms contained the shipping date on Line 1 and a "slash" mark ran through the rest of the order shipped. Many of the Order Forms did not contain a "slash mark" for every line completed.

Schedule III-V:

WALGREEN provided a distribution report which contained all the information required to be recorded for controlled substances. The records include the drug name, strength, form, quantity, Suppliers DEA Registration number, date of distribution, as well as the receiving pharmacies name, address, DEA Registration number.

Results of Accountability:

The audit did not reveal any discrepancies in any of the controlled substances audited.

List 1 chemicals:

1. An accountability of List 1 chemicals was not completed however WALGREEN COMPANY provided a closing inventory of all List 1 chemical products on hand.
2. The distribution records provided to the investigators did not identify the number of milligrams contained in the List 1 chemical products. Failure to provide this information resulted in a **violation of Title 21 CFR 1310.04(f): Failure to record amount of List 1 chemical in transaction, 21 CFR 1310.04(d): Failure to maintain readily retrievable reports of regulated transactions and 21 CFR 1310.06(a) (3).**

REPORT OF INVESTIGATION <i>(Continuation)</i>	1. File No. [REDACTED]	2. G-DEP Identifier
	3. File Title WALGREEN CO. 28727 Oregon Rd. Perrysburg, OH 43551	
4. Page 12 of 27		
5. Program Code	6. Date Prepared 05/18/09	

RECEIVING AND DISTRIBUTION PROCEDURES

Receiving procedures:

1. All controlled substances are received through a receiving bay door in the receiving wing. There are a total of forty-one (41) receiving bay doors, but only one is designated to receive controlled substances. All of the bay doors are equipped with contact switches and remain locked if they are not being used. Only designated individuals are allowed access involving controlled substances.

A. Unloader/checker:

- The designated person checks receiving screen REP0101 for any purchase order containing controlled substances.
- Counts the cases to verify the case count on the freight bill. The freight bill is signed and given to the Receiving Office clerk.
- Strip Tags are created and attached to one of the cases to help identify the case contents.
- Secure controlled substances in a locked cage or fastened the pallet to a building structure if not immediately moved to the Controlled Drug Room.

Prior to the controlled substances being stocked in the Controlled Drug Control room the following tasks must be performed:

B. Transporters:

- Obtain Secure Drugs Transport - Form 1501 (SDT) and complete the form to include all information pertaining to the shipment, including vendor and shipping information.
- Return Form 1501 to the Receiving Office clerk.
- The Receiving Office clerk enters the information into the computer identifying the receipt of controlled substances.
- Open and check each box to ensure no concealed shortages and verify lot numbers.
- Verify the controlled substance case count and transport the cases to the Controlled Substance room. Transporter remains with the controlled substances until a Controlled Substance Drug room checker accepts delivery.

REPORT OF INVESTIGATION <i>(Continuation)</i>	1. File No. [REDACTED]	2. G-DEP Identifier
	3. File Title WALGREEN CO. 28727 Oregon Rd. Perrysburg, OH 43551	
4. Page 13 of 27		
5. Program Code	6. Date Prepared 05/18/09	

C. Controlled Substance Drug Room checker (CS checker):

- CS checker verifies the case count, signs the 1501 and time of receipt. Each controlled substance case is either manually checked in using a Manual Check-in Form or scanned to verify receipt of the correct item.
- Packing slips reviewed to verify NDC number, product description to include strength and size, expiration dates and that purchase order has the appropriate DEA 222 Order Form attached.
- Note any discrepancies between quantities shipped and received.
- Create a pallet tag and attach to pallet. The creation of the pallet tag enters the details of the shipment into the computer system, to include drug name, strength, quantity, etc.

D. Controlled Substance Supervisor: (CS supervisor):

- CS supervisor physically verifies product using the packing slips.
- CS Supervisor signs off on the Manual check-in form and approves the order in the computer. The receiving report number is also documented.
- Initials pallet tag indicating the product is ready to be stocked.
- Signs name and time on the 1501.
- Returns manual check-in form to the administrative office.
- Returns packing slip with load information to the receiving office.

2. The yellow copy of Form 1501 is returned to the receiving office. The receiving office clerk will match the white copy to the yellow copy and communicate any discrepancies on the form to the Distribution Center DEA Compliance Officer. Receiving office assures the Form 1501 is returned to the receiving office within 48 hours.

3. After the pallet tag is created the department supervisor verifies the controlled substance count and returns the transport forms and packing slips to the Receiving Office.

4. After all checks have been completed and a supervisor has approved the delivery it is then stocked. The stocker must verify the supervisor has approved the item quantity by checking for the supervisor's initials on

REPORT OF INVESTIGATION <i>(Continuation)</i>	1. File No. [REDACTED]	2. G-DEP Identifier
	3. File Title WALGREEN CO. 28727 Oregon Rd. Perrysburg, OH 43551	
4. Page 14 of 27		
5. Program Code	6. Date Prepared 05/18/09	

the pallet tag. When an item is stocked the location is entered into the computer for additional tracking and perpetual inventory.

Distribution Procedures:

1. Controlled substances are distributed by utilization of an automated system. Each store order is printed on a pink document or downloaded to a "pick to light system." Pick documents are sorted and sent to the Controlled Drug Room. The orders are verified by a picker who checks the store orders on a "split case pick document".
2. The picker initials the order on the pick summary. A line count is verified for all "pick to light orders" during the download process. The picker then verifies the item quantity on the pick document and writes the item quantity picked in the quantity field column of the pick. If the quantity picked differs from the quantity billed, the picker must indicate the quantity picked in red.
3. After completing the picking process, the picker must initial the pick document and attach the shipping label to the carton.
4. After picking, a controlled drug packer verifies that the items and quantities orders picked match the quantity and items picked; packs and seals the carton for shipment; for Schedule II drugs includes copy 3 of the DEA 222 Order From and records the seal number on the Controlled Drug Shipping Manifest. Schedule III-V controlled substances are picked, audited and packed into totes and held in the controlled substance area until the trailer is ready for loading.
5. As the tote is completed and all items are picked, the computerized bay display will say everything is completed. After the completion of picking every item assigned to that store, the system will indicate to close the tote. At that point, the tote comes to the audit station and a separate team member scans the label on the tote and then audits the contents. A 100% audit is performed on the controlled substances. After the totes are sealed, the seal number is recorded on the controlled drug manifest/shipping manifest. The controlled substances are sealed with a red plastic zip strips which contains a recorded seal number.

REPORT OF INVESTIGATION <i>(Continuation)</i>	1. File No. [REDACTED]	2. G-DEP Identifier
	3. File Title WALGREEN CO. 28727 Oregon Rd. Perrysburg, OH 43551	
4. Page 15 of 27		
5. Program Code	6. Date Prepared 05/18/09	

6. Controlled substance totes are then loaded and placed in a locked, wheeled transport cage. At that point, the date is written on Form 1076, Controlled Drug Transport Record. The date, cage number, trailer, dock number store ID, store number, number of controlled drug items per each store, packers initials, RX manager initials, scan ID, seal number, and total number of controlled drug carts are recorded. The transport cage is then locked and the loading sheet is attached to the cage. The form is initialed by the transporter, shipping manager and the security guard as the cage is transported to the shipping area. Transport cages are chained to the pole/guard rail.
7. After the trailer is entirely loaded with non-controlled products, a designated shipping person will move the controlled substance tote to the trailer to finalize loading. The number of containers in the cage is verified against the loading sheet. A copy of the transport record is given to RX area, Loss Prevention, and Sales Office.
8. In most cases, Schedule III-V controlled substance shipments are sent via WALGREEN fleet. Truck drivers are not WALGREEN COMPANY employees. They are hired by CPC Logistics and are subject to pre-employment drug screening. All WALGREEN trucks utilized are semi trailers. Schedule II controlled substances are shipped via common carrier. WALGREEN COMPANY primarily utilizes UPS and Fed EX for delivery of Schedule II controlled substances.

LIST 1 CHEMICALS:

1. WALGREEN COMPANY is a handler of List 1 Chemicals and currently stocks 42 different products. D/I Honoway provided Steve KNELLER, Distribution Center Manager, with copies of the following information relative to listed chemical regulations and information (Enclosure #9):
- Chemical Handlers Manual
 - Suspicious Orders
 - Notice of List 1 & II chemicals
 - Listed chemicals and threshold amounts
 - Notice regarding Saforle and Sassafras

REPORT OF INVESTIGATION <i>(Continuation)</i>	1. File No. [REDACTED]	2. G-DEP Identifier
	3. File Title WALGREEN CO. 28727 Oregon Rd. Perrysburg, OH 43551	
4. Page 16 of 27		
5. Program Code	6. Date Prepared 05/18/09	

- Notice regarding Iodine
- Notice regarding Anhydrous Ammonia
- Notice regarding Methyl Sulfone
- Notice regarding Ephedrine and PSE
- Notice regarding OTC products
- Thefts of regulated products

2. D/I Honoway advised KNELLER of the requirement to report suspicious orders to DEA. Further inquiry of listed chemical records revealed WALGREEN COMPANY was not compliant with 21 CFR 1310.06(a), 1310.04(f), 1310.04(d) and 1310.06(a)(3). Of the records that were identified with PSE List 1, the firm did not record the milligram strength on any of the transactions, which did not provide an accurate description of the listed chemical. DI Honoway requested a report with milligram strength both from Administrative Assistant Tammy Trumbull and DCM KNELLER. WALGREEN COMPANY was unable to provide the requested report.

3. KNELLER advised DI Honoway that WALGREEN COMPANY's policy for suspicious orders of List 1 chemical products was consistent with the "Chemical Handler's Manual Appendix 3". All List 1 chemical products are sold to Walgreen pharmacies; however suspicious orders were unable to be determined due to the lack of milligram strength of List 1 chemical products not being identified. During the regulatory investigation in 2006, D/I Francis discussed with Justin JOSEPH, Administrative Manager the requirement to report suspicious orders to the DEA Detroit Diversion Group as well as the requirement to immediately contact the DEA and also to provide a written notification to DEA within 15 days of the suspicious order.

ARCOS:

WALGREEN COMPANY submits its ARCOS reports on a monthly basis via electronic media. Mona Thorstenson is the responsible person for ARCOS reporting. Thorstenson prepares her report via electronic in house data systems and then forwards her information to Marcia Parks who is located at the Windsor, Wisconsin Distribution Center. Ms. Parks then submits WALGREEN COMPANY ARCOS reports to DEA Headquarters.

REPORT OF INVESTIGATION <i>(Continuation)</i>	1. File No. [REDACTED]	2. G-DEP Identifier
	3. File Title WALGREEN CO. 28727 Oregon Rd. Perrysburg, OH 43551	
4. Page 17 of 27		
5. Program Code	6. Date Prepared 05/18/09	

Credits/Returns:

WALGREEN COMPANY does not handle returned controlled substance products. In an event that a "shortage" is reported in either shipping or receiving of controlled substances, this is documented as a "credit" or "return" in the computer system. This procedure is in place to account for the perpetual inventory.

Thefts/Losses:

1. A review of WALGREEN COMPANY's Forms 106 revealed them to be in compliance with DEA regulations. The DEA 106 forms revealed that since April 2007 there have been numerous losses of Methadone 10mg - 29,500 du's, Oxycontin 20mg - 4,600 du's, Oxycontin 40mg - 4,100 du's, and Oxycodone/Apap 10mg - 11,900 du's. A history of losses reported via DEA-106 is included as enclosure #10.
2. WALGREEN COMPANY cooperated with DEA Philadelphia DO in the ongoing investigation of alleged thefts of Schedule II controlled substances by a UPS driver, [REDACTED]. DI Honoway discussed the responsibility of WALGREEN to ensure against thefts as required in 21 CFR 1301.74(e). Asset Protection Jeremy WILLIS advised DI Honoway that he is working closely with the Loss Prevention Managers of both UPS and Fed Ex in an attempt to control further losses. WILLIS stated that if thefts occur, WALGREEN will switch carriers, review the patterns of thefts and follow through with the local police department. WILLIS estimated that 99% of the time he receives an immediate response to a loss from the Loss Prevention department of the carrier.

Suspicious Orders:

1. KNELLER explained that WALGREEN follows the "Chemical Handler's Manual Appendix 3" for determining suspicious orders.
 - Walgreen's corporate office has an automatic tracking of the previous 12 months ordering of controlled substances.
 - This amount is divided by 12 to obtain an average monthly ordering pattern.
 - The quantity currently ordered is multiplied by the "DEA factor" (3). Any store that orders controlled substances in excess of these

REPORT OF INVESTIGATION <i>(Continuation)</i>	1. File No. [REDACTED]	2. G-DEP Identifier
	3. File Title WALGREEN CO. 28727 Oregon Rd. Perrysburg, OH 43551	
4. Page 18 of 27	6. Date Prepared 05/18/09	
5. Program Code		

parameters for two consecutive months or any three months out of a six month period will be identified as a suspicious order.

2. Suspicious orders are sent from the corporate office to DEA as well as the Distribution Center. KNELLER was unaware of what measures the corporate office takes in investigating suspicious orders stating "this process is currently under review at their corporate office." KNELLER identified Dan Coughlin DEA Compliance Officer as the individual who will draft the final policy in CM-15 the published procedures of WALGREEN COMPANY.
3. The most current suspicious order report was received by the Detroit DO on 4/6/09. The report listed all suspicious sales originating from the Distribution Center to all Walgreen stores they service.

Drug Destruction

Any return of controlled substance products is handled by the WALGREEN COMPANY Distribution Center, 4400 Hwy 19, Windsor, Wisconsin, 53598, DEA Registration #PW0211158. Controlled substances requiring to be destroyed are sent to MED-TURN, 5332 Empire Rd., Fort Worth, TX 76155, DEA #RR0191902.

SUPPLIERS:

WALGREEN COMPANY has an extensive list of controlled substance and List 1 suppliers which is included as (Enclosure #11 & 12).

SECURITY:

WALGREEN COMPANY employs 14 security personnel who are on-site 24/7. Four security personnel work each shift. Prior to accessing the campus, all vehicles must be cleared through the security booth. The security booth is equipped with a panic button and the reception desk has the ability to lock all the entry doors. One security officer always roams the floor. All employees must enter through the main entrance. Scan reader cards are required to access the building.

Controlled substance storage:

1. There are two different areas for the storage of controlled substances, both of which are contained within the "RX room". This room is secured

REPORT OF INVESTIGATION <i>(Continuation)</i>	1. File No. [REDACTED]	2. G-DEP Identifier
	3. File Title WALGREEN CO. 28727 Oregon Rd. Perrysburg, OH 43551	
4. Page 19 of 27		
5. Program Code	6. Date Prepared 05/18/09	

with a locked door accessed with a magnetic card reader. The RX room restricts access to only those employees who are assigned entry into the room by the firm.

2. The first floor contains a vault for Schedule II controlled substances and the top floor contains the cage for Schedule III-V controlled substances. During the previous investigation in 2006 the Schedule II vault was not in place. The vault was approved after an on-site inspection on December 7, 2006.

Schedule II Vault:

1. In 2006, WALGREEN COMPANY requested the addition of Schedule II controlled substances. To accommodate security requirements, WALGREEN COMPANY purchased a pre-fabricated vault from CUSTOMVAULT, in Highland, IL. CUSTOMVAULT provided DEA with the enclosed documentation and the following specifications for the vault (enclosure #13):

- U.L. #608 Standard (Burglary Resistant Vault Doors and Modular Panels)
- ASTM Designation: F 1090-87: CustomVault U.L. Class-M panel is equivalent to 9" of reinforced concrete with (1) grid of #5 rebar on 4" centers.

2. Prior to approval of the vault, DI Albert obtained an email from DEA HQ's stating that the proposed vault "meets or exceeds the CFR requirements." During the on-site inspection, the following additional information was obtained pursuant to the vault:

"The vault is equipped with two (2) GSA Approved Class-AR5 security vault doors. These vault doors meet requirements of upgraded Federal Specification AA-D-00600C. The locking mechanisms for these doors are Sargent & Greenleaf Model #8560 Group 1r lock."

3. The Schedule II vault is located inside the previously approved Schedule III-V cage. Entrance to the cage requires key-card access. Once inside the cage, the previously mentioned two (2) GSA vault doors can be accessed. Both vault doors are equipped with day gates that contain contact switches.
4. The large day gate is equipped with a self closing, self locking device. The investigators found the bottom of the "day-gate" did not close

REPORT OF INVESTIGATION <i>(Continuation)</i>	1. File No. [REDACTED]	2. G-DEP Identifier
	3. File Title WALGREEN CO. 28727 Oregon Rd. Perrysburg, OH 43551	
4. Page 20 of 27		
5. Program Code	6. Date Prepared 05/18/09	

completely allowing access to the vault through the lower portion of the "day-gate".

5. The smaller vault door is equipped with a conveyer belt that folds out once the vault door and day gate are opened. WALGREENS requested that the conveyer belt be allowed to remain operational during picking hours, therefore preventing the "day-gate" from self-closing and self-locking. This request was initially denied by DEA. The investigators found the small day-gate remained open because the conveyor belt was being utilized. Pursuant to the additional security measures in place for the vault, the Detroit DO provided WALGREEN COMPANY with a letter authorizing an exception to 21 CFR 1301.72(a)(3)(iii), allowing the "day-gate" to remain open during the time Schedule II controlled substances were being picked and someone was in the vault (Enclosure #14).
6. A "partial" plan of the first floor, including the vault is included as enclosure #15.
7. The vault weighs 425,000 pounds and is equipped with 10 cameras that are monitored by security. The DVR tapes are maintained for 30 days. There are 33 motion sensors. There is an emergency exit on west side of the vault. The Class 5 vault doors are made of steel. The larger vault door is the main entrance to the vault and there is a combination lock on the right door of the double door entrance. There are keys that hang inside the vault door in the event someone gets locked inside the vault. The vault has a separate alarm system from the outside CII cage. The day gate has a card reader for access but is disabled if the vault alarm is activated.
8. The CII cage, which surrounds the vault, is equipped with 15 cameras which are also monitored by security with separate DVR tapes that are also maintained for 30 days. There are 22 motion sensors that secure the cage. Access to this area is controlled by keycard access on an as-needed basis. WALGREENS provided a list of management personnel who have access to this area (Enclosure # 16). The key card tracks access to the cage and vault.
9. A security check of the alarm on 4/29/09 reported all systems properly reporting (enclosure #17).

Schedule III-V:

DEA Form - 6a
(Jul. 1996)

DEA SENSITIVE
Drug Enforcement Administration

This report is the property of the Drug Enforcement Administration.
Neither it nor its contents may be disseminated outside the agency to which loaned.

Previous edition dated 8/94 may be used.

REPORT OF INVESTIGATION <i>(Continuation)</i>	1. File No. [REDACTED]	2. G-DEP Identifier
	3. File Title WALGREEN CO. 28727 Oregon Rd. Perrysburg, OH 43551	
4. Page 21 of 27	6. Date Prepared 05/18/09	
5. Program Code		

1. Pursuant to the installation of the vault, WALGREEN COMPANY installed a new cage for Schedule III-V controlled substances. On September 22, 2006 DI James Rafalski and Group Supervisor (GS) Angela R. Francis conducted an inspection and gave final approval of the new cage storage of controlled substances in Schedules III-V ([REDACTED], dated 9/29/06, Report Re: Approval of New Cage for WALGREENS DISTRIBUTION CENTER, 28727 Oregon Road, Perrysburg, OH 43552, DEA Registration #RW0294493).
2. The cage was constructed by Korte Company. The controlled substance cage is located on the fourth floor of a four level work area designated as "RX Module" (Enclosure #18).
3. The dimensions of the cage are 248' long, 50' wide, and 14' 2" tall. The cage walls are constructed of 10 gauge wire woven into three quarter inch square mesh. The steel framing material utilized to construct the mesh cage walls panels are constructed from one and one-quarter inch by one and one-quarter inch by one eighth inch material. The steel posts utilized between the mesh panels are constructed of two inch by two inch posts of 14 gauge steel. The floor of the cage is constructed of 20 gauge steel metal pan material which is placed on top of three quarter inch rosin covered plywood. The ceiling of the cage is the ceiling of the building and constructed of metal panels affixed on top of metal girded beams. The top of the metal panels are covered by approximately four inches of insulation material and heavy vinyl membrane roofing material which forms the exterior side of the roof. The walls of the cage extend from the floor of the cage to the ceiling and are attached by brackets held in place by brazed bolts.
4. The cage has two entrance doors measuring three foot by seven foot, constructed by 10 gauge wire woven material with steel frames. The entrance doors are both located on the south side of the cage at the east and west end of the cage. Each entrance door is self closing and equipped with a card reader to provide access and secured with a magnetic locking switch and alarming switch. When alarm system for the cage is activated the doors are locked and card readers are deactivated. The card reader system monitors the status of each card and denies access to any card the system detects with a status as already inside

REPORT OF INVESTIGATION <i>(Continuation)</i>	1. File No. [REDACTED]	2. G-DEP Identifier
	3. File Title WALGREEN CO. 28727 Oregon Rd. Perrysburg, OH 43551	
4. Page 22 of 27		
5. Program Code	6. Date Prepared 05/18/09	

the cage. The employee also cannot exit the cage if the magnetic card of the employee does not register them as being present inside the cage.

5. The cage also has two sliding safety gates, both located on the south side of the cage at the east and west end. Each gate is ten foot by ten foot and designed to be opened with a card reader to accept deliveries of controlled substances. The controlled substances are transported in a locked rolling metal cage and placed into the cage delivery door by a specialized forklift. The gates are powered, self closing, with reader card access, magnetic locks, magnetic alarm switches and electric eye sensors. The gates have a back-up closing mechanisms which automatically closes the gate after a 20 second time period.
6. The cage security system control panel is located inside the cage on the east wall. The system panel contains six control boxes. Each control box cover is secured with a key lock, nine screws, and armed with two AMSECO TSW 2T tamper switches. One tamper switch is positioned to detect unauthorized opening of the control box and the second switch is positioned to detect the removal of the control box from the original mounting position. Each of the control boxes has the following functions: 1) Cellular Back-up, 2) Card Reader Access Control, 3) Power Door Lock Control, 4) Electric Current for Fire Alarm Horns, 5) Burglar System Control, 6) Motion Detector Control. Each of control boxes contains a back-up battery that can maintain the function of the control box for approximately seven hours.
7. The cage alarm consists of 35 alarm zones and 21 passive infrared (PIR) motion detectors located within the cage as follows:
 - a. One set of three motion detectors placed each corner of cage mounted twelve feet from the floor.
 - b. One set of two motion detectors placed at the center of the north and south cage walls mounted twelve feet from the floor.
 - c. Five motion detectors are mounted along the center on the ceiling of the cage located approximately five feet apart.
8. The security system contains eleven fixed digital cameras inside the cage positioned to record activity in each of the aisles of the cage;

REPORT OF INVESTIGATION <i>(Continuation)</i>	1. File No. [REDACTED]	2. G-DEP Identifier
	3. File Title WALGREEN CO. 28727 Oregon Rd. Perrysburg, OH 43551	
4. Page 23 of 27		
5. Program Code	6. Date Prepared 05/18/09	

two fixed digital cameras inside the cage to record activity at both entrance doors to the cage; two security cameras on the roof of the exterior of the building to record/monitor activity directly above the cage.

9. WALGREEN COMPANY security personnel have monitoring capability of all interior and exterior cameras. If an activation of any of the detection devices of the alarm system occurs, F.E. Moran contacts security at WALGREENS COMPANY. The responsible security personnel make a determination on contacting the Perrysburg Township Police.
10. WALGREEN COMPANY performs an alarm test on the controlled substance cage on a monthly and quarterly basis. All exterior exits are tested on a weekly basis. An alarm test on 4/29/09 revealed all systems were properly reporting.

Employee Screening:

1. The DI's interviewed Lisa Obbish, Human Resources Manager. Obbish stated that WALGREEN conducts a pre-screening criminal background check on all employees through Choicepoint. DEA inquiries are also performed. These are requested through the DEA Detroit Divisional Office, Detroit, Michigan, 48226. The DEA inquiry is sent the first or second day within hiring by facsimile.
2. Random drug testing is conducted on a monthly basis. 10 primary and 10 alternate employees are chosen. Tested employees are selected by First Advantage. First Advantage collects the samples and performs the urinalysis. Pre-employment drug screens are completed by Quest Labs. Any employee testing is placed into a rehabilitation program and is not authorized access to the cage or vault. Drug testing is a mandatory condition of employment. Any positive criminal history determined in pre-screening is an automatic rejection of the application. A criminal conviction while employed will result in termination.

DISCUSSION WITH MANAGEMENT:

REPORT OF INVESTIGATION <i>(Continuation)</i>	1. File No. [REDACTED]	2. G-DEP Identifier
	3. File Title WALGREEN CO. 28727 Oregon Rd. Perrysburg, OH 43551	
4. Page 24 of 27		
5. Program Code	6. Date Prepared 05/18/09	

1. On May 7, 2009, DI Honoway and GS Francis held a management discussion at WALGREEN COMPANY. Present during the meeting were KNELLER, Justin Joseph and Jeremy Willis.

2. D/I Honoway summarized the scope of the accountability investigation. The following issues were noted during the management discussion but WALGREEN COMPANY had already taken measures to correct these issues prior to the investigation so they were not cited as violations:

- 21 CFR 1305.13(b): Order forms were not completely filled out to indicate the quantity/date of controlled substances received.
- 21 CFR 1301.74(e): Must provide more effective measures to thefts/losses during shipping through common carrier.

3. The following recordkeeping violations were cited:

- 21 CFR 1305.13(b): DEA 222 Order Forms not completed for items not received. The date items were shipped was not accurately identified on DEA 222 Order forms.
- 21 CFR 1301.72(a) (3) (iii): Failure to provide adequate security required for storage of Schedule II controlled substances.

4. The following violations pertaining to List 1 chemicals were previously cited during the in-depth regulatory investigation in 2006. WALGREEN responded to a Letter of Admonition stating the violations would be corrected (reference enclosure #2) however they were not corrected:

- 21 CFR 1310.04(d): Failure to maintain readily retrievable reports of regulated transactions.
- 21 CFR 1309.71(b) (8): Failure to identify suspicious orders.
- 21 CFR 1310.04(f): Failure to be able to identify regulated transactions.
- 21 CFR 1310.06(a) (3): Failure to maintain required reports of regulated transactions to include the name, quantity and form of packaging of the listed chemical.

REPORT OF INVESTIGATION <i>(Continuation)</i>	1. File No. [REDACTED]	2. G-DEP Identifier
	3. File Title WALGREEN CO. 28727 Oregon Rd. Perrysburg, OH 43551	
4. Page 25 of 27	6. Date Prepared 05/18/09	
5. Program Code		

5. In response to the above referenced List 1 chemical violations Justin Joseph projected WALGREEN computer records on a large screen, which identified sales of List 1 chemical products to various Walgreen stores. The computer records identified the strength of the Pseudoephedrine in the product, however, WALGREEN did not provide any printouts to reflect this information. As of May 19, 2009 no additional records have been provided which satisfy the previously referenced List 1 chemical violations.

CONCLUSION:

The results of the in-depth regulatory investigation were discussed with management and it was determined that a Letter of Admonition will be issued to WALGREEN CO. Additional information will be reported under separate cover.

INDEXING

1. WALGREEN COMPANY - [REDACTED] Repeat List 1 chemical violations, previously cited in 2006 Letter of Admonition.

2. KNELLER, Steve [REDACTED]
[REDACTED] Walgreen Distribution Center Manager

3. BEST, Brooke - [REDACTED]
[REDACTED] Walgreen Schedule II function lead

4. BETTERBRIDGE, Mark - [REDACTED]
[REDACTED], Walgreen RX function manager

5. BISH, Deb - [REDACTED]
[REDACTED] Schedule II function manager

6. CARR, Mike - [REDACTED]

7. FULFORD, Kyle - [REDACTED]
[REDACTED], Walgreen receiving weekend function manager

REPORT OF INVESTIGATION <i>(Continuation)</i>	1. File No. [REDACTED]	2. G-DEP Identifier
	3. File Title WALGREEN CO. 28727 Oregon Rd. Perrysburg, OH 43551	
4. Page 26 of 27		
5. Program Code	6. Date Prepared 05/18/09	

8. GMITTER, [REDACTED]
[REDACTED], Walgreen maintenance function manager

9. GOULD, Dave - [REDACTED]
[REDACTED], Walgreen Receiving 2 function manager

10. HUNYOR, Bill - [REDACTED]

11. JERNAS, Dave - [REDACTED]
[REDACTED], Walgreen maintenance function manager

12. JOSEPH, Justin - [REDACTED]
[REDACTED], Walgreen Inbound/Outbound manager

13. KNELLER, Justin - [REDACTED]
[REDACTED], Walgreen inbound/outbound manager

14. KUEHL, Marsha - [REDACTED]
[REDACTED], Walgreen receiving 3 function manager

15. MESSER, Karen - [REDACTED]
[REDACTED], Walgreen Schedule II function lead

16. OMAN, Matt - [REDACTED]
[REDACTED], Walgreen Inbound/Outbound Manager

17. PERKINS, Dave - [REDACTED]
[REDACTED], Walgreen maintenance function manager

18. SHOPE, Karole - [REDACTED]
[REDACTED], Walgreen function manager

19. TONEY, Kevin - [REDACTED]
[REDACTED], Walgreen industrial engineer

20. VAN DYK, Dan - [REDACTED]
[REDACTED], Walgreen inbound/outbound manager

REPORT OF INVESTIGATION <i>(Continuation)</i>	1. File No. [REDACTED]	2. G-DEP Identifier
	3. File Title WALGREEN CO. 28727 Oregon Rd. Perrysburg, OH 43551	
4. Page 27 of 27		
5. Program Code	6. Date Prepared 05/18/09	

21. WILLIS, Jeremy - [REDACTED]
[REDACTED], Walgreen Asset Protection Manager