

REPORT OF INVESTIGATION

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1. Program Code	2. Cross File Related Files	3. File No.	4. G-DEP Identifier
5. By: Wayne Groves, DI At: Detroit FDO			
7. <input checked="" type="checkbox"/> Closed <input type="checkbox"/> Requested Action Completed <input type="checkbox"/> Action Requested By:		6. File Title WALGREENS CORPORATION	8. Date Prepared 06-09-2015
9. Other Officers: GS Angela Francis and DI Jason Smith			
10. Report Re: Case Closing and Regulatory Investigation of WALGREENS CORPORATION - DEA# RW0294493			

SYNOPSIS

On May 5, 2015, Diversion Investigators Wayne Groves, Jason Smith, and Group Supervisor Angela Francis conducted an on-site in-depth regulatory investigation at WALGREENS CORPORATION Distribution Center (DC). This investigation was initiated in accordance with the Detroit Field Division Work Plan for Fiscal Year 2015.

WALGREENS CORPORATION DC is located 28727 Oregon Road, Perrysburg, Ohio, 43551. The firm is registered with DEA as a Distributor in controlled substance Schedules II through V under DEA Registration Number RW0294493, which expires 5/31/16.

WALGREENS CORPORATION DC no longer handles controlled substances and maintains no controlled substances on the premises. After the Detroit DO Diversion Group 12B's execution of an Administrative Inspection Warrant (AIW) in February 2013 (DEA Investigative Case File [REDACTED], WALGREENS CORPORATION DC, Perrysburg, Ohio, voluntarily ceased shipments of all controlled substances from the Perrysburg, Ohio, DC. Controlled substance distribution ceased since February 2013 and has continued to be inoperable with respect to such distribution. After that time, distribution of the controlled substances for WALGREENS CORPORATION DC was contracted to AMERISOURCE BERGEN. WALGREENS CORPORATION DC maintains Power of Attorney for Walgreen pharmacies throughout the United States and acts on their behalf with respect to the processing of DEA 222 Order Forms for Schedule 2 controlled substances. WALGREENS CORPORATION

11. Distribution: Division	12. Signature (Agent) Wayne Groves, DI	13. Date 07-22-2015
District	14. Approved (Name and Title) /s/ Angela Francis, GS	15. Date 07-23-2015
Other [REDACTED]		

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CCSF v. Purdue Pharma,
et al. 3:18-CV-7591
WAG-MDL-00468
Admitted: 06/08/2022

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DC is responsible for such for all Schedule 2 orders for the entire United States. DEA Headquarters Registration Unit has such on record and ships DEA Form 222 Order Forms to WALGREENS CORPORATION DC as appropriate. WALGREENS CORPORATION DC does handle List 1 Chemicals at the registered location. The List 1 Chemicals are being stored in the Schedule III through V controlled substance cage. No controlled substances are stored in the cage. WALGREENS CORPORATION DC has applied for a DEA List 1 Chemical Distributor license, and if approved, the firm anticipated no longer maintaining the DEA controlled substance distributor license.

Investigators inspected the WALGREENS CORPORATION DC facility's security and concentrated their inspection in the designated areas for the controlled substances, those being: the Schedule II cage/vault and the Schedule III through V cage. There were no controlled substances viewed in any of these areas. Because WALGREENS CORPORATION DC had not handled controlled substances for over two years, an accountability audit of controlled substances was not performed. The on-site was initiated on 5/5/15 and concluded on 5/5/15. Security was deemed adequate. No violations were noted during this investigation. No violations of the Memorandum of Agreement (MOA) the firm remains under were found. No further investigation is deemed warranted in this investigation and this case will be closed with the concurrence of GS Angela Francis.

ENCLOSURE PAGE

1. Notice of Inspection (DEA Form 82).
2. Cage Schematics for Schedule II cage & vault and Schedule III - V cage.
3. Alarm Test Results.
4. List of employees that have access to the Controlled Substance Areas.

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5. ARCOS REPORT

6. CHEMS REPORT

7. Summary of WALGREENS CORPORATION DC Suspicious Order Monitoring Program.

8. Description of WALGREENS CORPORATION DC Security for Perrysburg, Ohio.

DETAILS

SCHEDULED INVESTIGATION PREPARATION

On May 5, 2015, Diversion Investigators Wayne Groves, Jason Smith, and Group Supervisor Angela Francis conducted an on-site regulatory investigation at WALGREENS CORPORATION DC, 28727 Oregon Road, Perrysburg, Ohio, 43551, DEA Registration #RW0294493. The preparation for the regulatory investigation consisted of the following:

ARCOS

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A review of ARCOS was performed to determine the top customers and predominant types and strengths of controlled substances being distributed which would assist in determining which controlled substances would be audited. The review revealed no controlled substances had been ordered from the firm since February 2013.

Theft and Losses

DI Groves reviewed WALGREENS CORPORATION DC theft and losses on line. The query disclosed that the firm did not have and theft or losses during the past two (2) years.

Controlled Substance Ordering System (CSOS)

DI Groves contacted DEA Headquarters - Diversion Office of Technology (ODT) and confirmed that WALGREENS CORPORATION DC had not had any controlled substance ordering activity since 2013.

CHEMS

WALGREENS has submitted an application as a Chemical Distributor, DEA Control Number W15015323Y. The application is listed in RICS as date of record being 3/5/15.

Memorandum of Agreement

WALGREENS CORPORATION, to include this subject firm, entered into a Memorandum of Agreement (MOA) with the Drug Enforcement Administration, effective 6/11/13. The MOA remains in effect for a period of 3 years, thus expiring 6/11/16. No violations of the MOA were found during this investigation.

BASIS FOR INVESTIGATION

This investigation was initiated in accordance with the Detroit Divisional Office Fiscal Year Work Plan for 2015.

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SUBJECT FIRM'S BACKGROUND

1. WALGREENS CORPORATION DC is located at 28727 Oregon Road, Perrysburg, Ohio, 43551. The firm is a Distributor registered to handle Controlled Substances in Schedules II - V. WALGREENS 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 shares are widely held by individuals, corporations, and other.

2. In 2009, the Drug Enforcement Administration conducted an on-site investigation, which resulted in not identifying any accountability discrepancies, however, there were record-keeping and security violations noted.

- 21 CFR 1305.13(b): DEA 222 Order Forms not completed for items 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 inspections and had 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.

3. In 2013, the Detroit Divisional Office received information from a Source of Information, who communicated knowledge of alleged violations regarding the WALGREENS CORPORATION DC, located in Perrysburg, Ohio. Diversion Investigators interviewed the Source of Information and were provided intelligence regarding violations in security and record-keeping

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of controlled substances. In February 2013, the Detroit Divisional Field Office executed on-site an Administrative Inspection Warrant (AIW) and issued subpoenas for various records. The complaint investigation (DEA Investigative Case File [REDACTED]) disclosed the following violations:

- Schedule II Controlled substances were not properly secured in the vault, a violation of 21 CFR 1301.72(a).
- DEA 222 Forms were incomplete and did not record on Copies 1 and 2 the number of commercial containers furnished on each item and the date on which the containers were shipped to the purchaser, a violation of 21 CFR 1305.13(b). It was discovered that WALGREENS CORPORATION DC stored these records after shipments were made in a "red pen" room at the firm. The firm had various employees, at various times, no set schedule nor specific duty, perform the function of filling in the information with no verification performed of actual quantities or dates of shipments. Employees were instructed by management personnel to fill in the same dates as identified in the date block the purchasers had completed and fill in the same quantities as ordered by the purchasers. Thousands of incomplete DEA Form 222 Order Forms were seized during the execution of the AIW that had been piled up in the "red pen" room. This deficiency in recordkeeping resulted in lack of accountability of Schedule II controlled substances.
- The WALGREENS CORPORATION investigation conducted under DEA Investigative Case [REDACTED], was made part of a DEA National Investigation which resulted in a \$80,000,000.00 civil settlement agreement.

4. WALGREENS CORPORATION DC 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 was responsible for distributing controlled substances for six states and Schedule II controlled substances to another 22 states. WALGREENS CORPORATION DC distributes solely to all company owned pharmacies. Controlled substances account for less than 5% of the company's total sales.

5. The following individuals are WALGREENS CORPORATION principal officers:

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Gregory Wasson President/CEO

James A. Skinner Chairman of the Board

Sona Chawla President of E-Commerce

Jeffrey Berkowitz Pharmaceutical Development

Jason Dubinsky Finance

PERSONS INTERVIEWED AND INDIVIDUAL RESPONSIBILITIES

1. On May 5, 2015, Diversion Investigators Wayne Groves, Jason Smith, and Group Supervisor Angela R. Francis presented their credentials to Steve KNELLER, Distribution Center Manager, Richard MAIER, CPP Manager Supply Chain Integrity, Jeff DYKHUIS, Area Human Resources, Justin JOSEPH, Computer Specialist, and Tammy TRUMBULL-HENSLEY, Administrative Manager. Investigators provided Mr. KNELLER with a DEA Notice of Inspection (DEA Form 82), for his review and signature. Mr. KNELLER was explained his rights regarding the on-site inspection, he indicated he understood his rights. KNELLER signed the inspection notice and was given a copy for his records.

2. Mr. KNELLER advised WALGREENS CORPORATION DC no longer handled controlled substances and maintained no controlled substances on the premises. KNELLER further advised that after the Detroit DO Diversion Group 12B's execution of an Administrative Inspection Warrant (AIW) in February 2013 (DEA Investigative Case File [REDACTED]), WALGREENS CORPORATION DC, Perrysburg, Ohio, voluntarily ceased shipments of all controlled substances from the Perrysburg, Ohio, DC. Controlled substance distribution ceased since February 2013 and has continued to be inoperable with respect to such distribution. After that time, distribution of the controlled substances for WALGREENS CORPORATION DC was contracted to AMERISOURCE BERGEN. WALGREENS CORPORATION DC maintains Power of Attorney for Walgreen pharmacies throughout the United States and acts on their

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behalf with respect to the processing of DEA 222 Order Forms for Schedule 2 controlled substances. WALGREENS CORPORATION DC is responsible for such for all Schedule 2 orders for the entire United States. DEA Headquarters Registration Unit has such on record and ships DEA Form 222 Order Forms to WALGREENS CORPORATION DC as appropriate. WALGREENS CORPORATION DC does handle List 1 Chemicals at the registered location. The List 1 Chemicals are being stored in the Schedule III through V controlled substance cage. No controlled substances are stored in the cage. WALGREENS CORPORATION DC has applied for a DEA List 1 Chemical Distributor license, and if approved, the firm anticipated no longer maintaining the DEA controlled substance distributor license.

SCOPE OF THE INVESTIGATION

1. DIs Groves and Smith and GS Francis reviewed and verified with the firm's personnel that since the time stated by Mr. KNELLER, no controlled substances had been ordered or distributed shortly after the AIW executed in February 2013. DI Groves further verified such through ARCOS data. Inasmuch that the firm had not handled controlled substances for the past two (2) years, an audit was not deemed applicable. According to their records, the last time WALGREENS CORPORATION DC had maintained controlled substances and prescription medication products was March 2013. Additionally, the security inspection of the firm confirmed there were no controlled substances on the premises.

RECORDKEEPING

Initial Inventory:

Not Applicable (Registrant has been registered beyond the requirement for 21 CFR 1304.11).

Biennial Inventory:

According to Steve KNELLER the biennial inventory was done in December of 2012.

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Closing Inventory:

1. Investigators conducted an on-site inspection of the Schedule II Controlled Substance cage/vault vault and the Schedule III through V cage. There were no controlled substances present in the Schedule II cage/vault nor in the Schedule III through V cage. Based on the information that controlled substances had not been ordered by the firm in the past 2 years and no audit deemed necessary, no closing inventory was recorded.

2. WALGREENS CORPORATION DC contracted a ten year partnership with AMERISOURCE BERGEN to handle their controlled substance and prescription orders. WALGREENS CORPORATION DC will maintain itself as the Power of Attorney for various Walgreen pharmacies for Schedule II controlled substance orders, but will not handle the controlled substance products. Mr. KNELLER indicated the firm will maintain processing of the subject orders but is not tasked with review of the orders.

Receipts:

Not Applicable. WALGREENS CORPORATION DC has not handled controlled substances since February 2013.

Production Records:

Not Applicable

Distribution Records:

Not Applicable. WALGREENS CORPORATION DC has not handled controlled substances since February 2013.

Records of Returned or Damaged Goods:

Not Applicable. WALGREENS CORPORATION DC has not handled controlled substances since February 2013.

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Thefts or Losses:

WALGREENS CORPORATION DC has not had any thefts or losses. WALGREENS CORPORATION DC had stopped handling controlled substances two years ago.

ARCOS:

An ARCOS inquiry dated May 4, 2015, indicated the ceasing of controlled substance handling by the firm. The inquiry also revealed there were several uncorrected errors in the report. Tammy TRUMBULL-HENSLEY, Administrative Manager, stated the errors were from over a year ago, and they are working with DEA Headquarters trying to resolve the issue. She stated there was a problem with the Windsor facility and how they report to DEA ARCOS Headquarters.

Destructions:

WALGREENS CORPORATION DC had not destroyed any controlled substances in the last two years.

Quotas:

WALGREENS CORPORATION DC is not subject to quotas.

Suspicious Orders:

WALGREENS CORPORATION DC no longer handles controlled substances or prescription drugs. However, they are in process of obtaining there List 1 Chemical Registration, the DEA Control Number on the application is W15015323Y. If approved, the List 1 Chemical registration still requires WALGREENS to monitor sales to their retail pharmacy customers and report orders of extraordinary quantities. A summary of WALGREENS CORPORATION DC Suspicious Order Monitoring System was provided and is attached to this report. The system sets allocation limits on all controlled substance and the List 1 chemical products ordered. Limits will be based on the store's average prescription volume and are compared to "like" peer groups of stores throughout the chain. The suspicious order monitoring system is

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triggered when any order exceeds the threshold assigned to that specific store for that specific drug. All flagged orders are investigated as orders of interest by WALGREENS Pharmaceutical Integrity team to determine if it was a suspicious order. It is the store's responsibility to provide an explanation as to why more product was ordered than what the ordering system suggested for that store. The Pharmaceutical Integrity team then reviews each response to determine if the flagged order is suspicious and reports the order to the local DEA office if it is deemed suspicious.

DRUG AND EQUIPMENT SECURITY

1. WALGREENS CORPORATION DC, in Perrysburg, Ohio, is 685,000 square feet. The facility is monitored 24 hours a day, 7 days a week by an Asset Protection team consisting of one Function Manager and thirteen Asset Protection Officers.

2. The Schedule II cage measures 80' x 40'; the vault is 55'x 55' and the Schedule III through V cage measures 250' x 52'. The Schedule II cage has four (4) personnel doors and a self-closing, self-locking cage door, all have electronic contacts. There are several cameras throughout the cage. The vault has a separate key pad for access, there are approximately eight CCTV cameras inside of the vault, four cameras are on the back wall and four on the front wall and has motion detectors in the corners of the vault, all are diagrammed on the schematics supplied by WALGREENS CORPORATION DC. The Schedule III-V cage has three(3) personnel doors and three lifts(elevators for large orders). All the personnel doors have electronic contacts and the lifts have limited card access. All access doors into the cage are self-locking, self-closing. The Distribution Center is constructed of concrete block, concrete steel, and structural steel. Access to the property is controlled through an Asset Protection manned gatehouse. All vehicles, visitors, and team members must pass through this point of entry. The gatehouse is generally manned 24 hours a day, 7 days a week.

3. Fencing encloses the truck yard and is inspected on a daily basis for integrity operation and damage. The service gate on the North end of the fence perimeter is inspected on a daily basis to ensure integrity and operation. In addition, there is a seal placed on the gate monitor its

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use. The seal is verified weekly by an Asset Protection Officer and the results are recorded. Any unexplained seal variances are reported and investigated.

4. Close Circuit Television System(CCTV) is utilized to monitor the interior and exterior of the building. Asset Protection manages the CCTV system which is located in the Asset Protection Command Center.

5. WALGREENS CORPORATIION DC is equipped with intrusion and fire alarms. The intrusion alarm monitors approved and non-approved access into or from the facility. There are additional intrusion alarms for multiple controlled drug cages. These alarms are armed and secured when the cages are used to store drugs not in use. The fire alarm panels monitor all portions of the building.

6. All team members access the facility entrance via card access. This system is monitored and controlled by Asset Protection at all times. Team members must wear their company issued badge at all times while on the property. The badge includes their name, photo, and an embossed code, which allows it to be controlled and monitored through card access. Any team member without a badge is screened by Asset Protection prior to entry into the facility at two different check points, the main entrance to the grounds and the Asset Protection Command Center.

7. On May 5, 2015, DEA Diversion Investigators Groves and Smith and WALGREENS CORPORATION DC Distribution Manager Steve KNELLER and the Manger-Supply Chain Integrity Richard MAIER tested the alarm systems in the Schedule II cage/vault and the Schedule III through V cage. All points were tested, all access doors were tested to the cages and vault. An event report is attached to this report detailing the signals tested. There were no deficiencies noted with the alarm system.

INTELLIGENCE INFORMATION

None reported.

FOREIGN CUSTOMERS OR SUPPLIERS

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WALGREENS does not currently maintain a foreign customer base for its distribution registration at the Perrysburg, Ohio location.

DISCREPANCIES AND DISCUSSION WITH MANAGEMENT

1. On May 5, 2015, Investigators spoke with Steve KNELLER, Distribution Manager, Richard Maier, Manager-Supply Chain Integrity, Tammy TRUMBULL-HENSLEY, Administrative Manager, and Jeff DYKHUIS, Area Human Resource Manager, regarding the results of this regulatory investigation. DI Groves explained that an audit was not conducted because WALGREENS CORPORATION DC no longer handled controlled substances. DI Groves stated there were no violations disclosed during this investigation. Investigators did a security inspection of the facility and the former controlled substance area which resulted in no deficiencies. Investigators were informed that WALGREENS CORPORATION DC had submitted an application to handle List 1 Chemicals and intended to use the Schedule III - V cage to secure the List 1 Chemicals. Investigators received the security report for the Schedule III - V cage and there were no deficiencies noted.

VERIFICATIONS

Not applicable as the firm no longer handles controlled substances.

SPECIAL ASSIGNMENTS

None were conducted.

INDEXING

1. WALGREENS CORPORATION - [REDACTED] Regulatory investigation conducted at the WALGREENS CORPORATION DC, Perrysburg, Ohio, revealing no controlled substance violations. Firm does handle List 1 Chemicals but no longer handles controlled substances.

2. KNELLER, Steve - [REDACTED] Distribution Manager for WALGREENS CORPORATION in Perrysburg, Ohio; Present at scheduled regulatory investigation conducted 5/5/15.

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3. MAIER, Richard E. - [REDACTED] Manager Supply Chain Integrity, Perrysburg DC; Present at scheduled regulatory investigation conducted 5/5/15.

4. DYKHUIS, Jeff - [REDACTED]; Work Address: 28727 Oregon Road, Perrysburg, Ohio, 43551; Occupation: Area Human Resource Manager, Perrysburg, Ohio; Present at scheduled regulatory investigation conducted 5/5/15.

5. TRUMBULL-HENSLEY, Tammy - [REDACTED]; Administrative Manager for WALGREENS DISTRIBUTION CENTER, Perrysburg, Ohio; Present at scheduled regulatory investigation conducted 5/5/15.

6. AMERISOURCE BERGEN - [REDACTED] Supplier to WALGREENS CORPORATION DC pharmacies. Contracted with WALGREENS CORPORATION as supplier to their retail pharmacies.