



U. S. Department of Justice
Drug Enforcement Administration
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431 Howard Street
Detroit, Michigan 48226
(313) 234-4000

www.dea.gov

JUN 25 2009

Steve Kneller
Distribution Center Manager
Walgreen Company
28727 Oregon Road
Perrysburg, Ohio 43551

Dear Mr. Kneller:

In April 2009, Diversion Investigators (DIs) from the Drug Enforcement Administration (DEA), Detroit Division Office, initiated an on-site investigation at the Walgreen Company, Regional Distribution Center. The regulatory investigation revealed recordkeeping violations involving both controlled substances and List I chemical products.

Violations involving controlled substances are as follows:

1) DEA 222 Order Forms were not properly completed to include the date shipped on each line of the Order Form. The date shipped was listed on the first line of each form and a "slash" mark was drawn from the second line down the right hand side of the form. A review of random Order Forms identified Order Forms which did not contain a "mark" on all the lines which contained a Schedule II controlled substance. The investigators were unable to determine if the Schedule II controlled substance on that line was shipped.

21 CFR 1305.13(b) requires that 222 Order Forms are completed with the number of commercial or bulk containers furnished for each item and the date on which the containers were shipped to the purchaser.

2) The day-gate in the Schedule II vault was not self-closing and self-locking. The day-gate automatically closed, but the bottom half of the day-gate did not "connect" with the locking mechanism, leaving a space at the bottom of the day-gate which was not secured. Further inspection of the day-gate determined that additional hardware was required to be installed to ensure that the day-gate closed securely.

21 CFR 1301.72(a)(3)(iii) requires a vault which remains open for frequent access, is equipped with a day-gate which is self-closing and self-locking or the equivalent for use during hours of operation in which the vault door is open.

CCSF v. Purdue Pharma,
et al. 3:18-CV-7591

WAG-MDL-00126

Admitted: 06/17/2022

WAGMDL00493683

CONFIDENTIAL

WAG-MDL-00126.00001

In 2006, a regulatory investigation noted violations of 21 CFR 1310 regarding the failure to maintain required reports for regulated transactions involving List I chemical products. A Letter of Admonition was issued pertaining to these violations, and the Walgreen Company's response to the Letter of Admonition indicated corrective measures had been taken to resolve this issue. During the current regulatory investigation, investigators determined the violations had not been properly corrected. The reports provided by the Walgreen Company pertaining to transactions involving List I chemical products did not include the milligram strength of pseudoephedrine. During management discussion, DI Jacqueline Honoway and Group Supervisor Angela Francis were advised that the Walgreen Company documents the product strength in their computer system; however, no reports were provided which contained this information.

The following violations were noted pertaining to List I chemical products:

- 1) 21 CFR 1310.04(d) requires reports of regulated transactions be readily retrievable. The investigators were unable to obtain readily retrievable records of regulated transactions involving List I chemical products.
- 2) 21 CFR 1309.71(b)(8) requires the registrant to identify suspicious orders. Failure to provide milligram strength of products prohibited the identification of suspicious orders.
- 3) 21 CFR 1310.04(f) requires the registrant to be able to identify regulated transactions. A registrant is unable to identify regulated transactions if the milligram strength of a product is unknown.
- 4) 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.

The investigators advised Walgreen management of the following recordkeeping and security issues which had been corrected prior to initiation of the investigation:

- 1) 21 CFR 1305.13(b): Order forms were not completely filled out to indicate the quantity/date of controlled substances received. The investigators were advised that an internal audit identified this deficiency and this policy had been changed in November 2008. The investigators found DEA 222 Order Forms from March 2009, which were still not properly completed.
- 2) 21 CFR 1301.74(e): Must provide more effective measures to thefts/losses during shipping through common carrier. Since January 2007, the Walgreen Company experienced a large number of thefts involving Schedule II controlled substances shipped via common carrier. In the event of additional thefts and losses via common carrier, the Walgreen Company is required to consider additional measures to include, but not limited to, changing distribution centers and delivery dates.

This letter is formal notification that your failure to maintain adequate records for controlled substances and List I chemicals constitutes violations of the Controlled Substances Act. Violations involving List I chemicals have not been corrected since you were first notified in

2006 to meet the requirements of 21 CFR 1310. Additional violations of this site could result in further action against the DEA Registration of the Walgreen Company. At this time, you are being afforded the opportunity to comply with the requirements of the Controlled Substances Act which were outlined by DI Honoway and GS Francis during a management meeting on May 7, 2009. Please advise this office in writing within thirty (30) days of the action taken or planned to correct these violations.

If you have any questions concerning this matter, please contact GS Francis at 313-234-4307.

Sincerely,



Robert L. Corso
Special Agent in Charge
Detroit Field Division



FAX

For D. Pinon

Fax number 847.315.4660

From: Steve Kneller Walgreens PBDC

Fax number: 419.662.4071

Date: July 7, 2009

Re: Letter from DEA

Number of pages: 4 incl cover

Please call with questions.

Thanks,

Steve Kneller

**** Transmit Conf. Report ****

P.1

Jul 7 2009 08:05am

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