



July 28, 2009

VIA FACSIMILE (313) 234-4141
And First Class Mail

Robert L. Corso, Special Agent in Charge
Drug Enforcement Administration
Rick Finley Building
431 Howard Street
Detroit, Michigan 48226

Re: Walgreens Distribution Center
Perrysburg, Ohio

Dear Mr. Corso:

This letter is in response to your June 25, 2009 correspondence regarding the above referenced facility. Walgreens appreciates the opportunity to comply with the requirements of the Controlled Substances Act and any remedial actions that were taken to correct an alleged violation that was identified during the on-site investigation should not be construed as an admission or denial. Each issue listed in your correspondence is addressed separately below.

I. Controlled Substances

Issue: 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 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.

Response: We have reviewed and reinforced our policy & procedure for completing 222 Order Forms with each member of the receiving staff to ensure that each line containing a schedule II controlled substance is appropriately marked on the form to clearly indicate that the product was received.

Issue: 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.

Response: We have added an additional locking mechanism at the bottom of the day-gate to ensure that the day-gate closes securely.

II. List I Chemicals

Walgreen Co. • 28727 Oregon Road • Perrysburg, OH 43551
www.walgreens.com

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

WAG-MDL-00130

Admitted: 06/08/2022

CONFIDENTIAL

WAGMDL00493688

WAG-MDL-00130.00001



Issue: 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.

Response: Upon request, we are able to readily print off shipping, receiving, and other applicable reports that include the necessary information.

Issue: 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.

Response: We have made the necessary changes to the reports showing List I chemical products to include the milligrams per item and dose. This includes the package type and selling unit.

Issue: 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.

Response: All solid dosage forms containing a List I chemical product are packaged in "blister packs" containing a total amount of not more than 3.0 grams of base product. Item line limits are also in place, and all shipments are intra-company between the distribution center and individual pharmacies.

Issue: 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.

Response: Our List 1 chemical reports include the name, quantity, and milligrams for each List 1 chemical product. All solid dosage forms containing List I chemical products are packaged in "blister packs", in an amount compliant with the limits under applicable federal law. We are, however, currently reviewing the "suspicious orders" report to make sure that the name, quantity and form of packaging is included for each entry.

Thank you for the opportunity to respond and demonstrate our compliance with the requirements of the Controlled Substances Act. If you need additional information, please do not hesitate to contact me.

Sincerely,

Steven C. Kneller, Distribution Center Manager
28727 Oregon Road
Perrysburg, OH 43551
(419) 662-4000
steve.kneller@walgreens.com

Walgreen Co. • 28727 Oregon Road • Perrysburg, OH 43551
www.walgreens.com

CONFIDENTIAL

WAGMDL00493689

WAG-MDL-00130.00002



FACSIMILE TRANSMITTAL SHEET

TO: DWAYNE PINON & GARY PETERS**FROM:** STEVEN KNELLER - DCM**COMPANY:** WALGREENS**DATE:** 7-28-09**FAX NUMBER:** 847-315-4660**TOTAL NO. OF PAGES INCLUDING COVER:** 3**PHONE NUMBER:****SENDER'S PHONE NUMBER:** 419-662-4003**RE:** WALGREENS DC - PERRYSBURG, OH**SENDER'S FAX NUMBER:** 419-662-4071

NOTES/COMMENTS:

Signed copy.

PERRYSBURG DISTRIBUTION CENTER
28727 OREGON ROAD
PERRYSBURG, OH 43551

CONFIDENTIAL

WAGMDL00493690

WAG-MDL-00130.00003

Walgreens

FACSIMILE TRANSMITTAL SHEET

TO: ROBERT L. CORSO, SPECIAL AGENT IN CHARGE

FROM: STEVEN KNELLER - DCM

COMPANY: DRUG ENFORCEMENT ADMINISTRATION

DATE: 7-28-09

FAX NUMBER: 313-234-4141

TOTAL NO. OF PAGES INCLUDING COVER: 3

PHONE NUMBER:

SENDER'S PHONE NUMBER: 419-662-4003

RE: WALGREENS DC - PERRYSBURG, OH

SENDER'S FAX NUMBER: 419-662-4071

NOTES/COMMENTS:

Signed copy.

PERRYSBURG DISTRIBUTION CENTER
28727 OREGON ROAD
PERRYSBURG, OH 43551

CONFIDENTIAL

WAGMDL00493691

WAG-MDL-00130.00004