



Internal Audit Report

Date February 22, 2008

Subject DEA Compliance Review – Woodland Distribution Center

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Conclusion

In our opinion, with corrective action taken, the Woodland Distribution Center (DC) will be in substantial compliance with Drug Enforcement Administration (DEA) regulations. Instances of non-compliance were minor in nature. These matters, primarily related to deficiencies in controlled substance cage security, suspicious control drug order reporting, employee documentation and controlled substance handling procedures were reported to management with suggestions for improved security. Management has agreed to take appropriate action to resolve these deficiencies.

Background

Internal Audit’s examination for compliance with DEA regulations and company policies for the distribution of controlled substances was conducted January 14 - 18, 2008. The DEA last visited the Woodland DC in October 2004.

The Woodland DC is licensed to handle Scheduled II through V controlled substances.

Objective

The purpose of our review was to determine if the Woodland DC is in compliance with DEA regulations and Walgreens policies relating to controlled substances.

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 substances from the receiving dock to the shipping dock and developed an Audit Testing Program that encompasses Section 1300.



Findings

Our review found compliance with Woodland's Memorandum of Understanding (MOU) relating to DEA Form 106 filing, DEA inventory maintenance, ARCOS Reporting, List One substance records, as well as, Walgreens internal controls over primary records retention, all of which are areas that have been consistently tested during previous DEA reviews of Walgreens DCs.

Our review found non-compliance with certain DEA regulations. The particular DEA regulations, found in Title 21 of the Federal Code of Regulations, are:

Section 1301.71 – “All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances.” Per discussions with the DC Manager, the CII Cage/Vault can not always handle the Woodland receiving volume for controlled substances. At times, the Woodland DC has to stage CII controlled substances outside the CII Cage/Vault to allow for adequate working conditions. <**Finding 1**>

Section 1301.74 – DEA regulation states: “The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.” Walgreens is submitting the Monthly Suspicious Control Drug Orders Report 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. <**Finding 2**>

Section 1301.93 – “DEA recommends that inquiries concerning employees' criminal records be made as follows: Local inquiries and DEA inquiries.” Our review noted that of the twenty-eight sampled employees with access to controlled substances, three (11%) were missing the DEA Employee Screening Questionnaires, one (4%) was missing the National Criminal Records Check and seven (25%) were missing Local Criminal Records Checks. <**Finding 3**>

Section 1304.22(b) – Covers requirements for a variety of records, all of which must include “the name of finished form, number of commercial containers including the date and manner of distribution or disposal, the name, address, and registration number of the person to whom distributed, and the quantity in finished form distributed or disposed.” Our review noted that the vendor's shipping address was missing on the CII Receiving Reports (REPB307), a DEA required record. <**Finding 4**>

Section 1301.72 (a) (3) (iv) and (b) (4) (v) - The DEA requires that the controlled drug cage be “equipped with an alarm system which, upon unauthorized entry, shall transmit a signal directly to a central station protection agency or a local or state police agency, each having a legal duty to respond, or to a 24-hour control station operated by the registrant...” The Woodland DC has inadequate alarm testing procedures to ensure the cellular back-up connection was functioning correctly. During our review, Asset Protection had begun to take corrective action to update their control cage testing procedures and was working with F. E. Moran to assess the issue. <**Finding 5**>

Section 1305.18 – The DEA requires unused DEA Form 222s be returned to the nearest Field Office if the purchaser (Store) registration has been terminated. A judgmental sample of fifteen closed stores in the Woodland DC's AS/400 system disclosed the Woodland DC had unused DEA Form 222s for thirteen (87%) closed stores. The Corporate and Regulatory Law Department has advised that the DEA Form 222s be returned accordingly. <**Finding 6**>

The complete listing of Audit findings and recommendations are included in Attachment A. Findings have been reviewed with appropriate management and their comments are also included in Attachment A.