
From: Lisa A Scott
Sent: Thursday, December 13, 2012 1:15 PM
To: Boyer, Andrew; Soltis, Scott
Cc: Napoli, Thomas; Woods, Mary
Subject: Summary: Capital Wholesale
Attachments: Investigation Summary Capital.docx

FYI – Please see attached for tomorrow’s meeting.

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Overview

DEA Affairs performed an investigation into a controlled substance "order of interest," in support of the order review process for Watson's suspicious order monitoring program (SOM). As a component of our SOM program, DEA Affairs evaluates orders of controlled substances of unusual size, frequency and pattern from Watson's customers to ensure our product is not destined for illegitimate businesses.

Executive Summary

On October 24, 2012, Capital Wholesale placed an order for 48 units of Hydrocodone/APAP 10/650 mg (NDC 00591050301; Order # 580581) which pended in the SOM system. Capital had received 144 units MTD at that time which, prior to the Oct 24th order for 48, already constituted the largest quantity received within a month in the last rolling twelve months (order quantity range Oct 2011 – Oct 2012: 24-132).

Customer Relations contacted Capital utilizing the standard customer 'request for justification' e-mail. Denise Hanscel, Generics Buyer, responded with Capital's sales activity for the Hydrocodone SKU ordered during the period of 9/4/12 through 10/23/12. The sales data provided by Denise revealed sales of Hydrocodone to numerous pharmacy locations located primarily in Houston, Texas. Internet searches conducted for these pharmacies revealed "red flags" inconsistent with legitimate pharmacy businesses.

On November 15, 2012, Customer Relations and DEA Affairs hosted a Customer Partnership conference call with Capital management in an effort to explain Watson's review process for suspended orders, in addition to providing Capital's management an opportunity to describe their operation, customer vetting process and SOM system. Communications of note included:

- Capital added 280 new customers in the last year, after adding two individuals to their sales team with "requirements for prospecting"
- Capital management stated: "Wholesalers are cutting back in certain parts of the country and cutting off legitimate customers"
- Customer Relations and DEA Affairs informed Capital that their orders would remain on hold until Watson receives the requested documentation (SOPs, questionnaire, etc).

Following the call, Capital forwarded copies of various internal controlled substance procedures, a SOMS overview and customer questionnaire via e-mail.

After reviewing the investigative findings, DEA Affairs has determined Capital's order to be suspicious and in accordance with federal regulation,¹ must report suspicious orders to the DEA. As a result, DEA Affairs recommends discontinuing sales of controlled substances to Capital.

Capital Wholesale

Capital Wholesale Drug Co., a full line wholesaler carrying both pharmaceuticals and health related products, began operations in 1950. Capital is located in Grandview Heights, Ohio and is a member of OptiSource.

¹ 21 CFR 1301.74(b) "The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant."