
From: Friel, Kevin </O=CEPHALON/OU=US01 ADMINISTRATIVE GROUP/CN=RECIPIENTS/CN=KFRIEL>
To: McGinn, Colleen
Sent: 8/19/2009 12:46:43 PM
Subject: RE: Suspicious Order Monitoring
Attachments: Order Management SOP.pdf

Colleen,

This was approved on June 1st. Attached is a copy for your reference.

Thanks,

Kevin

From: McGinn, Colleen
Sent: Wednesday, August 19, 2009 7:29 AM
To: Friel, Kevin
Subject: Suspicious Order Monitoring

Kevin,

I have some people coming in sometime over the 4th quarter to do an internal DEA audit. One of the things they mentioned they wanted to review was our suspicious order monitoring program. I know we were working on SOP, but was it ever finalized? If not, we need to get that done before the audit. If there's anything I can do to help, let me know.

Thanks,


Colleen

PLAINTIFFS TRIAL
EXHIBIT
P-19152_00001

Confidential

TEVA_MDL_A_09576608

P-19152_00001


Standard Operating Procedure		DOCUMENT NO. SOP-0013489	VERSION 1.0	STATUS Effective	EFFECTIVE DATE 01-Jun-2009
		<small>TITLE</small> Order Management			

OWNING FUNCTION: Logistics and Distribution

OWNING SUBFUNCTION: General

APPROVALS

Approver	Meaning	Approval Date (GMT)
Friel Kevin	Author Approval	28-May-2009 01:55:01 PM
Kelly Ernest	QA Approval	01-Jun-2009 12:07:29 PM
Bradway Randy	Affected Area Approval	01-Jun-2009 02:13:19 PM

Standard Operating Procedure		DOCUMENT NO. SOP-0013489	VERSION 1.0	STATUS Effective	EFFECTIVE DATE 01-Jun-2009
 Cephalon		TITLE Order Management			

1 PURPOSE AND SCOPE

This procedure describes the order management process within Cephalon Commercial Operations. The scope of this procedure is limited to U.S. domestic (including Puerto Rico) activity.

2 SITES AND FUNCTIONS IMPACTED

This SOP affects the following functions at the following sites:

<u>Affected Sites</u>	<u>Affected Functions</u>
WC-Frazer	Logistics and Distribution Quality Assurance

3 RESPONSIBILITY

The oversight of the order management process is the direct responsibility of Cephalon Commercial Operations.


4 PROCEDURE

4.1 Initiation of the Order Management Process

- (1) The order management process begins with the receipt of an order from an approved Cephalon customer designated as an "Authorized Distributor of Record" (ADR). To achieve ADR status, a client must execute a Distribution Services Agreement (DSA) with Cephalon. Customer records are maintained by Commercial Operations within SAP, and a listing of all ADRs is posted on Cephalon's webpage at www.cephalon.com.
- (2) Orders received from unauthorized customers are held and subsequently will not be processed. The Logistics Manager or designate contacts the unauthorized entity and notifies them that their order cannot / will not be accepted. If the unauthorized business wishes to purchase direct from Cephalon, a New Account Application must be completed and submitted to Cephalon for consideration. An order received from an unauthorized customer that is considered to be suspicious or abnormal will be investigated by the Logistics Manager or designate. If the aforementioned follow-up still suggests the order is suspicious / abnormal, a Commercial Operations associate will communicate the specifics of the order to Quality Assurance, who will notify the appropriate DEA contact for further follow-up and investigation. Commercial Operations will file the order details for reference.


4.2 Order Processing

- (1) All necessary federal and / or state licenses must be current and on file before an order is processed. If the customer's licenses are not current,

Standard Operating Procedure		DOCUMENT NO. SOP-0013489	VERSION 1.0	STATUS Effective	EFFECTIVE DATE 01-Jun-2009
 Cephalon		TITLE Order Management			

Commercial Operations will notify the customer that updated copies are needed in order to process the order, and the order will be held until these documents are received and verified. In instances where a particular customer's license has been revoked or suspended, Commercial Operations has implemented strict controls to ensure orders received from these locations are not processed.

- (2) Order management rules and controls are in place that monitor number of orders per week, average weekly purchases, etc. Percentage based tolerances are established by DC location and down to the NDC level to hold orders that exceed historical average weekly purchases. These tolerances are maintained by the Logistics Manager or designate and may change / vary based on the customer, product, etc.
- (3) Utilizing analyses performed using inventory Days On Hand (DOH) data, and with reference to metric compliance levels contained in the DSAs, the Logistics Manager or designate may elect to reduce / cancel orders based on the current inventory position at individual DC locations. If a given order exceeds established tolerances or appears suspicious / abnormal, it is placed on hold and an exception is generated. The Logistics Manager or designate will contact the customer in order to understand the specific issues / circumstances related to the order.
- (4) An increase in order volume may relate to a business change in the wholesaler's distribution network (new business / contract awarded, reasonable stocking quantities requested for new distribution center opening, etc.) If approval to release the order for processing is granted by the Logistics Manager or designate based on substantiated reasons, the Logistics Manager or designate will obtain proper documentation from the customer acknowledging the reason for the increase, and the order will be released and the reason / approval noted on the order. If the customer is unresponsive or unable to furnish a substantiated reason for the increase, the Logistics Manager or designate will escalate the issue to the Sr. Director, Client Financial Services for review and subsequent approval / rejection of the order. If Commercial Operations does not approve the order for processing, the order will be rejected. Rejected orders cannot be subsequently filled; rather, the wholesaler must submit a new order. All rejected orders are communicated to appropriate members of Cephalon, SPS, and the affected customer. In cases where the order appears suspicious / abnormal and the customer is not able to provide an appropriate business explanation, Commercial Operations will request that Quality Assurance notify appropriate DEA personnel for follow-up and investigation.
- (5) Order frequency from wholesaler distribution centers is defined in Cephalon's Trade Policy, which is included as a formal Attachment to the

Standard Operating Procedure		DOCUMENT NO. SOP-0013489	VERSION 1.0	STATUS Effective	EFFECTIVE DATE 01-Jun-2009
 Cephalon		TITLE Order Management			

DSA. In certain circumstances (inventory shortages, natural disasters, medical necessity, etc.), Cephalon Commercial Operations will allow additional orders to be placed. As with all other orders, these special orders are reviewed and approved by Commercial Operations before released for pick, pack and shipping.

5 DEFINITIONS

ADR: Authorized Distributor of Record

DSA: Distribution Services Agreement

DOH: Days On Hand

SPS: Specialty Pharmaceutical Services

6 REFERENCES

None

7 ATTACHMENTS

None

8 SUMMARY OF CHANGES

SOP Number	Version	Change
SOP-0013489	1	New Document

Author: Kevin Friel