## PURPOSE:

To assure distribution of controlled drugs is monitored for excessive use by an individual location using the DEA number as the identifier.

## SCOPE:

This procedure applies to all controlled drugs distributed by Watson Laboratories, Inc. and its Subsidiaries.

## DOCUMENT REFERENCES:

| Document Number | Document Title |
|---|---|
| CTMAN 80-041-CC-OPR | Order Processing |
| CTMAN 80-045-CC-LEM | License Entry and Maintenance |

## ATTACHMENTS:

| Document Number | Document Title |
|---|---|
| N/A | N/A |

## DEFINITIONS:

- DEA — Drug Enforcement Administration -- A component of the Justice Department whose regulations enforce 21CFR, Part 1300 to end.
- SOMS — Suspicious Order Management System

## PROCEDURE:

### 1.0 Process for Suspicious Orders of controlled drugs

| Responsibility | Action | |
|---|---|---|
| General | 1.1 | The SAP system compiles a past history of controlled substance drug product orders by each customer to establish a normal order size and order frequency. This is accomplished through the normal Sales Order process see CTMAN 80-041-CC-OPR, Order Processing, for details on this process. |
| Call Center Management/ Controlled Substance Compliance Management | 1.2 | The SOMS Multiplier Table is determined by Call Center Management and the Controlled Substance Compliance Department. |
| | 1.2.1 | See CTMAN 80-045-CC-LEM, License Entry and Management for description of system functionality with regards to the establishment of SOM levels, as well as how to access this information. |

Writer Initials:

EXHIBIT
Allergan 30(b)(6)
4
Woods 1-9-19



PLAINTIFFS TRIAL EXHIBIT
P-31234_00001



P-31234 _ 00001

| Responsibility | Action | |
|---|---|---|
| License Administrator | 1.3 | If a processed order generates a SOMS excessive order flag in SAP (See CTMAN 80-041-CC-OPR, Order Processing), due to more frequent or larger than the normal order pattern, Order Processing will generate a Suspicious Order Controlled Drug (SOMS) report and email it to the License Administrator. See CTMAN 80-041-CC-OPR, Order Processing for details on the system generation of this report. |
| | 1.4 | The license administrator will review the SOMS report, and then, if warranted, contact the customer to confirm the quantity ordered and verify the reason for a larger or more frequent order. |
| | 1.5 | Once this SOMS report is confirmed and verified by the Customer, the SOMS report is signed and marked with a reason code by the license administrator and submitted to the Supervisor or Management for review, and signature. |
| | 1.6 | The license administrator will be responsible to ensure that pending sales orders on hold due to suspicious order (SOMS) violation are investigated. |
| | 1.7 | The license administrator will release pending orders due to SOMS violations by canceling the order, or reducing the quantity, per customer requirements. |
| | 1.8 | If the SOMS violation cannot be resolved by canceling the order or reducing the quantity, the license administrator will escalate the suspicious order to the next level. |
| Call Center Management | 1.9 | Determine if the order does or does not classify as suspicious. |
| | 1.10 | If a valid reason (based on objective criteria) does not exist, the order will be deemed as a suspicious order and will not be filled. Report suspicious issue to Control Substance Compliance Department. |
| Controlled Substance Compliance Department | 1.11 | The Control Substance Compliance Department will be responsible for reporting the order to the Drug Enforcement Administration. |
| License Administrator | 1.12 | File a copy of the SOMS Report, along with the customer purchase order, in the suspicious order record file. |

Writer Initials:

**CHANGE HISTORY:**

| Initiation / Change Control Number | Revision Number | Effective Date | Change Summary |
|---|---|---|---|
| C2004-0260 | 00 | 05/03/2004 | New CSOP. |
| C2005-0317 | 01 | SEP 19 2005 | DEFINITIONS: DEA<br>"Agency" changed to "Administration".<br>"involve controlled substances, etc." changed to "enforces 21CFR, Part 1300 to end".<br>1.3 Change Responsibility from "Order Processing Representative" to "License Administrator".<br>1.4 "if warranted" added to action.<br>1.11 "determine next level of communication" replaced with "be responsible for reporting the order to the Drug Enforcement Administration."<br>1.12 Change Responsibility from "Order Processing Representative" to "License Administrator". |

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**APPROVALS:**

| | |
|---|---|
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| Mary J Woods (Print) | Mary J Woods 8/30/05 (Signature / Date) |
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| Tracey L. Hernandez (Print) | Tracey L. Hernandez 9/7/05 (Signature / Date) |
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