

**Call Center Operations
Call Center Operational Procedure**

PROCEDURE:	Suspicious Orders of Controlled Drugs		
WRITTEN BY:	Judy Callahan	DATE:	May 3, 2004
Call Center Policy Number:	GUROPDCCO 507002.00	Policy Effective Date	September 23, 2005
REVISION WRITTEN BY:	Ella David	REVISION DATE:	09/23/05
Supersede CC Policy #	OPDCC 507509-03.01	CC Policy Date:	May 3, 2004
cSOP Reference #	cSOP 11-004.01	cSOP Ref. Date:	September 19, 2005

- I. **Purpose:** To assure distribution of controlled drugs is monitored for excessive use by an individual location using the DEA number as the identifier.
- II. **Scope:** This procedure applies to all controlled drugs distributed by Watson Laboratories, Inc. and its Subsidiaries.

DOCUMENT REFERENCES:

<u>Document Number</u>	<u>Document Title</u>
CTMAN-80-041-CC-OPR	Order Processing
CTMAN-80-041-CC-OPS	Order Processing Supervisor

ATTACHMENTS:

<u>Document Number</u>	<u>Document Title</u>
N/A	N/A

DEFINITIONS:

•	DEA	Drug Enforcement Administration
•	SOMS	Suspicious Order Management System

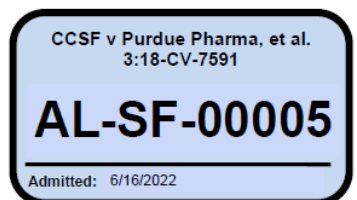
III. Procedure:

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

Controlled Substance Compliance Management **1.2**



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|------------------------------|---|---|--|
| License Administrator | 1.3 | The list is to be updated by written request to the customer approximately 30 days prior to the expiration date of the current registrations. | |
| | 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. | |
| | 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 concerns 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 Administrations. |
| | License Administrator | 1.12 | File a copy of the SOMS Report, along with the customer purchase order, in the suspicious order record file. |