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 080-023-CC-OPR	Order Processing
CTMAN 080-045	License Entry and Maintenance

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:

Responsibility	Action	
	1.0	**Process for Suspicious Orders of Controlled Drugs**
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 080-023-CC-OPR Order Processing, for details on this process).
Controlled Substance Compliance Management	1.2	The Controlled Substance Compliance Department determines the SOMS Multiplier Table.
	1.2.1	See CTMAN 080-045, 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.

Responsibility	Action	
Master Data Administrator	1.3	If a processed order generates a SOMS excessive order flag in SAP (See CTMAN -80-023-CC- OPR, Order Processing), due to more frequent or larger than the normal order pattern, Master Data Administrator will generate a Suspicious Order Controlled Drug (SOMS)
	1.4	The Master Data 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 Master Data Administrator and submitted to the Manager for review, and signature.
	1.6	The Master Data Administrator will be responsible to ensure that pending sales orders on hold due to suspicious order (SOMS) violation are investigated.
	1.7	The Master Data Administrator will release pending orders due to SOMS violations by canceling the order, or reducing the quantity, per SOMS procedure.
	1.8	If the SOMS violation cannot be resolved by canceling the order or reducing the quantity, the Master Data 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.~~ Upon confirmation that the order is suspicious, the Control Substance Compliance Department will be responsible for reporting the order to the Drug Enforcement Administration and the applicable State Board of Pharmacy. Department of Regulatory Affairs will also report the incident to FDA within three business days.
Master Data Administrator	1.12	File a copy of the SOMS Report, along with the customer purchase order, in the suspicious order record file.

CHANGE HISTORY:

Initiation / Change Control Number	Revision Number	Effective Date	Change Summary
C2004-0260	00	05/03/2004	New CSOP.
C2005-0317	01	09/19/2005	DEFINITIONS: DEA "Agency" changed to "Administration". "involve controlled substances, etc." changed to "enforces 21CFR, Part 1300 to end". 1.3 Change Responsibility from "Order Processing Representative" to "License Administrator". 1.4 "if warranted" added to action. 1.11 "determine next level of communication" replaced with "be responsible for reporting the order to the Drug Enforcement Administration." 1.12 Change Responsibility from "Order Processing Representative" to "License Administrator".

CHANGE HISTORY (in HotDox):

HotDox Workflow ID	Revision Number	Effective Date	Change Summary
CD-6798767	02	~~See effective date in header.~~ 04/07/2009	Change all reference of Licensing Administrator Title to : Master Data Administrator Change all reference of CTMAN 080-041-CC-OPR – to CTMAN 080-023-CC-OPR 1.2 The SOMS Multiplier Table is determined by the Controlled Substance Compliance Department. – Delete " Call Center Management" 1.3 "Order Processing will generate a Suspicious Order Controlled Drug (SOMS) report and email it to the License Administrator. – Change -Order Processing to Master Data Administrator – Delete" and email it to the License Administrator" 1.5 "the Supervisor or Management for review, and signature" Remove – Supervisor or.
CD-8330136	03		Change to Section 1.11, Upon confirmation that the order is suspicious, the Control Substance Compliance Department will be responsible for reporting the order to the Drug Enforcement Administration and the applicable State Board of

			Pharmacy. Department of Regulatory Affairs will also report the incident to FDA within three business days.