From: Simmons, Sandra
Sent: Friday, May 30, 2014 10:41 AM
To: Simmons, William
Cc: Napoli, Thomas
Subject: RE: Reminder: CSOPs Past Due for Periodic Review - Sales & Marketing
Attachments: RE: Reminder: CSOPs Past Due for Periodic Review - Sales & Marketing; CSOP_011-004,_Suspicious_Orders_of_Controlled_Drugs.pdf

CSOP was reviewed by me on May 2nd . I entered Will as a reviewer. I am not sure if you reviewed the document. At that time no changes were made and the document was approved. All of the emails back and forth is to find our who is the HotDox approver. If you want them to reject the document and sent it back for another review I can do this.

I am available both days, let me know when you are available .

Thanks
Sandra Simmons
Manager Support Services
Actavis Pharma, Inc.
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400 Interpace Parkway Bldg A
Parsippany, NJ 07054
(T) 862-261-7072
(C) 973-997-2118
email: sandra.simmons@actavis.com

From: Simmons, William
Sent: Friday, May 30, 2014 11:43 AM
To: Simmons, Sandra
Cc: Napoli, Thomas
Subject: FW: Reminder: CSOPs Past Due for Periodic Review - Sales & Marketing

Hi Sandy –

Can we sit down next week sometime to discuss **CSOP 011-004 Suspicious Orders of Controlled Drugs.**

Tom and I have some ideas and I think with the position that you are trying to fill we can make this a more robust document in terms of how we handle SOMS.

I'm traveling Mon-Tues but will be available the rest of the week.

Thanks,

Will

From: Woods, Mary
Sent: Friday, May 30, 2014 8:43 AM
To: Leplar, Chloe Gyda; Napoli, Thomas
Cc: Simmons, Sandra; Simmons, William
Subject: RE: Reminder: CSOPs Past Due for Periodic Review - Sales & Marketing

I would suggest that Sarosh may be appropriate to start with, and he can determine if this should be escalated to Molly. Thank you.

Best Regards,

Mary J. Woods
Executive Director, US Order Management
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✉mary.woods@actavis.com
www.actavis.com

From: Leplar, Chloe Gyda
Sent: Wednesday, May 28, 2014 9:10 AM
To: Napoli, Thomas; Woods, Mary
Cc: Simmons, Sandra; Simmons, William
Subject: RE: Reminder: CSOPs Past Due for Periodic Review - Sales & Marketing

Hi all,

Please forgive me if I ask then, who is the QA approver of this document? This is basically what I need to know, we in the documentation department verify that the correct QA approver is assigned to each section in Livelink. This document is in section 011 and we had Wanda Eng in our matrix for QA approver for section 011. Wanda says she is part of post marketing so should not approve.

Mary, you say this document has move to the supply chain side of the business. Would Molly Martin or Sarosh Printer be QA approvers?

Sorry for my confusion.

Kind regards,
Chloe

Chloe Gyda Leplar
Documentation Specialist Senior

Actavis

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From: Tom P Napoli [mailto:Tom.Napoli@actavis.com]
Sent: 28. maí 2014 13:00
To: Mary J Woods
Cc: Sandra I Simmons; William Simmons; Chloe Gyda Leplar
Subject: RE: Reminder: CSOPs Past Due for Periodic Review - Sales & Marketing

I am in total agreement, Mary!

From: Mary J Woods
Sent: Wednesday, May 28, 2014 8:54 AM
To: Chloe Gyda Leplar
Cc: Sandra I Simmons; Tom P Napoli; William Simmons
Subject: FW: Reminder: CSOPs Past Due for Periodic Review - Sales & Marketing

Hi Chloe,

The SOP is part of US Order Management. I believe that when the department was moved from the commercial side of the business to the supply chain side, the signatories were not moved. Sandra Simmons owns the initial document, she reports to me, and the DEA Affairs team would be the final approver from the operational aspect. It should be Sandra Simmons who submits, sent to me to review and approve, and then to Tom Napoli (or his designee) for final approval operationally.

Tom, are you in agreement?

Thanks

Best Regards,

Mary J. Woods
Executive Director, US Order Management
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✉mary.woods@actavis.com
www.actavis.com

From: Baran, Nancy
Sent: Friday, May 23, 2014 6:09 PM
To: Woods, Mary
Cc: Leplar, Chloe Gyda
Subject: FW: Reminder: CSOPs Past Due for Periodic Review - Sales & Marketing

Hi Mary,

I researched this CSOP and you are the owner, so I thought that perhaps putting you in touch would Chloe may give her exactly what she is looking for. I didn't think of you upon first hearing "SOM" only because she was looking for a "Quality" approver. I'm not sure if you are the person, but please let us know.

Thanks,
Nancy

Nancy Baran
Director, Customer Relations
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☎ 908-425-1380 (cell)
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From: Leplar, Chloe Gyda
Sent: Tuesday, May 13, 2014 11:19 AM
To: Baran, Nancy
Subject: RE: Reminder: CSOPs Past Due for Periodic Review - Sales & Marketing

Thanks Nancy, I appreciate that!

Chloe Gyda Leplar
Documentation Specialist Senior

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From: Nancy Baran [mailto:NBARAN@actavis.com]
Sent: 13. maí 2014 13:09
To: Napoleon D Clark; Chloe Gyda Leplar; Wanda Eng
Cc: Anke von Harpe
Subject: Re: Reminder: CSOPs Past Due for Periodic Review - Sales & Marketing

Just taking off on a flight. I don't know, but would be willing to ask around. I will get back with you. Tx
Nancy

From: Napoleon D Clark
Sent: Tuesday, May 13, 2014 09:06 AM
To: Chloe Gyda Leplar; Wanda Eng; Nancy Baran
Cc: Anke von Harpe
Subject: RE: Reminder: CSOPs Past Due for Periodic Review - Sales & Marketing

Sorry Chloe: but I have no idea who the Quality approver is.

NaP

Napoleon D. Clark
Exec. Director of Marketing, Generics
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400 Interpace Parkway
Parsippany, NJ 07054
Napoleon.Clark@Actavis.com
P: 862-261-7268
F: 862-261-7944

From: Chloe Gyda Leplar
Sent: Tuesday, May 13, 2014 9:04 AM
To: Wanda Eng; Nancy Baran; Napoleon D Clark
Cc: Anke von Harpe
Subject: RE: Reminder: CSOPs Past Due for Periodic Review - Sales & Marketing

Hi Wanda,

Thanks for your suggestions. But we are specifically looking for the Quality approvers and Nancy and Napoleon are not in Quality.

Nancy, Napoleon,

Do you have suggestions for Quality approvers for Sales and Marketing CSOPs in Livelink (section 011) ? The document we are looking at here is CSOP 011-004, Suspicious Orders of Controlled Drugs.

Many thanks
Chloe

Chloe Gyda Leplar
Documentation Specialist Senior

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From: Wanda Eng
Sent: 12. maí 2014 15:07
To: Chloe Gyda Leplar
Cc: Nancy Baran
Subject: RE: Reminder: CSOPs Past Due for Periodic Review - Sales & Marketing

Let's try Napoleon Clark in Sales & Marketing or Nancy Baron in Customer Service.

From: Chloe Gyda Leplar
Sent: Monday, May 12, 2014 10:45 AM
To: Wanda Eng
Cc: Anke von Harpe
Subject: RE: Reminder: CSOPs Past Due for Periodic Review - Sales & Marketing

HI Wanda,

Please advise who should be the QA approver for section 011 in Livelink in your place.

Many thanks
Chloe

Chloe Gyda Leplar
Documentation Specialist Senior

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From: Wanda Eng
Sent: 12. maí 2014 14:40
To: Chloe Gyda Leplar
Subject: RE: Reminder: CSOPs Past Due for Periodic Review - Sales & Marketing

I am not part of Sales & Marketing. Please change.
I am part of post marketing.

From: Chloe Gyda Leplar
Sent: Monday, May 12, 2014 10:24 AM
To: Wanda Eng
Subject: RE: Reminder: CSOPs Past Due for Periodic Review - Sales & Marketing

Dear Wanda,

You are getting these because you are the QA signer for section 011 (Sales and Marketing) in Livelink in our signature matrix for CSOPs. This matrix was established in Cori Pino's old department.
Is this not correct? Please advise.

Many thanks
Chloe

Chloe Gyda Leplar
Documentation Specialist Senior

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From: Wanda Eng
Sent: 12. maí 2014 14:12
To: Chloe Gyda Leplar
Subject: RE: Reminder: CSOPs Past Due for Periodic Review - Sales & Marketing

Dear Chloe

Why am I part of the Author/Management periodic review for CSOP 011-044, Suspicious Orders of Controlled Drugs .
I'm not in the Sales & Marketing Department.

Do you need to re-direct your request?

Wanda Eng
Executive Director
Global Compliance

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400 Interpace Parkway
Parsippany , NJ 07054
United States
T 862-261-7139
E WENG@actavis.com
www.actavis.com

From: Chloe Gyda Leplar
Sent: Monday, May 12, 2014 9:54 AM
To: Sandra I Simmons; Wanda Eng
Cc: Anke von Harpe; Kristin Petursdottir; Rosemary Cunningham
Subject: Reminder: CSOPs Past Due for Periodic Review - Sales & Marketing

Attention: Sales & Marketing CSOP Author/Management

This CSOPs is past due for its **Biennial Periodic Review**. This is a compliance issue. As stated in CSOP 001-129, "Corporate Standard Operating Procedures and Corporate Forms" - **CSOPs must be reviewed every two years.**

1) If the CSOP **needs to be revised**, initiate and complete a Livelink Change Workflow as soon as possible. Refer to CTMAN 130-002 for Livelink help.

2) If the CSOP **does NOT need to be revised**, initiate and complete a Livelink Periodic Review Workflow as soon as possible. Refer to CTMAN 130-002 for Livelink help.

Your prompt attention to this matter is appreciated.

If you have already initiated a Livelink workflow, it will be indicated in yellow in the table(s) below.

We thank you for your efforts in updating these procedure(s).

Past Due:

Document Number	CSOP Title	Last Date Reviewed	Author/Contact Name	Manager/QA	Status
CSOP 011-004	Suspicious Orders of Controlled Drugs	07/19/2011	Sandra I Simmons	Wanda Eng	

Chloe Gyda Leplar
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From: Simmons, Sandra
Sent: Wednesday, April 30, 2014 11:34 AM
To: Leplar, Chloe Gyda; Eng, Wanda; Simmons, William
Cc: Anke von Harpe; Petursdottir, Kristin; Rosemary Cunningham
Subject: RE: Reminder: CSOPs Past Due for Periodic Review - Sales & Marketing

Hi Chloe and Wanda,
Initiated Periodic Review Request(PR-2288049).

Will, you are assigned to Review.

Thanks

Sandra Simmons
Manager Support Services
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400 Interpace Parkway Bldg A
Parsippany, NJ 07054
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(C) 973-997-2118
email: sandra.simmons@actavis.com

From: Chloe Gyda Leplar
Sent: Friday, April 11, 2014 7:58 AM
To: Sandra I Simmons; Wanda Eng
Cc: Anke von Harpe; Kristin Petursdottir; Rosemary Cunningham
Subject: Reminder: CSOPs Past Due for Periodic Review - Sales & Marketing

Attention: Sales & Marketing CSOP Author/Management

This CSOPs is past due for its **Biennial Periodic Review**. This is a compliance issue. As stated in CSOP 001-129, "Corporate Standard Operating Procedures and Corporate Forms" - **CSOPs must be reviewed every two years.**

1) If the CSOP **needs to be revised**, initiate and complete a Livelink Change Workflow as soon as possible. Refer to CTMAN 130-002 for Livelink help.

2) If the CSOP **does NOT need to be revised**, initiate and complete a Livelink Periodic Review Workflow as soon as possible. Refer to CTMAN 130-002 for Livelink help.

Your prompt attention to this matter is appreciated.

If you have already initiated a Livelink workflow, it will be indicated in yellow in the table(s) below.

We thank you for your efforts in updating these procedure(s).

Past Due:

Document Number	CSOP Title	Last Date Reviewed	Author/Contact Name	Manager/QA	Status
CSOP 011-004	Suspicious Orders of Controlled Drugs	07/19/2011	Sandra I Simmons	Wanda Eng	

Chloe Gyda Leplar
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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 080-045	License Entry and Maintenance
CTMAN 080-203	Order Processing

DEFINITIONS:

- DEA — Drug Enforcement Administration – A component of the Justice Department whose regulations.
- SOMS — Suspicious Order Monitoring 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 080-203 Order Processing, for details on this process).
DEA Affairs	1.2	The DEA Affairs 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 080-045, License Entry and Maintenance), due to more frequent or larger than the normal order pattern, Master Data Administrator will generate a Suspicious Order Monitoring System (SOMS) form.
	1.4	The Master Data administrator will review the SOMS form, 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 form is analyzed, the SOMS form is signed and marked with a reason code by the Master Data Administrator and if necessary 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 releasing the order in full, canceling the order, or reducing the quantity, per SOMS procedure.
	1.8	If the SOMS violation cannot be resolved by research and justification, canceling the order or reducing the quantity, the Master Data administrator will escalate the suspicious order to the next level.
	1.9	If a valid reason (based on objective criteria) does not exist, the order will be deemed as an order of interest or a suspicious order and held for further review. Orders deemed as an order of interest or as suspicious, will be forwarded to the DEA Affairs Department for further review.
DEA Affairs	1.10	Upon confirmation that the order is suspicious, the DEA Affairs 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	1.11	File a copy of the SOMS form, along with any back up documentation, in the suspicious order record file.

CHANGE HISTORY (before Livelink):

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 Livelink):

Livelink Workflow ID	Revision Number	Effective Date	Change Summary
CD-6798767	02	04/07/2009	Change all reference of Licensing Administrator Title to : Master Data Administrator Change all reference of CTMAN 080-041-CC-OPR – 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.

CHANGE HISTORY (in Livelink):

Livelink Workflow ID	Revision Number	Effective Date	Change Summary
CD-8330136	03	06/12/2009	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.
CD-11129819	04	See effective date in header.	Changed: SOMS Report to SOMS Form Call Center to Customer Relations Controlled Substance Compliance Dept. to DEA Affairs 1.3 – CTMAN 80-023-CC OPR, Order Processing to CTMAN 080-045 License Entry & Maintenance; Suspicious Order Controlled Drug to Suspicious Order Monitoring System. Added: 1.5 – if necessary 1.7 – releasing the order in full 1.9 – an order of interest or a ; Orders deemed as an order of interest or as ; , will be forwarded to the 1.11 – any back up documentation Removed: 1.9 - Determine if the order does or does not classify as suspicious.

UserName: Larry E. Shaffer (lscheffe)
Title: Master Data Administrator
Date: Tuesday, 28 June 2011, 10:52 AM Pacific Time
Meaning: I have authored this document.
==========

UserName: Sandra I. Simmons (ssimmons)
Title: Mgr, Support Services
Date: Friday, 01 July 2011, 06:41 AM Pacific Time
Meaning: I have reviewed and approved this document.
==========

UserName: Marleah M. Martin (mmartin)
Title: Exec Dir, Corp Quality Assurance
Date: Monday, 11 July 2011, 01:07 PM Pacific Daylight Time
Meaning: I have reviewed and approved this document.
==========