SOMS UPDATE

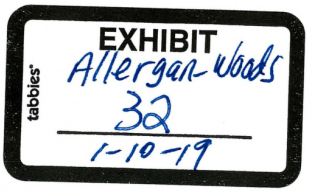
Tuesday, June 22, 2010
8:36 AM

Subject	**SOMS UPDATE**
From	Judy L Callahan
To	Mary J Woods
Sent	Tuesday, June 22, 2010 8:06 AM
Attachments	 SOMS UPDATE  SOMS UPDATE (a...

Click the OneNote attachment if you want to view or edit the notes in OneNote.
If you don't have OneNote 2007, you can click the second attachment to view the notes as a Web page.

You can download a free OneNote trial version from:
http://r.office.microsoft.com/r/rlidOneNoteTrial?clid=1033&ver=12&app=onenote.exe&p1=12

PLAINTIFF TRIAL EXHIBIT
P-02850_00001



Response on to Request for System Distribution Limits

Saturday, September 24, 2011
1:30 PM

Subject	**RE: CRITICAL questions**
From	Tom P Napoli
To	Mary J Woods; Lisa A Scott
Sent	Friday, September 23, 2011 10:54 AM

Hi Mary & Lisa,
Below is some suggested verbiage in response. Please let me know if you are both in accord. It's a professional way of saying "take a hike"!
Tom

Each individual customer's allowable quantity of controlled product is not established in terms of a static annual number. Quantities are dictated by appropriate ordering behavior based on a set of established historical markers. Providing a customer with a quantity or allowable threshold would likely result in a change in ordering behavior and affect the sensitivity of the overall SOM system. Therefore, it would not be prudent to provide customers with any type of aggregate allowable ordering quantity.

Thomas Napoli, CPP
Manager, Security & DEA Affairs
Watson Pharmaceuticals

21 CFR 1301.74

Thursday, September 29, 2011
7:26 AM

DEA phrase:

In accordance with 21 CFR 1301.74, we are required to conduct an independent analysis of orders prior to completing a sale to determine whether substances are likely to be diverted from legitimate channels. You have been contacted due to the fact that your order placed today has prompted further analysis based on a deviation in one of the following areas; unusual size, frequency, or pattern.

In an effort to expedite the investigation process and mitigate any delays or inconvenience, we are requesting supporting information necessary to justify the fulfillment of the order in question.

DEA Places Carisoprodol in Schedule IV

Monday, December 12, 2011
4:23 PM

Subject	**DEA Places Carisoprodol in Schedule IV**
From	Mary J Woods
To	#Master Data Group
Cc	Judy L Callahan; Laura J Pinti; #GenericsMT2; Rose Bentrovato; Dennis M Brandt; Richard Foster; Glenn G Novick; Tom P Napoli; Lisa A Scott; Diane F Miranda
Sent	Monday, December 12, 2011 9:27 AM
Attachments	 cariso

All -

Please see the notice below from Tom Napoli regarding the FDA decision to move Carisoprodol to a CIV controlled substance scheduled product, effective January 11, 2012. A copy of the Federal Register is attached.

The pages that are most impactful to read and understand, are 1, and 28 (Regulatory Requirements Section: pg. 28-31)

Tom noted, on page 28, section titled "labeling and Packaging," DEA is requiring that **all product that is manufactured on or after April 10, 2012, must have the compliant labeling bearing the "CIV" symbol. Product distribution with the new CIV labeling and packaging is effective June11, 2012.**

-

-

I will be working with the Customer Relations Operations Master Data team to ensure that we complete all components to support this addition to the SOM program effective January 11, 2012. I will also communicate with Material Master to understand that all activities are completed in the material master records.

ERP

Material will need to be classified as a CIV within JDE & SAP

- Compliant Recordkeeping & Reporting
- Registration Verification
- SOM

-

Please let me know if you have any questions as they relate to the Customers, or SOM system and the affect of these changes.

Thank you.

Best Regards,

Mary J. Woods
Executive Director, Customer Relations
A Watson Pharma, Inc., Corona, CA 92880
- 951-493-5951 🖷 951-493-1510 (C) 951-316-3616
- mary.woods@watson.com
www.watson.com

On Dec 12, 2011, at 10:05 AM, "Tom P Napoli" <Tom.Napoli@watson.com> wrote:

DEA Places Carisoprodol in Schedule IV

Pursuant to the Notice of Proposed Rulemaking published within the Federal Register in November, 2009, the US Drug Enforcement Administration has issued a final rule to place Carisoprodol (Soma) into Schedule IV of the Controlled Substance Act effective January 11, 2012.

Thereafter, any person or entity that engages in the manufacture, distribution, dispensing, importing, exporting, as well as any person or entity that possesses the drug will be subject to the provisions of the Act and DEA regulations, including the Act's administrative, civil, and criminal sanctions which are applicable to schedule IV controlled substances.
As originally communicated in November of 2009, the scheduling will require action in the following areas:

Controls & Procedures
Material will be handled in accordance with established procedures for the handling of controlled substances Schedule III-V.
- Record keeping, operational/ physical security controls, storage, receipt, manufacturing, testing, sampling, & distribution.

ERP
Material will need to be classified as a CIV within JDE & SAP
- Compliant Recordkeeping & Reporting
- Registration Verification
- SOM

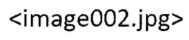
Labeling and Packaging
All labels and labeling for commercial containers of Carisoprodol which are distributed need to comply with requirements of 21 CFR 1302.03-1302.07, i.e. individual units must bear the "CIV" symbol, and the JDE generated shipper labels cannot bear the product name.

Inventory
An initial inventory of all stocks of Carisoprodol on hand must be taken to reflect date of scheduling action and material will be subject to annual inventory pursuant to established policy.

Import
We will be required to process the required documentation prior to each import from India (i.e. DEA Form 236, Import Declaration) fifteen days prior to estimated date of shipment.
Submit to DEA, our annual needs for Assessment consideration.
Each site that imports Carisoprodol will require the appropriate registration with drug code added.
The DEA Affairs Department is committed to supporting our internal customers, ensuring that this transition occurs in a seamless manner.

Thomas Napoli, CPP
Manager, Security & DEA Affairs
Watson Pharmaceuticals
U.S. Generics Division
T (862)261-7193
C (914)671-3773

<image001.jpg>



FW: WAC + Contract Price Increase with Allocation

Monday, July 02, 2012
12:56 PM

Subject	**FW: WAC + Contract Price Increase with Allocation**
From	Mary J Woods
To	Scott K Soltis; Tom P Napoli
Sent	Thursday, June 28, 2012 12:27 PM
Attachments	 Q2-2012 Generic Pr...  Walgreen - Price Chan...  Direct  WAC

Best Regards,

Mary J. Woods
Executive Director, Customer Relations
A Watson Pharma, Inc., Corona, CA 92880
- 951-493-5951 🖷 951-493-1510 (C) 951-316-3616
- mary.woods@watson.com
www.watson.com

From: Kathy M Conlon
Sent: Thursday, June 28, 2012 8:04 AM
To: Judy L Callahan; Mary J Woods; Sandra I Simmons
Subject: FW: WAC + Contract Price Increase with Allocation

I'm sorry, attached please find yesterday's price increase letters, thank you.

From: Kathy M Conlon

Sent: Tuesday, June 26, 2012 7:25 PM
To: Tara B Asea; Julia Kim
Cc: Dawn Gamma; Carmela Palmiotto; Rob Summer-Brason
Subject: FW: WAC + Contract Price Increase with Allocation

Please spot check the letters linked below, then work with Dawn and Carmela to prepare the individual letters to send tomorrow after InfoLert. Thanks.

V:\Contract Operations\ Contract Admin\ PRODUCT-PRICING Related\GLOBAL Adjustments\ 2012\06-2012 WAC + Contract Price Increase (HCBA, SSD)

-----Original Message-----
From: Christina M Koleto
Sent: Friday, June 22, 2012 5:54 PM
To: Rick C Rogerson; Kathy M Conlon
Subject: RE: HCBA

Meeting 7/2/2012

Tom P Napoli; Lisa A Scott; Scott K Soltis; Sandra I Simmons; Rick C Rogerson; Kathy M Conlon; Toni M Picone; Napoleon D Clark; Andrew S Boyer

---

Sandy
Tom
Lisa
Kathy
Toni
Andy
Scott

Send the Template over to DEA Affairs in order to modify. They will add a DEA verbiage for the controlled substance price increases.

2012-0067

INFOLERT

PRICE ADJUSTMENT NOTIFICATION

June 27, 2012

Effective July 27, 2012, Watson Pharma, Inc. will implement the following Wholesale Acquisition Cost (WAC) price adjustments as noted below. Please make the necessary adjustments in your files. All Third Party Agencies have been notified of these changes.

NDC	PRODUCT	Size	SWP	WAC
00591-0540-01	HYDROCODONE/APAP 10/500MG TAB	100	$53.27	$25.38
00591-0540-05	HYDROCODONE/APAP 10/500MG TAB	500	$253.03	$120.51
00591-0503-01	HYDROCODONE/APAP 10/650MG TAB	100	$97.76	$15.84
00591-0503-05	HYDROCODONE/APAP 10/650MG TAB	500	$454.58	$67.32
00591-0517-01	HYDROCODONE/APAP 10/660MG TAB	100	$71.53	$22.50

SOMS System Review & Assessment

Wednesday, April 27, 2011
10:00 PM

Subject	**SOMS Review & Assessment**
From	Tom P Napoli
To	Mary J Woods; Frank Chen; Sanjay R Bhat; Lisa A Scott; Ione M Graziosi; Sandra I Simmons; Laura Pinti
Cc	Scott K Soltis
Sent	Wednesday, April 27, 2011 6:46 AM

Team,
I am currently working on establishing a review and assessment of our existing SOM program with consultants Cegedim-Dendrite. The review and assessment will take place at our Parsippany Headquarters facility. Based on the fact that this assessment will require travel for some of you, I wanted to reach out prior to scheduling to ensure that we establish a date that is convenient to all team members.

The review and assessment will be performed as detailed below.

Compliance Solutions (Cegedim- Dendrite) will provide Watson an onsite review and assessment of its current SOM system. Compliance Solutions will meet with Watson's SOM team to conduct a thorough discussion and review of the SOM system. The assessment will involve an onsite meeting at Parsippany, HQ facility.

During this assessment, Compliance Solutions consulting team will review, discuss, and evaluate the following elements of Watson's SOM system*:

- Review and analyze Watson's SOM system.
- Discuss and review Watson's approach used to design its SOM system.
- Meet with Watson's IT and compliance teams to gain an understanding of the available data tables, schemas, fields, etc. in your current orders tracking system and how these items have been integrated into Watson's approach to SOM.
- Discuss the data that is available and what is the appropriate sampling of the actual data needed to "train" a set of statistically based and supportable index modeling formulas, if appropriate.
- Discuss those parameters and data points that are inherently unique to each account type and the requirements for developing a statistically justifiable SOM model specific to each account type.
- Discuss the systems validation of the SOM system if applicable.

The deliverable for this onsite review will be a report that identifies any gaps or other recommended changes to assist Watson in enhancing their SOM system to comply with DEA regulations and associated memorandum regarding SOM.

The two person consulting team will consist of a Ph.D. statistician and an individual with former DEA experience, both of whom are well versed in SOM regulations and systems.

I am tentatively looking to establish meeting in June, I would appreciate it if you could provide me with your most convenient dates. I really appreciate all of your commitment to this important compliance initiative. Please feel free to contact e with any questions or concerns.
Regards,
Tom

Thomas Napoli, CPP
Manager, Security & DEA Affairs
Watson Pharmaceuticals
U.S. Generics Division
T (973)355-8114
C (914)671-3773

Verify for FDA - CONFIDENTIAL REQUEST 4/21/2011

Tuesday, April 26, 2011
8:11 AM

Subject	**RE: CRITICAL: Need to Verify for FDA - CONFIDENTIAL REQUEST**
From	Larry E Shaffer
To	Mary J Woods; #Master Data Group
Cc	Kathleen A Karlsson
Sent	Monday, April 25, 2011 12:39 PM
Attachments	 For MW 042511

Consultants Meeting

Make sure to bring up Product Launches - initial purchasing of customers that may purchase more than one month worth of inventory.

New Customers or Customers with new product no history.

Please see attached.

Thanks,

Larry

From: Mary J Woods
Sent: Friday, April 22, 2011 8:49 PM
To: #Master Data Group
Cc: Kathleen A Karlsson
Subject: CRITICAL: Need to Verify for FDA - CONFIDENTIAL REQUEST

Sandy and Team,

We have a request from the FDA to check several account below. I did verify with Pete that we will go back to 2004 which is the existence of SAP. Please thoroughly check for the names of all of the accounts below.

1. We need a copy of any record you find on them, even if we do not currently sell to them. If we sold to them prior to 2009, and do not sell currently, I will need the last ship date.
2. If we locate any of the accounts with these exact names, we need to supply all sales information from 2009 to current.
3. If we locate any of the accounts I will also need Kathleen's team to look for any purchasing or distribution agreements that we may have had. They will need to be submitted to the FDA.

They interchange names or use various versions of the names. I'm looking for anything you have on them, including purchase/sales records since Jan 2009 (or verification that you don't currently sell, when you did sell to them, or if you have never sold to them) to include Drug, Dosage, Count, NDC Code, Lot #'s and Expiration Dates, and purchasing/distribution agreements.

Please let me know if you have any questions.

Best Regards,

Mary J. Woods
Executive Director, Customer Relations
A Watson Pharma, Inc., Corona, CA 92880
- 951-493-5951 🖷 951-493-1510 (C) 951-316-3616
- mary.woods@watson.com

From: Pete J Herrera
Sent: Friday, April 22, 2011 10:22 AM
To: Mary J Woods
Cc: Nancy E Radcliffe
Subject: FW: FDA Compliance Report Request

Hi Mary,

As you can see the FDA Agent Palmer has more questions....is this something we can answer?

Thanks,
Pete

Watson Pharmaceuticals
Peter J. Herrera
Supervisor, Security
Global Security & DEA Affairs
951-493-5380 Office
www.watson.com

Watson
Helping People Live Better

From: Palmer, Michelle [mailto:Michelle.Palmer@oci.fda.gov]
Sent: Thursday, April 21, 2011 1:10 PM
To: Pete J Herrera
Subject: RE: FDA Compliance Report Request

Thanks Pete. That was quick. Was the only discrepancy the one that was noted?

Thanks for the distribution records. Which brings me to another request based on one of the customer's listed – **FMC Distributors**. I highlighted them below too.

Can you find out if Watson or any of your subsidiary drug companies currently sells or has ever sold

drugs to the following businesses (any locations whether U.S., Puerto Rico-PR or worldwide):

- **FMC** (aka **FMC Distributors** Inc., FMC Drogueria PR, FMC Drogueria Distributors PR, FMC Distributors of Nevada Inc., FMC of California, FMC Drogueria de la Villa, FMCdist.com, FMC Specialty Care)
- **Drogueria de la Villa** (aka Drogueria, FMC Drogueria de la Villa)
- **LLC Wholesale Supply** (aka LLC Wholesale, LLC, LLCwholesale.com, LLC Patient Services)
- **Flar Medicine**
- **Arbudol Corp** (aka Arbudol)

They interchange names or use various versions of the names. I'm looking for anything you have on them, including purchase/sales records since Jan 2009 (or verification that you don't currently sell, when you did sell to them, or if you have never sold to them) to include Drug, Dosage, Count, NDC Code, Lot #'s and Expiration Dates, and purchasing/distribution agreements. Please give me a call on my cell if you have any questions, or shoot me an email. I know it's a lot of work/info. Whenever you could get it to me would be great.

Thanks so much for your help. Let me know if you need more info for the search. I really appreciate it.

Michelle

From: Pete J Herrera [mailto:pete.herrera@watson.com]
Sent: Thursday, April 21, 2011 11:58 AM
To: Palmer, Michelle
Subject: FW: FDA Compliance Report Request

Michelle,

Will this fulfill your request?

Please let me know if you have any questions.

Pete

Watson Pharmaceuticals
Peter J. Herrera
Supervisor, Security
Global Security & DEA Affairs
951-493-5380 Office
www.watson.com

From: Mary J Woods
Sent: Thursday, April 21, 2011 11:56 AM
To: Pete J Herrera
Cc: Judy L Callahan
Subject: FDA Compliance Report Request

Hi Pete,

Per your request, please find the authentication report.

Please let us know if you have any additional questions.

Best Regards,

Mary J. Woods
Executive Director, Customer Relations
A Watson Pharma, Inc., Corona, CA 92880
- 951-493-5951 🖷 951-493-1510 (C) 951-316-3616
- mary.woods@watson.com

Compliance - Meth Act Regs Meeting 8/10/2010

Tuesday, August 03, 2010
5:47 PM

Effective date Aug 6th 2010. Meth Act – List 1 Chemicals

Any Mfg, who distributes to wholesaler, dist, chains, etc. OTC, RX. Not ARCOS. Is responsible for reporting. Info

This new regulation was sent to DEA Affairs in 2007, however they somehow were not notified. Tom got wind, and when searching and found this.

Perrigo – List One Chemical Number

Packing slip/Invoice should display

1. Name
2. Address
3. DEA- if applicable (if Florida)
4. Date of trans
5. Product
6. Qty
7. Form of pkg.
8. Shipper
9. Method of ID- Lot #

- Look at a packing list and an invoice
- As long as the purchaser can extract the records and all info is included, no changes are necessary (if all data is included between the two documents we do not need to make any changes)
- We need a list of the Watson products affected List 1 – Ione

    Sandy to send the current list of Meth Act to Ione to compare for any possible changes

    OPD – Needs to change: No more one day license

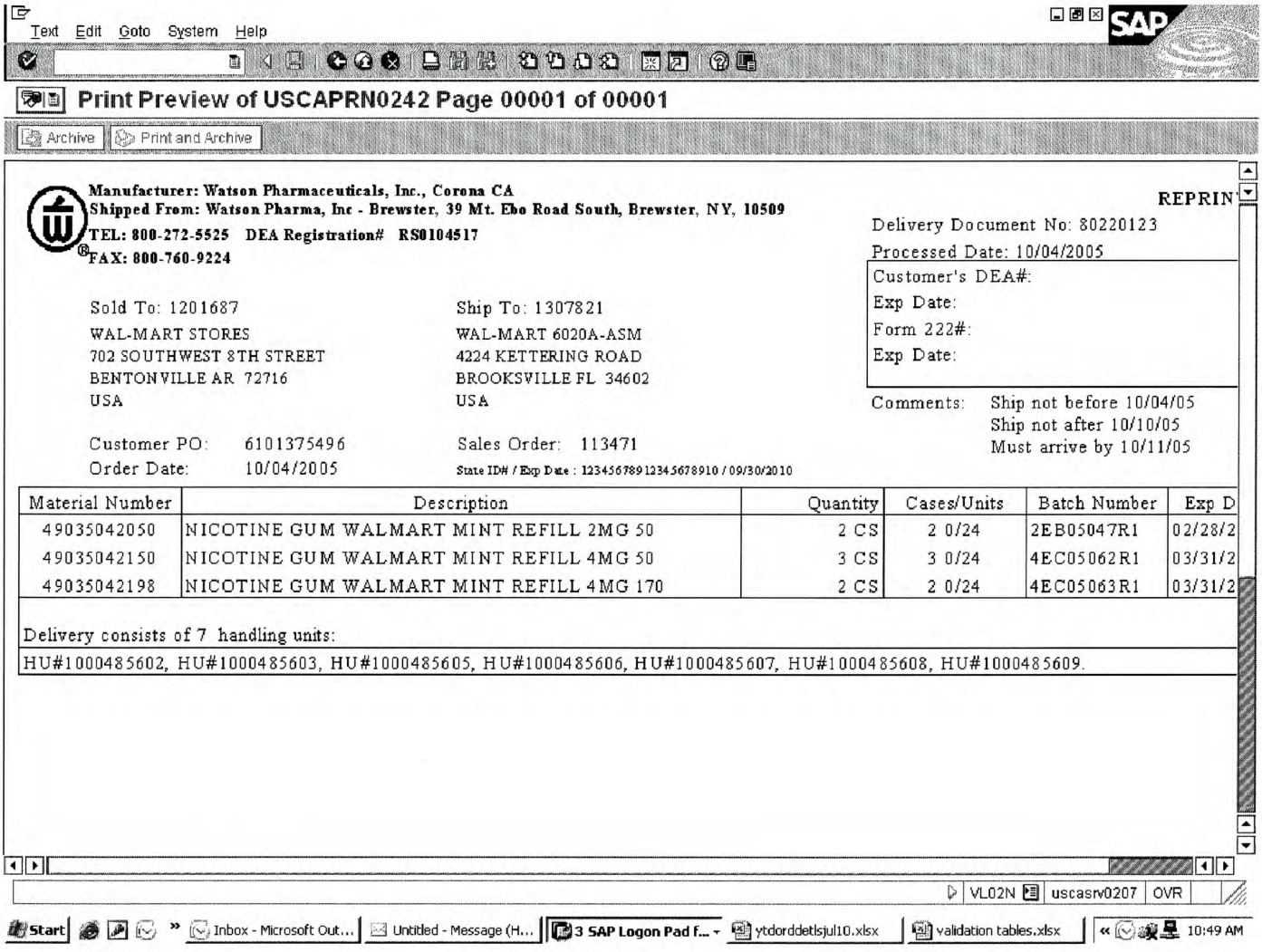
If the order is a Meth-Act product, the DEA is populated on the packing list, if the DEA is not required, and the Cust. does not have a DEA, the State Lisc. Will populate the state license.

Revision-approval needed 10/20/2010

Tuesday, October 19, 2010
3:54 PM

Subject	**Revision-approval needed**
From	Laura Pinti
To	Mary J Woods; John S Motta; Ione M Graziosi; Sandra I Simmons; Richard T Lichtenberger
Sent	Tuesday, October 19, 2010 11:23 AM

Avnish provided a sample with the field change to State ID/Exp Date. The font is the largest based on the # of characters. Please let me know your feedback so we can continue to move this forward. IT is working on test scenarios and then we can plan for UAT.



Text Edit Goto System Help

Print Preview of USCAPRN0242 Page 00001 of 00001

Archive | Print and Archive

Manufacturer: Watson Pharmaceuticals, Inc., Corona CA
Shipped From: Watson Pharma, Inc - Brewster, 39 Mt. Ebo Road South, Brewster, NY, 10509
TEL: 800-272-5525 DEA Registration# RS0104517
FAX: 800-760-9224

REPRIN

Delivery Document No: 80220123
Processed Date: 10/04/2005

Customer's DEA#:
Exp Date:
Form 222#:
Exp Date:

Sold To: 1201687
WAL-MART STORES
702 SOUTHWEST 8TH STREET
BENTONVILLE AR 72716
USA

Ship To: 1307821
WAL-MART 6020A-ASM
4224 KETTERING ROAD
BROOKSVILLE FL 34602
USA

Comments: Ship not before 10/04/05
Ship not after 10/10/05
Must arrive by 10/11/05

Customer PO: 6101375496
Order Date: 10/04/2005

Sales Order: 113471
State ID# / Exp Date : 123456789 12345678910 / 09/30/2010

Material Number	Description	Quantity	Cases/Units	Batch Number	Exp D
49035042050	NICOTINE GUM WALMART MINT REFILL 2MG 50	2 CS	2 0/24	2EB05047R1	02/28/2
49035042150	NICOTINE GUM WALMART MINT REFILL 4MG 50	3 CS	3 0/24	4EC05062R1	03/31/2
49035042198	NICOTINE GUM WALMART MINT REFILL 4MG 170	2 CS	2 0/24	4EC05063R1	03/31/2

Delivery consists of 7 handling units:

HU#1000485602, HU#1000485603, HU#1000485605, HU#1000485606, HU#1000485607, HU#1000485608, HU#1000485609.

VL02N | uscasrv0207 | OVR

Start | Inbox - Microsoft Out... | Untitled - Message (H... | 3 SAP Logon Pad f... | ytdorddetlsjul10.xlsx | validation tables.xlsx | 10:49 AM

From: Laura Pinti
Sent: Tuesday, October 19, 2010 10:49 AM
To: Avnish S Mohan
Subject:

Hello Avnish,

Do you know approx when the development would be done ? I am looking at the calendar to see when we maybe able to schedule a tentative UAT?

State Lic validation for MethAct, print on packing slip

Laura Pinti
Project Manager, Call Center Operations
Watson Pharma, Inc.
360 Mt. Kemble Avenue
Morristown, NJ 07960
(P) 973-355-8425 or x58425
laura.pinti@watson.com

DEA Verbiage

Monday, August 16, 2010
12:53 PM

Subject	**FW: Verbiage**
From	Sandra I Simmons
To	Mary J Woods
Sent	Monday, August 16, 2010 12:12 PM
Attachments	 In accordanc...

FYI

Sandra I. Simmons
Manager, Support Services
Watson Pharma, Inc
Morristown, NJ 07962
Direct - 973-355-8372
Cell - 973-997-2118
Fax # 973-355-8222

From: Tom P Napoli
Sent: Tuesday, July 20, 2010 12:27 PM
To: Sandra I Simmons
Cc: Mary J Woods; Lisa A Scott
Subject: Verbiage

Hi Sandy,
Attached is the recommended verbiage that we discussed in our meeting.
Regards,
Tom
In accordance with 21 CFR 1301.74, we are required to conduct independent analysis of orders prior to completing a sale to determine whether substances are likely to be diverted from legitimate channels. You have been contacted due to the fact that your order placed on 7/20/10, has prompted further analysis based on a deviation in one of the following areas; unusual size, frequency, or pattern. In an effort to expedite the investigative process and mitigate any delays or inconvenience, we are requesting supporting information necessary to justify the fulfillment of the order in question.
Answering the following questions may explain a deviation from normal pattern, size, and frequency:

- Has business increased? If so explain.
- Is this a new item for a customer?
- Is there Back order situation with alternate supplier?

Your prompt response and supporting documentation in regards to this matter are greatly appreciated.

Pasted from <file:///C:\Temp\OneNote\1\In%20accordance%20with%2021%20CFR%201301.docx>

Meeting 11/13/2010

Intention is to long. Customer does not seem to read.

SOMS Requirements

Tuesday, August 24, 2010
8:09 AM

Subject	**SOMS Requirements**
From	Lisa A Scott
To	Laura Pinti; Sanjay R Bhat
Cc	Tom P Napoli; Mary J Woods; Ione M Graziosi
Sent	Friday, July 30, 2010 5:58 AM
Attachments	 SOMS Ref Docs

Good morning.

Please see attached reference documents providing additional detail re: SOMS requirements.

Please feel free to contact me if you require additional information/clarification. Thank you.

Lisa Scott
Security & Compliance Auditor
Global Security & DEA Affairs
Watson Pharmaceuticals, Inc.
360 Mt. Kemble Ave
Morristown, NJ 07960
Office: 973.355.8265

Meth Act Compliance Requirements -Aug 10th

Wednesday, September 01, 2010
10:22 AM

- List of Meth Act cust. For 2010
  - Do all customers that we customer that we ship to have license.
  - We may have to reach out to customers to get a license.
- Nancy run ZVSEL ship for Jan-Aug 2010
- NDC identified at the material master like controls
- Look at the MD for either a DEA or State License
- The license would have to populate on the packing list, either the DEA or the State
- They must have one or the other license in order to ship
- Not sure if this is a "Pend" it is a VE31 pend, but I am not sure this is captured as a "Pend"
- All customers purchasing Meth Act must have a state license or DEA license

Good Morning,

In follow up to our meeting of August 10, 2010, I have reviewed our product list and did not find anything to add to your list of Meth products. To review our requirements, (the new rule is effective August 6, 2010) here is the statement I read to you from the Final Rule that was published:

The only information required in records for regulated transactions is the (1) name and address of the seller and purchaser (plus their DEA registration numbers, if applicable);(2) the date of the transaction; (3) the name, (4)quantity, and (5) form of packaging of the listed chemical; the (6)method of transfer; and the (7)method of identification used by the customer (ndc) and (8)any unique identification number associated with the identification(we talked about the lot number/ndc number for this purpose). This information is normally included on (9)purchase orders or invoices and the shipping papers and is needed to complete and track the transaction. As long as the purchaser can extract the records for examination, if necessary, no additional effort is needed. Because almost all business records for manufacturers, importers, and distributors are now generated and transmitted electronically, DEA does not expect that any registrant will need additional recordkeeping.

As we discussed, I believe the only thing we were missing to make our shipping records complete would be a State license number if the customer was not already registered with DEA. As stated above, a DEA registration is required only if applicable. By adding a state license number in lieu of DEA number if the customer does not have one should ice the cake.

Let me know if any further discussion is needed on this subject and I will set up a conference call. If not, we will put this issue to bed and I look forward to working with you on other issues that may arise in the future.

Thanks and have a good weekend.

Ione

Meeting 9/8/2010

Vicky, Ione, Sandy, Laura, Mary, Avnish, Sanjay
Header area is our first option 15-25 char for state numbers **"State ID"**:

Laura open the service now ticket

From: Sandra I Simmons
Sent: Tuesday, August 10, 2010 2:04 PM
To: Ione M Graziosi
Cc: Laura Pinti
Subject: FW: Meth Act Products OPD - Current list
Importance: High

Hi Ione,

Attached is our OPD, which contains a list of Meth Product .

FYI – License procedure on Meth Act.

A. Methamphetamine Control Act:

The Master Data Administrator (MDA) will create a virtual "MethAct" license in the format of MA and the business entity phone number (i.e. MA6029992002). Material classification "RX" (prescription) should be entered on the ExpContrClass tab. The license will be attached at the account/Master Data level and is valid for one business day. The MDA will "re determine" (unblock) the sales order and the sales order will be released for delivery.

The MDA will check sales order document flow (VA03 Display Sales Order) to confirm a delivery document has been generated. The MDA will "Expire" the newly created MethAct license(s) once the order has shipped, usually the day after the license has been created. This will ensure a validation process is in place for future orders.

Let me know if you have questions.

Thanks

Sandra I. Simmons
Manager, Support Services
Watson Pharma, Inc
Morristown, NJ 07962
Direct - 973-355-8372
Cell - 973-997-2118
Fax # 973-355-8222

From: Victoria Lepore
Sent: Tuesday, August 10, 2010 10:37 AM
To: Sandra I Simmons
Cc: Victoria Lepore
Subject: FW: Meth Act Products OPD - Current list
Importance: High

Vicky Lepore
WATSON
Master Data Administrator
360 Mount Kemble Avenue
Morristown, NJ 07962-1953
P. 973.355.8329
F. 973.355.8326

NDC No. 00536-	Size	Description	Ingredient subject to Act	Other Active Ingredients
0510-97	4 oz.	Allerfrim Syrup	Pseudoephrine HCl 30 mg	Triprolidine HCl
0510-85	Pint`	Allerfrim Syrup	Pseudoephrine HCl 30 mg	Triprolidine HCl
3421-35	24	Allerfrim Tablets	Pseudoephrine HCl 60 mg	Triprolidine HCl
1360-97	4 oz.	Bromaline DM Elixir	Pseudoephrine HCl 15 mg	Brompheniramine Maleate & Dextromethorphan HBr
1360-85	Pint	Bromaline DM Elixir	Pseudoephrine HCl 15 mg	Brompheniramine Maleate & Dextromethorphan HBr
0880-97	4 oz.	Bromaline Oral Solution	Pseudoephrine HCl 15 mg	Brompheniramine Maleate
0880-85	Pint	Bromaline Oral Solution	Pseudoephrine HCl 15 mg	Brompheniramine Maleate
2303-75	1 oz.	KidKare Drops	Pseudoephedrine HCl 7.5 mg	
2310-97	4 oz.	KidKare Liquid	Pseudoephedrine HCl 15 mg	Chlorpheniramine Maleate & Dextromethorphan HBr

Meth Act Products List 0110 0810.xlsx

Wednesday, September 08, 2010
2:39 PM

Subject	**Meth Act Products 0110 0810.xlsx**
From	Nancy E Radcliffe
To	Mary J Woods; Sandra I Simmons
Sent	Wednesday, September 01, 2010 4:56 PM
Attachments	 Meth Act Products 0...

Mary & Sandy,

Attached are the Meth Act sales from January through August 2010. The first tab shows subtotals, the second tab show the detail.

Let me know if there's anything else you need.

Nancy Radcliffe
Administrative Assistant II
Customer Relations
A Watson Pharmaceuticals, Inc.
US Generics Division
Corona, CA 92880
P 951-493-5921
F 951-493-1233
Nancy.Radcliffe@watson.com

DEA license Info

Tuesday, April 05, 2011
4:42 AM

Subject	**FW: Question regarding DEA license**
From	Lynn DaCunha
To	Mary J Woods; Judy L Callahan; Sandra I Simmons
Cc	Ione M Graziosi; Laura Pinti
Sent	Monday, April 04, 2011 8:57 AM

All,

Just wanted to give you the update on the Walgreen's DEA account issue. Please see Chief Boyd's responses below. It looks like Walgreen's just dropped their DBA at the end of March. They are going through the renewal period so it would be the best time to get it fixed. I would suggest you request a copy of their new license. Interesting though that they didn't tell you they made that change.

Richard Boyd asked me who the account was, so I had to send him the information, but he did clarify for future reference that the DEA address should match. So everyone hold onto this e-mail for future reference as it came straight from the Chief in charge.

Lynn

From: Boyd, Richard A. [mailto:Richard.A.Boyd@usdoj.gov]
Sent: Monday, April 04, 2011 11:11 AM
To: Lynn DaCunha
Cc: Ione M Graziosi
Subject: RE: Question regarding DEA license

That is correct, the shipping document and the DEA address should match

Rick Boyd
Chief, Registration and Program Support
Office of Diversion Control
DEA

From: Lynn DaCunha [mailto:Lynn.DaCunha@watson.com]
Sent: Monday, April 04, 2011 10:11 AM
To: Boyd, Richard A.
Cc: Ione M Graziosi
Subject: RE: Question regarding DEA license

Thank you so much. However, is the rule of thumb still that the DEA registration should match exactly as the address on the shipping documents?

Lynn DaCunha
DEA Compliance Analyst
Watson Pharmaceuticals, Inc.
360 Mt. Kemble Avenue

Morristown, NJ 07962
lynn.dacunha@watson.com
973-355-8167

From: Boyd, Richard A. [mailto:Richard.A.Boyd@usdoj.gov]
Sent: Monday, April 04, 2011 10:08 AM
To: Lynn DaCunha
Cc: Ione M Graziosi
Subject: RE: Question regarding DEA license

They just changed their DEA registration on 03/21 to delete their DBA, they are just:

Business or Facility Name: WALGREEN CO

Additional Company Info.:

Registrant Address: 2455 PREMIER ROW
ORLANDO, FL 32809

Rick Boyd
Chief, Registration and Program Support
Office of Diversion Control
DEA

From: Lynn DaCunha [mailto:Lynn.DaCunha@watson.com]
Sent: Monday, April 04, 2011 9:43 AM
To: Boyd, Richard A.
Cc: Ione M Graziosi
Subject: RE: Question regarding DEA license

Good morning,

The DEA license is for one of the Walgreen Distributor accounts located in Orlando, FL. The DEA number is PW0122262.

Thanks, Lynn

Lynn DaCunha
DEA Compliance Analyst
Watson Pharmaceuticals, Inc.
360 Mt. Kemble Avenue
Morristown, NJ 07962
lynn.dacunha@watson.com
973-355-8167

From: Boyd, Richard A. [mailto:Richard.A.Boyd@usdoj.gov]
Sent: Monday, April 04, 2011 9:30 AM
To: Lynn DaCunha
Cc: Ione M Graziosi
Subject: RE: Question regarding DEA license

Hi Lynn- what is the DEA# you are talking about?

Rick Boyd
Chief, Registration and Program Support
Office of Diversion Control
DEA

From: Lynn DaCunha [mailto:Lynn.DaCunha@watson.com]
Sent: Friday, April 01, 2011 4:14 PM
To: Boyd, Richard A.
Cc: Ione M Graziosi
Subject: Question regarding DEA license

Dear Mr. Boyd,

I am hoping you can help me resolve an issue that I am having with one of our customers who has a wholesale DEA distributor registration that contains a DBA under their company's name. We have this company set up in our system exactly the way their DEA license was permitted. They are asking us to remove the DBA line. They are registered in the state of Florida without the DBA and the two licenses not being identical seems to be having some issues with the inspectors in their state and our packing slip. We were always told that the information on the DEA registration had to match exactly on our shipping documents when we shipped controlled substances to any business. Please advise if that is still the case .

Your prompt response would be very much appreciated.

Thank you in advance for your guidance in this matter.

Kind Regards,

Lynn DaCunha
DEA Compliance Analyst
Watson Pharmaceuticals, Inc.
360 Mt. Kemble Avenue
Morristown, NJ 07962
lynn.dacunha@watson.com
973-355-8167

DEA Request: 4 Items Total

Thursday, July 07, 2011
2:18 PM

Subject	**DEA Request: 4 Items Total**
From	Lisa A Scott
To	Mary J Woods
Cc	Tom P Napoli; Jenna K Graham
Sent	Thursday, July 07, 2011 2:01 PM

Mary:

Just to summarize, I have four requests for your group from the DEA Diversion Investigators in support of the Corona inspection. The first two I previously requested and identified numerically below. Please also see below for two more.

1. Overall customer list for customers ordering controlled substances - Friday July 8th
   Customers for one full year - July 1, 2010 - June 30, 2011 - Please include customer name, full address and DEA registration # - I think that would be sufficient.

2. Copy of the customer questionnaire for new customers- Mary to provide Friday July 8th

A summary overview of the functions of your group (departments, responsibilities) and location (Corona v. Parsippany) along with corresponding documentation as it relates to the overall SOM program. For example, new customers handled in Corona, questionnaires stored there... Orders of interest evaluated by Master Data in Parsippany, associated documents there... Lisa - call me - Do I need to explain the system, or just the process.

3. The last request and the trickiest one... They would like a list of all of our customers (that order c/s) who ship Oxycodone and Hydrocodone to customers of theirs that have locations in Florida. Is this feasible? I told them that this request would take some time, so definitely not something that we need to turn over today... Also, I wasn't sure if we would have all this information... Would we only have it for customers on EDI and then the various customer spreadsheets sent to us by customers during the evaluation of orders of interest? With this request, I think the most reasonable approach is to give them the most we have without spending hours upon hours pulling the information or contacting customers. What do you think – are we able to get some of this?

   Only customers with 867/ this will take a few days. Sandy need to provide a list of who we get 867. Sandy will need to get list of customers that supply 867, and the list from Tom B.

Thanks, Mary! I really appreciate all of your assistance with this...

Lisa

Lisa A. Scott
Security & Compliance Auditor
Global Security & DEA Affairs
Watson Pharmaceuticals, Inc.
Morris Corporate Center III
400 Interpace Parkway
Parsippany, NJ 07054
lisa.scott@watson.com
862.261.7197 Office
862.222.3249 Mobile

FW: DEA Request for Customer Questionnaires

Wednesday, July 20, 2011
9:19 PM

Subject	**FW: DEA Request for Customer Questionnaires**
From	Mary J Woods
To	Lisa A Scott
Cc	Sandra I Simmons; Judy L Callahan; Tom P Napoli; Jenna K Graham
Sent	Wednesday, July 20, 2011 9:19 PM
Attachments	Accts Created D...

Hi Lisa,

Please see my responses below in red.

Best Regards,

Mary J. Woods
Executive Director, Customer Relations
A Watson Pharma, Inc., Corona, CA 92880
- 951-493-5951 🖷 951-493-1510 (C) 951-316-3616
- mary.woods@watson.com
www.watson.com

-

From: Lisa A Scott
Sent: Tuesday, July 19, 2011 8:49 AM
To: Sandra I Simmons; Mary J Woods; Judy L Callahan
Cc: Tom P Napoli; Jenna K Graham
Subject: DEA Request for Customer Questionnaires

Sandy/Judy/Mary,

I'd like to verify a few items re: DEA's request for customer questionnaires for the customer list Larry had provided (Watson customers located in FL, KY, GA that ordered Oxy and Hydro). Based on the "sold-to" and/or "ship-to" account set-up dates (especially considering 15 of the 25 were cutover from the Manfact system to SAP), the large majority of these customers have been with Watson for years. Here is what I would like to confirm so that I can ensure we are providing an accurate response to DEA's request:

1. The statement, "A large majority of these businesses have been Watson customers for over 10

years" (since they were part of system cutover 7 years ago and onboard for several years while Manfact was in place)... Would this be a reasonably accurate statement?***[mwoods]*** I would have to assume so. They were already set up when I came to Corona in 1999 to the best of my knowledge. I think that would be a fair statement.

2. Based on what I have reviewed from all the spreadsheets Larry sent on July 12th, (for sake of e-mail space constraints I did not re-forward) it looks like Smith Drug Company and Cochran Wholesale Pharmaceutical are the only 2 new customers (located in FL, KY or GA) that Watson brought on board since transitioning to SAP in 2004.
   Of the other 8 account set-ups since 2004,
   a. CVS (2)
   b. H D Smith (2)
   c. Publix
   d. Walgreen (3)

   all were the addition of new ship-to locations, not a new sold-to or parent account. Please confirm if accurate.

[mwoods] From reviewing the data provided, that is correct. I hate to provide a long answer, but I want to make sure we are clear. Actually, I am not even sure if we can state that Cochran or Smith Drug are new customers. Cochran was actually a Manfact customer that we did transition to SAP under account number 1131654 (Ship to). They were attached to the payer of Harvard and under the sold To of Cochran #1201139 created in 2004 by Richard McLane as well. On July 20, 2010, we set them up as their own sold to/ship to under #1325066 (same address as account #1131654. We would not have requested a questionnaire to set up their own sold to/ship to and move them from the payer of Harvard.

Smith Drug Company – The Sold to is 1201605 created in the 2004 transition from Manfact as well. The Ship to locations are as follows and their create dates:
1023292 –Spartanburg SC – Create April 2004
1323069 – Valdosta, GA – Create Feb 2009 is an additional ship to of the existing Sold To, a Q.Q would not be required.

3. If Smith Drug Company and Cochran Wholesale Pharmaceutical are the only 2 new customers (located in FL, KY or GA) that Watson brought on board since transitioning to SAP in 2004, could we pull a copy of their customer questionnaire to provide to DEA? ***[mwoods]*** Response under #2

In lieu of providing customer questionnaires for the other 23 ship-to locations (provided to DEA on the spreadsheet containing Watson customers located in FL, KY, GA that ordered Oxy and Hydro), we will develop a brief summary explaining that these are "legacy" customers, etc.

[mwoods] Please let me know if you have additional questions.

Thank you,

Lisa

Lisa A. Scott
Security & Compliance Auditor
Global Security & DEA Affairs
Watson Pharmaceuticals, Inc.
Morris Corporate Center III
400 Interpace Parkway
Parsippany, NJ 07054

lisa.scott@watson.com
862.261.7197 Office
862.222.3249 Mobile

RE: Additional DEA Request

Wednesday, July 20, 2011
9:58 PM

Subject	**RE: Additional DEA Request**
From	Larry E Shaffer
To	Mary J Woods; Sandra I Simmons
Cc	Lisa A Scott; Judy L Callahan
Sent	Tuesday, July 12, 2011 1:07 PM
Attachments	 Accts Created D...  LS - CVS ORLANDO ...  LAF - HD Smith Wh...  JH - Publix Super Mar...  JH - CVS Vero FL Di...  JH - H D Smith Wh...  VL - Smith Drug Co - ...  MM - Cochran ...  LS - Walgreens...

LS -
Walgreens...

VL -
Walgreen ...

MM -
Walgreens...

Here is the spreadsheet "Accts Created Date ..." Note: there are 3 tabs on this spreadsheet so all the data including raw data is there. The Pivot Table View tab is the one you will probably want Lisa.

There were 25 accts, 10 of those accts were created after the switch to SAP. I have included the Master Data request forms for those, hope that helps.

Thanks,

Larry

From: Mary J Woods
Sent: Tuesday, July 12, 2011 3:01 PM
To: Sandra I Simmons; Larry E Shaffer
Cc: Lisa A Scott; Judy L Callahan
Subject: Re: Additional DEA Request

Correct, Judy will let Larry know if she needs assistance with documentation! Thanks
Mary Woods Executive Director,Customer Relations
(T)951-493-5951
(F)951-316-3616

From: Sandra I Simmons
To: Larry E Shaffer
Cc: Lisa A Scott; Judy L Callahan; Mary J Woods
Sent: Tue Jul 12 14:51:55 2011
Subject: FW: Additional DEA Request
FYI

Lisa, Larry is working on this.

Sandra I. Simmons
Manager, Support Services
Watson Pharma, Inc
U.S. Generics Division
Parsippany, NJ 07054
Direct - 862-261-7072
Cell - 973-997-2118

Fax # 862-261-7804

From: Lisa A Scott
Sent: Tuesday, July 12, 2011 1:52 PM
To: Sandra I Simmons
Cc: Tom P Napoli; Mary J Woods; Judy L Callahan
Subject: RE: Additional DEA Request

Sandy:

I spoke with Judy re: the second part of this request:

*Additionally, DEA wants to review any **due diligence documentation** for each one of those customers, i.e. customer questionnaire, etc. (any documentation that demonstrates Watson performed their due diligence in "knowing our customer"). Judy: Would you be able to assist with this once the report is run? (Before the report is run, I'm sure we can count on some obvious customers: ABC, Anda, Cardinal, Caremark, CVS, HD Smith, Henry Schein, McKesson, Publix, Walgreen, Wal-mart, Rite Aid, Smith Drug, Richie Pharmacal, etc.)*

Would your group be able to provide the dates the customers identified in Larry's spreadsheet were set up in SAP? We'd like to identify if any of these customers were brought on board after the Manfact cutover in May 2004. Thank you!

Lisa

Lisa A. Scott
Security & Compliance Auditor
Global Security & DEA Affairs
862.261.7197 Office

From: Larry E Shaffer
Sent: Monday, July 11, 2011 5:12 PM
To: Mary J Woods; Lisa A Scott; Sandra I Simmons; Judy L Callahan
Cc: Tom P Napoli; Scott K Soltis; Jenna K Graham
Subject: RE: Additional DEA Request

Please see attached.

From: Mary J Woods
Sent: Monday, July 11, 2011 3:23 PM
To: Lisa A Scott; Sandra I Simmons; Judy L Callahan; Larry E Shaffer
Cc: Tom P Napoli; Scott K Soltis; Jenna K Graham
Subject: Re: Additional DEA Request

Lisa, we have the data, it should be quick for retrieval!
Sandy & Larry, please copy me when this is completed!
Thanks.
Mary Woods Executive Director,Customer Relations
(T)951-493-5951
(F)951-316-3616

From: Lisa A Scott
To: Mary J Woods; Sandra I Simmons; Judy L Callahan
Cc: Tom P Napoli; Scott K Soltis; Jenna K Graham
Sent: Mon Jul 11 14:27:30 2011

Subject: Additional DEA Request
Mary and Sandy:

Mary, I know you are on vacation, but I'm pretty sure Sandy and her team assisted with the last sales request from DEA. I just received an additional request from the Diversion Investigators via phone (they arrived onsite in Corona at 1:45 pm EST). They would like a report containing the following:

A list of all Watson customers **located in FL, KY and GA** that we shipped **Oxycodone and Hydrocodone products (each SKU)** to between July 1, 2010 and June 30, 2011 (same time period as the last report) and the **quantities** associated with these shipments. For example:

AMERISOURCE BERGEN DRUG CORPORATION	11200 NORTH CONGRESS AVE	KANSAS CITY	MO	64153	RA0326276

00591034901	HYDROCODONE/APAP 5/500MG TAB 100	2,400 units

Additionally, DEA wants to review any **due diligence documentation** for each one of those customers, i.e. customer questionnaire, etc. (any documentation that demonstrates Watson performed their due diligence in "knowing our customer"). Judy: Would you be able to assist with this once the report is run? (Before the report is run, I'm sure we can count on some obvious customers: ABC, Anda, Cardinal, Caremark, CVS, HD Smith, Henry Schein, McKesson, Publix, Walgreen, Wal-mart, Rite Aid, Smith Drug, Richie Pharmacal, etc.)

I realize this is a time-consuming request, but I would appreciate your immediate attention to this, as I want to make sure we can demonstrate that our records are "readily retrievable". Please feel free to call me with any questions. Thank you.

Lisa

Lisa A. Scott
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Global Security & DEA Affairs
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862.261.7197 Office
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KK- Contract Verbiage - DEA

Thursday, July 21, 2011
7:44 AM

Subject	**RE: Outstanding Items for DEA**
From	Kathleen A Karlsson
To	Lisa A Scott; Rose Bentrovato; Mary J Woods; Diane F Miranda
Cc	Jenna K Graham; Tom P Napoli; Scott K Soltis
Sent	Tuesday, July 19, 2011 11:35 AM

Without pulling every contract, I have included below our standard confidentiality language. While actual agreement language may differ slightly, they are basically the same.

The pricing, terms and conditions of this Agreement are considered proprietary and confidential and each party will maintain in confidence and not disclose to third parties any confidential and/or proprietary information of the other party, which may come as a result of the relationship evidenced by this Agreement, including all material terms and conditions of this Agreement, without the prior written consent of the non-disclosing party. The obligations of confidentiality set forth in this Section shall not apply to information which (i) is or becomes generally available to the public or the pharmaceutical industry other than as a result of the parties hereto; (ii) was available on a non-confidential basis prior to the disclosure by either party hereto; or (iii) becomes available to either party on a non-confidential basis from a person other than the parties hereto, provided that such disclosing party is not subject to a confidentiality agreement that would prohibit the disclosure of such information. The obligations of confidentiality in this Agreement shall survive the expiration or any termination of the Agreement for a period of five (5) years thereafter.

Nothing contained in this Section shall restrict any party from disclosing confidential or proprietary information of any other party pursuant to a valid court order or subpoena or as required under applicable statute, rule, or regulation or by any federal, state, county, municipal, local, or foreign governmental or governmental agency, bureau, commission, authority, or body, with competent jurisdiction over any party hereto or the requested information. In the event that either party is required to disclose confidential or proprietary information in accordance with this paragraph, the disclosing party shall notify the non-disclosing party of the disclosure.

Neither party shall publicly announce or disclose the existence of this Agreement or its terms and conditions, or advertise or release any publicity regarding this Agreement, without the prior written consent of the other party. This provision shall survive the expiration or earlier termination of this Agreement.

From: Lisa A Scott
Sent: Tuesday, July 19, 2011 10:48 AM
To: Kathleen A Karlsson; Rose Bentrovato; Mary J Woods; Diane F Miranda
Cc: Jenna K Graham; Tom P Napoli; Scott K Soltis
Subject: RE: Outstanding Items for DEA

Kathleen: Thank you for providing this information. I realize the period of time was not detailed in this e-mail chain, but DEA's various requests for sales data was for the July 2010 – June 2011 timeframe.

Kathleen/Mary/Diane: I know at some point there was some discussion re: Watson's ability to share this information with DEA. Are we restricted by contractual agreement? Would you be able to share the language included in the contract so we can make the determination as to whether it is appropriate for us to provide this information to DEA?

Thank you.

Lisa A. Scott
Security & Compliance Auditor
Global Security & DEA Affairs
862.261.7197 Office

From: Kathleen A Karlsson
Sent: Friday, July 15, 2011 3:40 PM
To: Rose Bentrovato; Mary J Woods; Lisa A Scott; Jenna K Graham; Diane F Miranda
Subject: FW: Outstanding Items for DEA

The attached file contains shipments to Florida indirect customers. The wholesaler column indicates Watson's direct customer. I was not sure what period of time you were researching, so this is just Q2. Please let me know if you have any questions.

Kathleen Karlsson
Executive Director, Contract Operations

Watson Pharma, Inc.
Morris Corporate Center III
400 Interpace Parkway, Bldg A
Parsippany, NJ 07054
Ph: 862-261-7037

From: Diane F Miranda
Sent: Thursday, July 14, 2011 5:30 PM
To: Kathleen A Karlsson
Cc: Rose Bentrovato; Mary J Woods; Lisa A Scott; Jenna K Graham
Subject: FW: Outstanding Items for DEA

As discussed, please review the second item that was requested on July 7th. I believe you are the best person to access indirect sales data via chargeback info. Thanks !

***** Request for Watson's customers who sell Oxy and Hydro to customers located in Florida *****

From: Rose Bentrovato
Sent: Thursday, July 14, 2011 5:05 PM
To: Diane F Miranda
Subject: FW: Outstanding Items for DEA

Other piece of what we were discussing

Rose Bentrovato
Director, Demand Management
Watson Pharmaceuticals
Morris Corporate Center III
400 Interpace Parkway Bldg A
Parsippany, NJ 07054
(T) 862-261-7258
(C) 973-420-9353
email: rose.bentrovato@watson.com

From: Lisa A Scott

Sent: Tuesday, July 12, 2011 3:07 PM
To: Jenna K Graham
Cc: Tom P Napoli; Pedro M Fernandez Aviles; Lynn DaCunha; Mary J Woods; Judy L Callahan; Sandra I Simmons; Rose Bentrovato
Subject: Outstanding Items for DEA

Jenna,

Just wanted to give you a quick status update on the outstanding requests for documentation:

Requested July 7:
DEA Screen Forms for Corporate Officers
In-process. Lynn is waiting on approximately 8 additional forms
Request for Watson's customers who sell Oxy and Hydro to customers located in Florida
In-process. Working with Customer Relations/Demand Management to pull this information

Requested July 11:
International Holdings
In-process. Lynn is verifying the global locations with her contacts in Regulatory and Materials Management
Customer Due Diligence Questionnaires
In-process. Working with Customer Relations to pull this information
Product Catalog (all products)
Requested – to be shipped to Corona

Thank you,

Lisa

Lisa A. Scott
Security & Compliance Auditor
Global Security & DEA Affairs
Watson Pharmaceuticals, Inc.
Morris Corporate Center III
400 Interpace Parkway
Parsippany, NJ 07054
lisa.scott@watson.com
862.261.7197 Office
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DEA - Marketing - Compliance Hydro 4/18/2012

Wednesday, April 18, 2012
11:30 AM

DEA Conference is starting at 3PM ET - 4/18

Marketing wants to start shipping more to assist

Hi Napoleon and Toni,

I have a few marketing questions regarding the Hydrocodone market demand which I am hoping you can assist with. As you know the increased order volume in many of the Hydrocodone skus has been significant over the past several weeks. I am intending to use the information provided to discuss the market demand, and market share with the DEA Compliance team.

Can you provide the Hydrocodone sku's presenting a market demand in the supply chain.?
Toni to provide begin of 4/23
All Hydrocodone skus
5/500 - Amneal discontinued to certain customers only- most likely kept retail - We were not primary with Anda-they were primary with Amneal, Mallinckrodt thru May interruptions - quota issues, Qualitest

Watson 44%
Mallinckrodt 31% - TRX going down
Qualltest 21% - RX going up
Amneal 3%

Marketing is canceling significant volumes of OMS
Marketing is expecting large volumes as an increase due to support - Chargeback data from Dennis

Which supplier(s) impacted the increase in market demand?
Qualitest
Amneal
Mallinckrodt

Is this a temporary or permanent change in the market place?
May not be able to provide
Amneal - permanent.
Mallinckrodt - temp - May
Qualitest - unknown

If temporary, do we know what the time period will be?

What is the (potential anticipated range) percent of market share increase per sku that Watson will recognize as a result of the market demand?
Same format to give to DEA.
Approx. 15 - 20 %

Are all customers providing Marketing with increased forecast for all increased volumes of Hydrocodone?
No, they just order - we could just ask if they have a recent forecast in Marketing. If they don't have we

can go to the customer, we can get.

If so, have all forecast been passed on to the Master Data team.
They will

Is Watson planning of fulfilling all increases in business from a Market and Demand aspect?
As much as we possibly can, to support the market.

How can we get market updates from Marketing consistently, can we get copied when the DNA's are copied?

Anda issue: Orders Response has not yet been provided on 4/12

As requested, here are the two order pending in SOMS for Anda

po # 241356 (customer not contacted on this one) Sandy is sending and will copy Mary so I can monitor the response.

288 EA 00591038505 HYDROCODONE/APAP 7.5/500MG TAB 500
with this order, they will be 406 pcs. over
852 FOR 4/15 shows they have 3 weeks on hand

480 EA 00591034905 HYDROCODONE/APAP 5/500MG TAB 500
with this order, they will be 709 pcs. over
852 for 4/15 shows they have 1.2 weeks on hand

72 EA 00591034901 HYDROCODONE/APAP 5/500MG TAB 100
with this order, they will be 240 over
852 for 4/15 shows they have 4.9 weeks on hand

60 EA 00591038501 HYDROCODONE/APAP 7.5/500MG TAB 100
with this order, they will be 213 over
852 for 4/15 shows they have 4.3 weeks on hand

144 EA 62037052401 HYDROCODONE/IBUPROFEN 7.5/200MG TAB 100
with this order they will be 133 over
852 for 4/15 shows they have 2.5 weeks on hand

po# 1008665 (sent email to customer, they haven't responded yet)

120 EA 00591038505 HYDROCODONE/APAP 7.5/500MG TAB 500
with this order, they will be 56 over
852 for 4/15 shows they have .9 weeks on hand

432 EA 00591034905 HYDROCODONE/APAP 5/500MG TAB 500
with this order they will be 646 over
852 for 4/15 shows they have 1.5 weeks on hand

144 EA 00591034901 HYDROCODONE/APAP 5/500MG TAB 100
with this order they will be 888 over
852 for 4/15 shows they have .1 week on hand

COT	STARTED WITH	CHANGED	RECENT (2010)	6/24/2010
CHAIN	3	6	1.5	3
DISTRIBUTOR	1.5	3	1.25	[redacted]
MAILORDER	1.5	3	1.25	1.25
MANUFACTURE	1.5	3	1.25	1.25
WHOLESALER	1.5	3	1.25	2

New Customers, New Product for existing customer, Product Launches-SOMS System: Process and System flow Meeting 3/30

Monday, March 21, 2011
3:38 PM

Subject	**SOMS System: Process and System flow- New Customers, New Product for existing customer, Product Launches**
Date and Location	Thursday, March 31, 2011 8:30 AM - 9:30 AM, Conference Call #: 888-858-6182 Participant code: 550636 Host: Mary Woods
Attendees	Mary J Woods; Sandra I Simmons; Lisa A Scott; Tom P Napoli
Message	All, would like to discuss some review of SOMS system flow as it pertains to: Current customers- New controlled product New Customers – controlled product Product Launches – increased order qty Sandy, please feel free to invite appropriate team members from the Master Data team.

Mary J Woods
Sandra I Simmons
Lisa A Scott
Tom P Napoli
Laura Pinti
Justin J Park
Sanjay R Bhat
Vicky, Mary, Larry

I would like one of the BSA's to attend this meeting. Who would be the most knowledgeable regarding the logic behind SOMS? We are going to discuss the three scenarios below and determine how to change the system without a lot of logic changes.

- IE. New customers – block all orders for first 90 days for controlled substances for review of qty. (just example, not determined logic)

- IE. Product Launches – Marketing may have agreement to allow :6-8 weeks of inventory at launch, that will sku threshold, and if customer places orders for the next few weeks, along with multiplier, they will have a false baseline going forward. How to manage. All orders for the 1st month will bypass since there is no history.
    - Do we have ability to set

- IE. Current Customer New product- may or may not be able to order controls, based on COT may not be correct measure, how to measure accuracy for new product?

Email from Laura 3/1/2011
The baseline for Manuf is currently set an zero. However, confirmed with IT, the baseline pertains only to OMS.

It appears since the customer did not have an established history it looked at COT average. It is possible that the average was less than the other manuf orders:

Additional info from Mr Justin:

CUS Av/mth (12) -> CUS Av/ord (13) -> COT Av/mth (10) -> COT Av/ord (11)

If there is no history for CUS (ship-to) and this particular product, it won't check 12 and 13.
It goes to 10 and 11 checking directly. I assumed the order quantity was less than the threshold of COT.

<u>Short Term Plan/ Separate Develop Table Separate T Code: (Similar to OMS table) - Need for May 2nd launch</u>

1) Customer (New Customer)- Ship To
2) Materials(New Product Launches)- SOMS Block 12

3) Customers/Materials (Specific Need to temporarily monitor)

- Add To From/Date in each component
- DEA Compliance Team will manage table
- Laura to complete the Change Control on April 6th
- Justin to discuss with Sanjay as far as timing if there are any issues, he will contact me.

Medco:

Hi Mary, I just spoke w/ Sandy about 3 orders from Medco where they are over. We are going to cancel the lines that are over, but we wanted to check with you to see if you wanted to reach out to the customer regarding a partnership call *before* we cancel the line items. Order details below:

PO# 6003189453 – SD# 466638
00591038801 HYDROCODONE/APAP 2.5/500MG TAB 100 – QTY 180 / MTD 204 / Cust Allow 133 / + current will be over by 251.
00591039501 PENTAZOCINZE/NALOX HCL 50/0.5MG TAB 100 – QTY 60 / MTD 240 / Cust Allow 205 / + current will be over by 95.

PO# 6003189492 – SD# 466643
52544046960 ANDRODERM (PIGMENT US) 2.5MG/DY P60 – QTY 72 / MTD 264 / Cust Allow 303 / + current will be over by 33.
52544047030 ANDRODERM (PIGMENT US) 5MG/DY P30 – QTY 720 / MTD 2,448 / Cust Allow 2,875 / +current will be over by 293.

PO# 6015109323 – SD# 466645
00591054005 HYDROCODONE/APAP 10/500MG TAB 500 – QTY 258 / MTD 1,416 / Cust Allow 1,431 / + current will be over by 243.
00591320301 HYDROCODONE/APAP 7.5/325MG TAB 100 – QTY 1,206 / MTD 2,746 / Cust Allow 2,639 / +current will be over by 1,313.

Meeting with Laura on April 11th to approve CR:
Justin trying to complete by the end of the month. Mary confirmed w/ LP that all needs to be completed and in development by end of month, launch is May 2nd.

RE: Hydrocodone Supply Issues - Market Demand

Monday, April 30, 2012
6:27 PM

Subject	**RE: Hydrocodone Supply Issues - Market Demand**
From	Toni M Picone
To	Mary J Woods; Napoleon D Clark
Cc	Lisa A Scott; Tom P Napoli; Sandra I Simmons; Scott K Soltis; Andrew S Boyer
Sent	Thursday, April 26, 2012 2:43 PM
Attachments	Hydrocodon e APAP W... AR-M550N_ 20120412...

Hello All – Please see answers to the below questions as per our meeting today.

1) Amneal, Qualitest, and Mallincrodt are the suppliers that customers are telling us are the reasons for the supply shortages in the market. Amneal has discontinued to select customers only, and Mallincrodt sent letters that they have backlog and are trying to ramp up as a result of quota.
2) The customers who are no longer receiving product from Amneal is a permanent change, and those who are short from Mallincrodt we expect to be temporary
3) We do not know how long the increased demand will be for the temporary change. Mallincrodt's letter states through May
4) Customers typically do not proactively provide marketing with increased forecasts. However, we are closely monitoring the orders and when we see large increases in orders we do reach out to customers to ask for revised forecasts and/or monitor the 852/chargeback data to determine if their sales out is increasing
5) If we receive increased forecasts from customers, we will provide them to the master data team. In addition, if the master data team receives revised forecasts they will provide to marketing
6) There is a potential market share increase of approximately 15%-20% based on our share vs our competitors as of Q4'11 per the IMS EU data

I have attached recent TRx data from IMS so you can see the market trends by competitor. I also attached a copy of Mallincrodt's letter that they sent to customers for your reference.

Please let me know if you have any questions, or need any additional information from me.

Thanks,
Toni

Toni M. Picone
Sr. Marketing Manager, Generics
Watson Pharmaceuticals
Morris Corporate Center III

400 Interpace Parkway
Parsippany, NJ 07054
T 862-261-7060

From: Mary J Woods
Sent: Tuesday, April 17, 2012 6:14 PM
To: Napoleon D Clark; Toni M Picone
Cc: Lisa A Scott; Tom P Napoli; Sandra I Simmons; Scott K Soltis
Subject: Hydrocodone Supply Issues - Market Demand

Hi Napoleon and Toni,

I have a few marketing questions regarding the Hydrocodone market demand which I am hoping you can assist with. As you know the increased order volume in many of the Hydrocodone skus has been significant over the past several weeks. I am intending to use the information provided to discuss the market demand, and market share with the DEA Compliance team.

Can you provide the Hydrocodone sku's presenting a market demand in the supply chain.?

Which supplier(s) impacted the increase in market demand?

Is this a temporary or permanent change in the market place?

If temporary, do we know what the time period will be?

What is the percent of market share increase per sku that Watson will recognize as a result of the market demand?

Are all customers providing Marketing with increased forecast for all increased volumes of Hydrocodone?

If so, have all forecast been passed on to the Master Data team.

Is Watson planning of fulfilling all increases in business from a Market and Demand aspect?

These answers will be very helpful to our team.

Thank you.

Best Regards,

Mary J. Woods
Executive Director, Customer Relations
A Watson Pharma, Inc., Corona, CA 92880
- 951-493-5951 🖷 951-493-1510 (C) 951-316-3616
- mary.woods@watson.com

www.watson.com

-

Customer Profiles

Friday, May 04, 2012
10:32 AM

Subject	**Customer Profiles**
Date and Location	Friday, May 04, 2012 10:30 AM - 11:00 AM, Will call Mary's office
Attendees	Lisa A Scott; Mary J Woods; Judy L Callahan; Tom P Napoli
Message	When: Friday, May 04, 2012 1:30 PM-2:00 PM (GMT-05:00) Eastern Time (US & Canada). Where: Will call Mary's office Note: The GMT offset above does not reflect daylight saving time adjustments. *~*~*~*~*~*~*~*~* ALL SET FOR 1:30! Customer Profiles: General discussion for potential DEA Affairs project initiative going forward Feel free to propose an alternative date/time if this is not convenient. We'd like to have the meeting by the end of the week if possible. Thanks.

Notes
Customer Questionnaire
Articulate what our customers look like
What our customers look like
Base looks like
Order most controlled substances

Customer Profile - Quick reference

- **Demographic of what they order**
- **Show that we know our customers**
- **Top 10 customers yoy**

Meeting with Dennis on 5/11 (Mary, Judy, Lisa, Tom, Dennis)
Questionnaire
Profile
Data Base

Per Dennis , this query already exist.

1. **Purpose to develop data to know our customer base.**
2. **Top Control substance customers**
3. **Top 50 hydro**
4. **Top 50 oxy**
5. **Contribution to the total control purchases**
6. **Want to go down to unit dosage level**

Report Requirements:

7. Develop a separate query, to show our customers/ customer - does not include brand products will be as much data as available in charge backs
8. Safety stock level volatility
9.

2013 Meeting

Wednesday, January 02, 2013
5:13 PM

Tom and Lisa, On Jan.7th, I have been requested to present DEA Compliance updates to the Sales and Marketing team. I would like to meet with the two of you to gain some suggestions from your vantage point as to what may be useful to include in the presentation that will be beneficial to this team. I would appreciate this time to discuss. Thank you.

Tuesday: Mary to talk Scott to ask if Tom can attend

Would you have time to attend meeting and present in partnership. Is at office. (Lisa to send me a slide)

- DEA Perspective of combined organizations
  - Products we are bringing on from Actavis
  - Immediate release Oxy are the most widely diverted, and are
  - Mfg and Dist are being held accountable
  - We mfg the #1 and #2 most scrutinized products by the DEA

- U.S Order Mgmt. Responsibility vs. DEA Compliance

- **DEA commitment and support to the Sales Team**
  - Would you be willing to attend the meeting to speak on the partnership with our team
  - Our job is protecting the company and support the business at the same time. We follow the compliance business rules.

- **Know your customers - extended program and investigation**
  - Due diligence
  - Continued due diligence
  - Full due diligence on all current customers based on combined organization
  - Enhanced SOMS program
  - Increase in Distributors evaluation process for controls

  - New customer vetting will be critical
    - Forecast
    - Partnership calls

- **Market Place in the last year**
  - Walgreens
  - Cardinal
  - Continual call to our customer service

- Commitment to response time back to the DNA team.
  a. Bi-Lo Winn Dixie, Maureen states that she has not received a response yet.

1. Capital - Done
2. QCP – Lake Erie: What is the status
3. Southern Anesthesia – We are waiting for info
4. Martek
5. QK – Tony sent e-mail for info to be sent back
6. Dakota

Actavis DEA Compliance Overview

Friday, January 18, 2013
10:05 AM

Meeting 1/18/2013

As discussed prior to the holidays, I would like to provide a brief update on what Actavis has done with respect to monitoring data of controlled products down to a pharmacy level. I would like to highlight some discussions that were underway with customers at the time of the acquisition to ensure these are not overlooked as we move forward. Additional follow-up is needed to address concerns we had identified following our review of sales data, and I want to ensure this gets the proper attention it needs.

I was going to include DNA's for some of the accounts involved in some current discussions, but thought we may want to start off with some high level planning discussions and drill down into the details as a second step. I also recognize that the extent to which some individuals were involved in the past may change within the new organization, while others will be added. On that note, I have added my Actavis colleagues that have been instrumental in these endeavors to participate in this discussion. Regardless of the extent to which they may be participating in future SOM activities or not, I wanted to ensure where necessary we had a smooth transition of responsibilities.

If I have missed anyone that should be included in this initial discussion, please let me know so they can be added. Otherwise, we will certainly want to involve others once we have a transition plan identified.

Unfortunately, I do not have visibility to the Watson calendar to confirm availability. Therefore, if the time requested does not work for you , please make every effort to suggest an alternate time for Friday, January 18th or preferably no later than Monday, January 21st . I will also need some assistance in securing a conference room in Parsippany so these details will follow.

Mike Clarke

ABC Meeting:
Cardinal Meeting:
McKesson Meeting:

Rachael - key on the SOM team/ instrumental on the indirect meeting
There is no requirement to know your customer - customer by DEA

NB - Regulation: left to interpretation
TN- DEA 2007 sited need to conduct due diligence, know your customer, responsibility, then pushed to the mfg.

Chargeback Data -wholesalers
Valuecentric - Distributor data via 867

NB- Key Highlights of DEA Meeting/Actavis:

- Wake up everyone in the company
- Pleased to see where Actavis was at
- Look at Publix
- Happy Harrys (part of Walgreens)
- Do not use Controlled as sales drug
- Your customers should provide ARCOS data

- Contracts should be modified
- We want a 30% reduction, you are being put on notice
- Top Oxy accounts, being serviced by ABC

States:
TN

Accounts
Food City

Follow Up Meeting DEA Meeting/Actavis :
- Would it help you to strong arm you, or will you go willingly

ABC
- Knew a lot regarding the top customers

Measurements:
1. Customer buying increased trends
2. Disproportionate trends
3. Multiple wholesalers

Combined Company Approach
ABC - Chargeback Data for the same DEA numbers - Dennis
TOPCO Contract
Contracts from Customer Kathleen

Meeting 2/1/2013

SOMS Consultant Meeting

Monday, May 09, 2011
8:24 AM

Consultants Meeting

Make sure to bring up Product Launches - initial purchasing of customers that may purchase more than one month worth of inventory.

New Customers or Customers with new product no history.

VMI -Controls

Friday, April 26, 2013
8:35 AM

Brett H - Meet with Andy

Q3- remove from VMI

1. Value Drug - Tom Donahue
2. Wal- Mart review with Andy

- Are other controlled vendors doing VMI, we need to investigate before we move vendors

Allocation Compliance Language

Wednesday, May 29, 2013
8:33 PM

From: Mary J Woods
Sent: Wednesday, May 29, 2013 8:32 PM
To: Tom P Napoli; Napoleon D Clark
Cc: Laura J Pinti; Thomas P Belverio
Subject: RE: June DRAFT allocations--Response needed by EOB 5/29/13

Tom, I changed just slightly to highlight SOMS in addition to other compliance evaluations, since that is the most common customer comment. I underlined the verbiage I added. Is this OK?

Please note: The allocation quantities for controlled substance products have been established on the basis of inventory availability only and are subject to SOMS and/or other compliance evaluations in accordance with 21 CFR 1301.74(b)

I believe this is simple, and can be used for other compliance needs i.e. Price Increase allocations etc.

Napoleon, can you comment from a Marketing standpoint?

Best Regards,

Mary J. Woods
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Actavis Corona, CA 92880
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✉mary.woods@watson.com
www.actavis.com

From: Tom P Napoli
Sent: Wednesday, May 29, 2013 1:06 PM
To: Mary J Woods
Cc: Laura J Pinti; Thomas P Belverio
Subject: RE: June DRAFT allocations--Response needed by EOB 5/29/13

Does this work?

Please note: The allocation quantities for controlled substance products have been established on the basis of inventory availability only and are subject to SOMS and/or other compliance evaluations in accordance with 21 CFR 1301.74(b)

Thanks,
Tom

SOMS Table May 2013

Monday, May 19, 2014
1:01 PM

ZVMULDATA

May 6th 2013

From: Tom P Napoli
Sent: Monday, May 06, 2013 3:23 PM
To: Mary J Woods
Cc: Sandra I Simmons
Subject: RE: SOMS Table - Effective May 1, 2013

It's all good. Taken care of!

From: Mary J Woods
Sent: Monday, May 06, 2013 2:53 PM
To: Tom P Napoli
Cc: Sandra I Simmons
Subject: RE: SOMS Table - Effective May 1, 2013

Tom – it could be me. I may have interpreted that our plan was to make the move to 2 for all COT's since we discussed the fact we have been doing thorough investigations and releasing accounts based on these same considerations. I am sure you would have changed only the two Lisa changed when she left? I did not mean to add confusion to a complex situation.

Thank you, and I will ensure that I clearly define the COT's in the future.

Best Regards,

Mary J. Woods
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From: Tom P Napoli
Sent: Monday, May 06, 2013 10:54 AM
To: Mary J Woods
Cc: Sandra I Simmons
Subject: RE: SOMS Table - Effective May 1, 2013

I think we have a communication issue here, I will bring them all to two.

From: Mary J Woods
Sent: Monday, May 06, 2013 1:26 PM
To: Tom P Napoli
Cc: Sandra I Simmons
Subject: FW: SOMS Table - Effective May 1, 2013

Tom – is there a reason that we would not have change all COT's to "2". This may be the issue. Thank you.

From: Tom P Napoli
Sent: Monday, May 06, 2013 3:23 PM
To: Mary J Woods
Cc: Sandra I Simmons
Subject: RE: SOMS Table - Effective May 1, 2013

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✉mary.woods@watson.com
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From: Tom P Napoli
Sent: Monday, May 06, 2013 10:54 AM
To: Mary J Woods
Cc: Sandra I Simmons
Subject: RE: SOMS Table - Effective May 1, 2013

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From: Mary J Woods
Sent: Monday, May 06, 2013 1:26 PM
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Cc: Sandra I Simmons
Subject: FW: SOMS Table - Effective May 1, 2013

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From: Mary J Woods
Sent: Monday, May 06, 2013 9:59 AM
To: Tom P Napoli; Nardo B Catahan
Cc: Sandra I Simmons (Sandra.Simmons@watson.com)
Subject: FW: SOMS Table - Effective May 1, 2013

Tom –
Please see the email below. Does not appear the changes to the COT's occurred?

Best Regards,

Mary J. Woods
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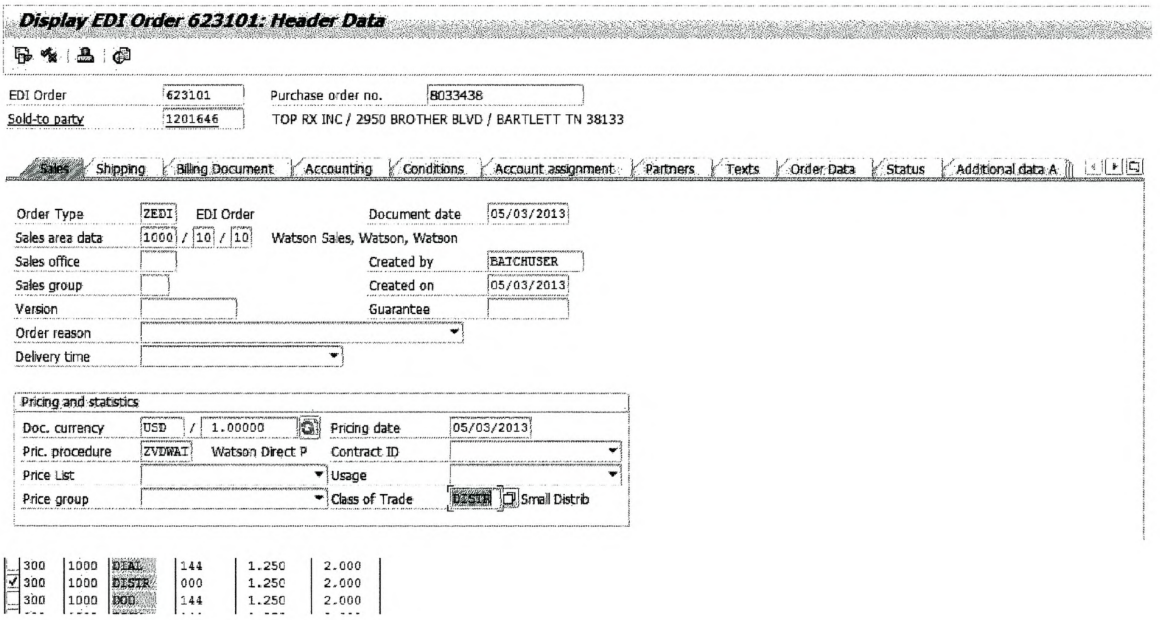
From: Sandra I Simmons
Sent: Monday, May 06, 2013 9:51 AM
To: Mary J Woods
Subject: FW: SOMS Table - Effective May 1, 2013

FYI

From: Nardo B Catahan
Sent: Monday, May 06, 2013 11:41 AM
To: Sandra I Simmons
Cc: Hemal Fernando
Subject: RE: SOMS Table - Effective May 1, 2013

Actually the multiplier for SOMS is 1.25 and for OMS it is 2.00 (see below):



But still you are right.
I will request Hemal to look into it.
Just a heads up it may take a while.
All the folks here are extremely busy.

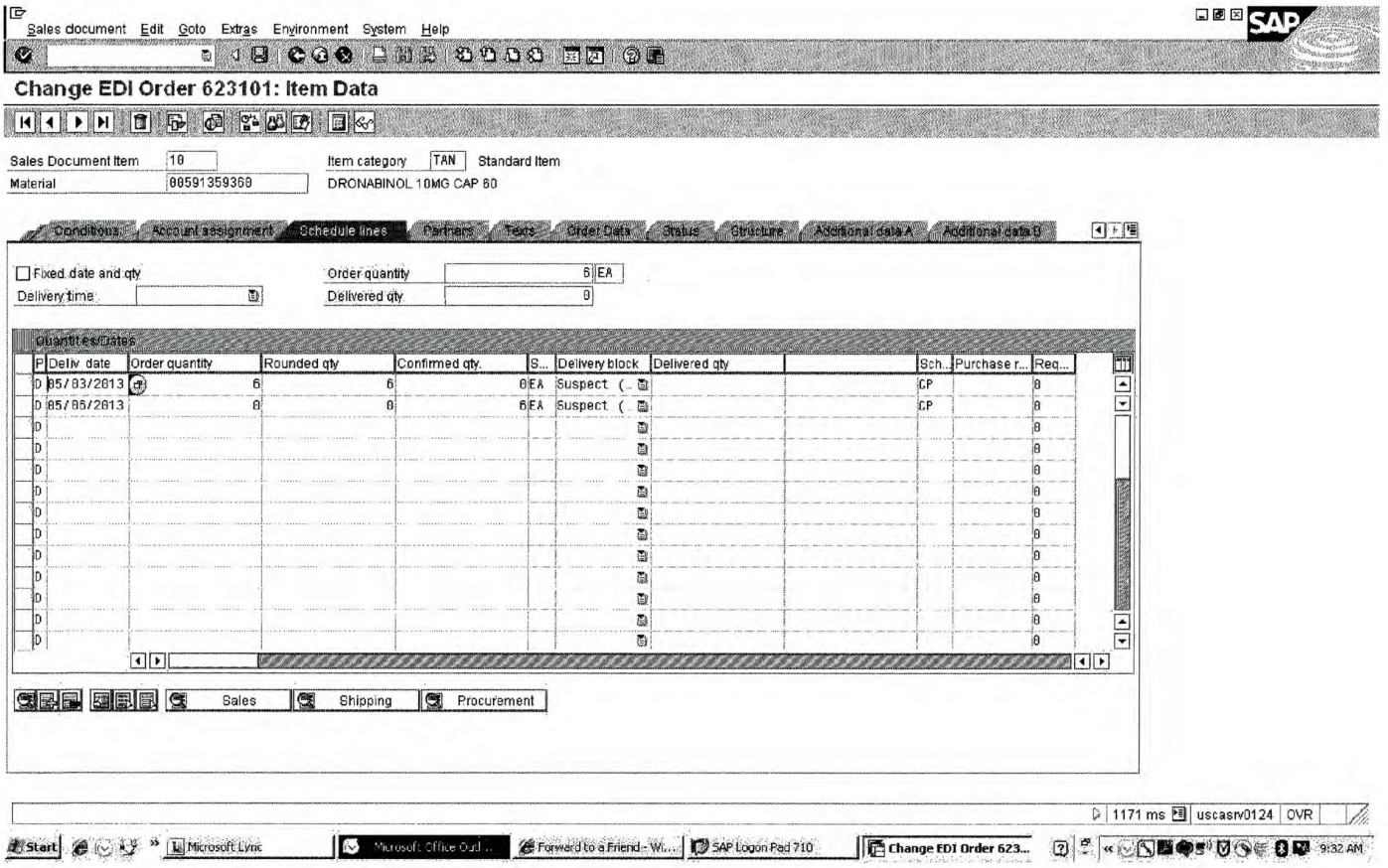
Nardo

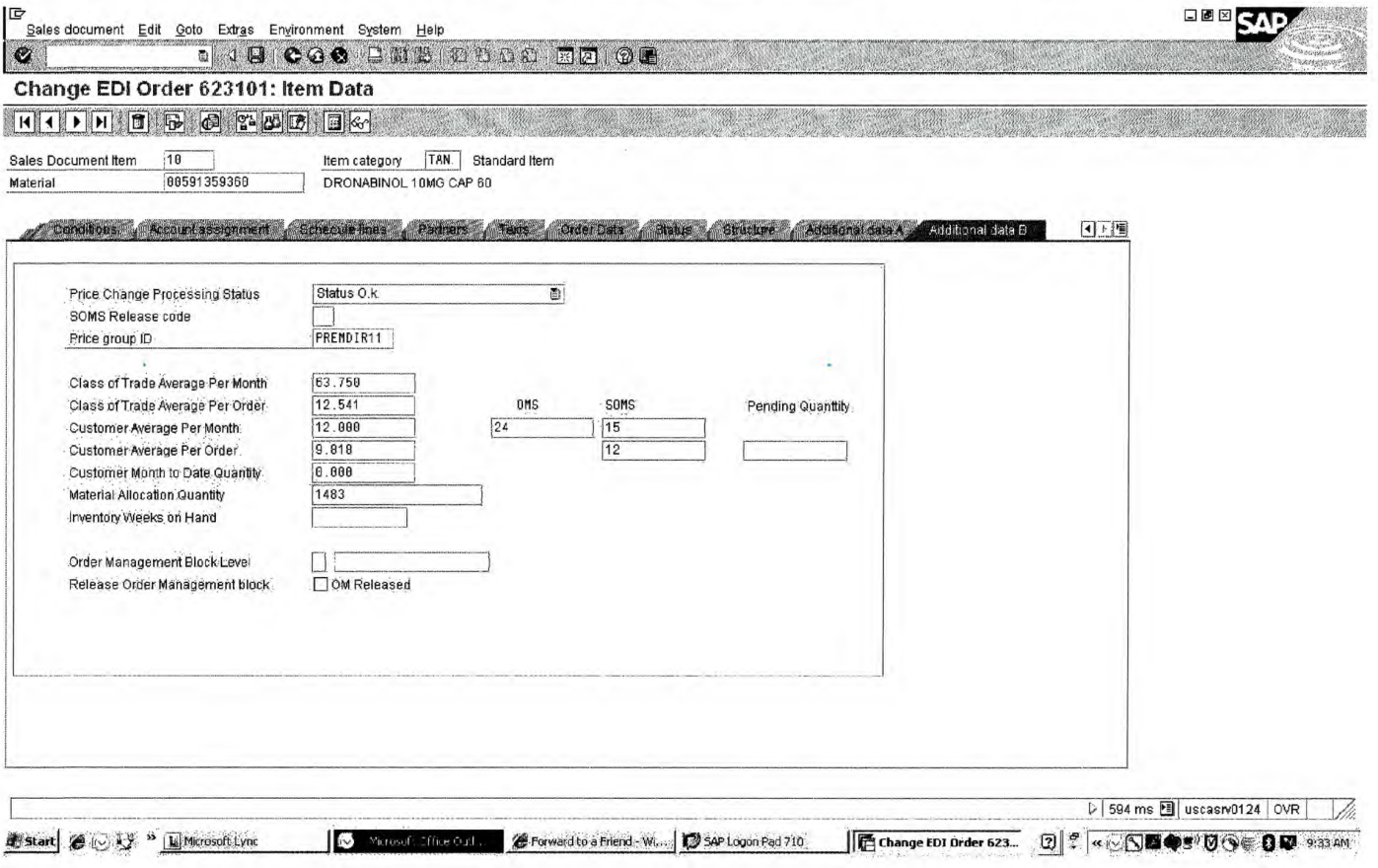
From: Sandra I Simmons
Sent: Monday, May 06, 2013 6:34 AM
To: Nardo B Catahan
Subject: FW: SOMS Table - Effective May 1, 2013

Can you please check this for me when you can a chance. The multiplier was change to 2.

Checking the data on SO # 623101 line 10. Customer ordered a quantity of 6 the, line is on SOMS block and I don't think it should be if the multiplier is 2.

Thanks





From: Mary J Woods
Sent: Wednesday, May 01, 2013 5:27 PM
To: Tom P Napoli
Cc: Sandra I Simmons
Subject: RE: SOMS Table - Effective May 1, 2013

SO AWESOME - Thanks so much!!!! You the MAN!!!!

Best Regards,

Mary J. Woods
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From: Tom P Napoli
Sent: Wednesday, May 01, 2013 7:25 AM
To: Mary J Woods
Cc: Sandra I Simmons
Subject: RE: SOMS Table - Effective May 1, 2013

Multiplier for Chain and Wholesaler has been changed to "2"
Thanks,
Tom

From: Mary J Woods
Sent: Wednesday, May 01, 2013 12:30 AM
To: Tom P Napoli
Cc: Sandra I Simmons
Subject: RE: SOMS Table - Effective May 1, 2013

Thanks Tom. Sorry to be so anxious, the impact to the team and the volume is greatly impacting the work to the DC, and service to our customers.

Best Regards,

Mary J. Woods
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From: Tom P Napoli
Sent: Tuesday, April 30, 2013 12:21 PM
To: Mary J Woods
Cc: Sandra I Simmons
Subject: Re: SOMS Table - Effective May 1, 2013

Mary,
I have not received a response yet from Hans. As soon as I receive instruction from him I will accomplish the change in the most efficient manner possible. I will keep you posted.
Regards
Tom

From: Mary J Woods
Sent: Tuesday, April 30, 2013 03:05 PM
To: Tom P Napoli
Cc: Sandra I Simmons
Subject: SOMS Table - Effective May 1, 2013

Hey Tom - can you let me know if the SOMS multiplier table has been updated so that we are starting off May 1st with the new change in the table? It would be advantageous to have the change occur at the start of any given month so the calculations are predicated on the same calculations for the entire month. Sorry, for the highlighting, I sent in an IM, and did not realize you were off line, so I cut and pasted in an email. It won't get rid of the ridiculous highlight.

Thanks

Best Regards,

Mary J. Woods
Executive Director, US Order Management

Cegedim - Best Practices for Controlled Substance Inventory Management.htm

Friday, June 13, 2014
8:14 AM

Subject	**Emailing: Cegedim - Best Practices for Controlled Substance Inventory Management.htm**
From	Gatrad, Adil
To	Byers, Nathaniel; Khade, Pritam; Huang, Kuoyung; Cherian, George; Tang, Victor; Rich Riotto; Ray, David; Carolan, Alan; Morris, Andrienne
Cc	Woods, Mary; Kuganathan, Nadarajah; Raimondo, Raechelle
Sent	Thursday, June 12, 2014 9:28 AM

- FYI.
  Adil
-

Newsletters

Cegedim US Minute

Episode 8: How to Use Integrated Health System Data to Define and Improve Commercial Engagement Strategies

Episode 7: How to Manage Customer Relationships with Covered* Recipients Defined by the Sunshine Act

Episode 6: How to Manage Medical Device Registrations in Puerto Rico

Episode 5: How to Implement an Integra

Home > News and Events > Newsletters > US Article Archive > Best Practices for Controlled Substance Inventory Management

Best Practices for Controlled Substance Inventory Management

DEA regulations require manufacturers and distributors of controlled substances to track their inventory throughout their supply chain. Properly documenting inventories per 21 CFR Part 1304.11(e)(1)(ii) requires, for each controlled substance in the process of manufacture on the inventory date, the name of the substance and the quantity of the substance in each batch and/or stage of manufacture identified by the lot number. Here are 4 best practices you can implement to enhance your inventory management compliance programs.

1. Convert paper records to electronic records.

Converting paper records to electronic files allows you to better manage information and track status of orders and distribution, leading to increased compliance. It also grants you a holistic view of all your inventory and their movement among multiple DEA registrants. There are three main options for electronic handling of controlled substance records:

- Enterprise Resource Planning systems such as SAP or Oracle work well with bar code scanners and are common in commercial manufacturing.
- Familiar tools like Excel and Access are good options for getting started on a pilot project, though, in reality, this approach is harder to sustain in the long run because it is not fully automated and requires more manual processes which can lead to errors.
- The third option is using fully automated web based software solutions. These web-based solutions have the advantage of being accessible wherever you are, often from mobile devices such as iPads or other tablet devices, and benefit from more frequent, faster software updates that continuously optimize the solution.

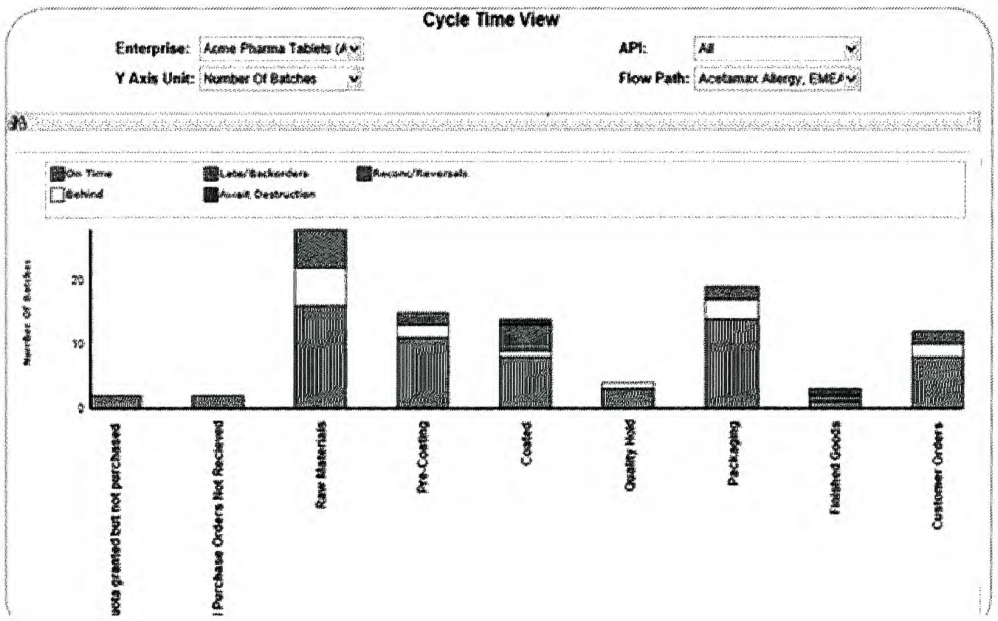
2. Consolidate multiple data sources into a single dashboard.

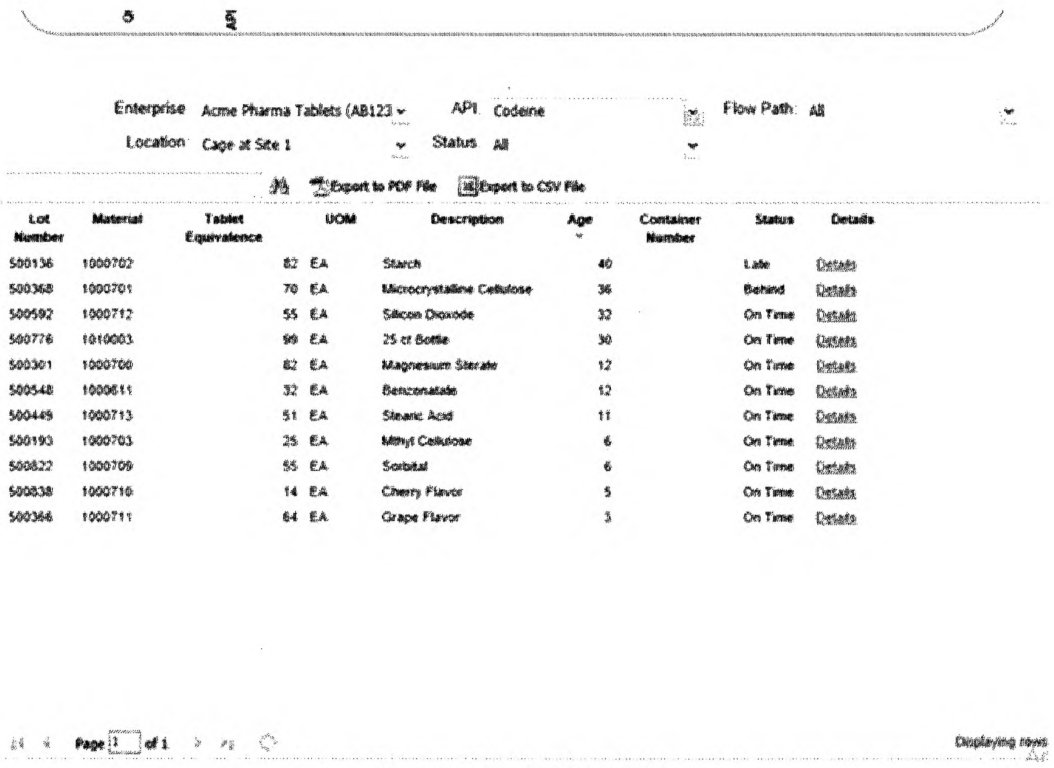
In order to properly manage your controlled substances inventory and your DEA compliance, you need a complete picture of all your controlled substance inventory data. Unfortunately, most companies do not track all of their controlled substance inventory in a single system. This is a particularly common challenge at companies with multiple DEA registrants: commercial manufacturing might be in SAP or Oracle, Analytical Labs might be using a Laboratory Information Management System (LIMS), while product development or R&D might be tracking inventory in Excel or even on paper. Trying to manually combine information from these multiple systems is time-consuming, could lead to potential mistakes and risky compliance issues.

The best practice is to consolidate the data from these multiple systems into one dashboard, allowing you to see where each product is across the entire business. Web based software solutions can offer this ability to consolidate data into a single dashboard. Typically, these systems automatically pull data from SAP, Oracle, Excel, Access, and LIMS, plus sources such as, Documentation Management and Manufacturing Execution Systems (MES). This automation saves times, prevents mistakes, and reduces the risk of DEA compliance issues.

3. Create real time visibility.

Having real time visibility into your controlled substances inventory allows you to see problems and act quickly when something goes wrong, thus enhancing your compliance. An ideal system will provide you with alerts to prevent either excessive inventories or shortfalls in API availability. With real-time visibility, you and your colleagues can see the location and status of your controlled substance inventory, and each group that touches the inventory can get instant reporting via so you can increase accountability across your locations. This is particually helpful when you extend visibility to R&D, product development, samples, and analytical labs.

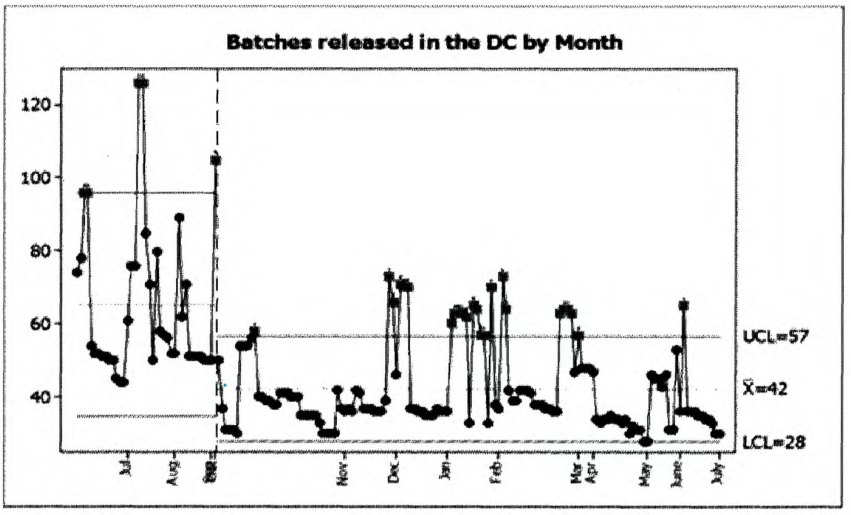




4. Accelerate decisions and tracking.

With these best practices in place, your company wil be able to measure how fast your controlled substances are moving through your locations (often called "cycle times") and identify areas for improvement. Reduced cycle times will not only eliminate reporting delays but will accelerate reconciliation investigations and reduce the time required to prepare reports. This will allow you to raise the bar on expectations and accountability and find the right balance among inventory levels, customer demand, costs, and cycle times through the supply chain.

Example of measured and reduced cycle time:



The ideal solution

In summary, the ideal solution for controlled substance inventory management will create a consolidated, accurate, electronic, real-time view of your company's entire controlled substance inventory. This will allow you to not only enhance your DEA compliance by ensuring accuracy, but it will minimize inefficient supply chain shortages or overages and optimize controlled substance inventory levels from laboratories to manufacturing to delivery.

BuzzeoPDMA has recently partnered with software provider Invistics to offer this solution. This web-based software:

- converts paper records to electronic records
- consolidates data sources ito a single dashboard
- creates real time visibility, and
- accelerates decisions and tracking.

To learn more about how our joint solution can help optimize your controlled substances inventory management, please contact compliance@cegedim.com

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A Case for 8

Resource Center

9/9/ 14 DEA Releases Final Prescription Drug Disposal Regulations

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Important Hotel Information for NASCSA's Upcoming Annual Conference

NASCSA's reduced room rate at the Desoto Hilton Hotel in Savannah, Georgia is now sold out, however there is still limited availability. Attendees may have to pay a higher room rate per night.

We have identified several nearby hotels within a short distance that attendees can contact which are listed below:

Country Inn By Carlson, Savannah
320 Montgomery Street, Savannah, Georgia, 31401, USA
(912) 921-5300
www.countryinns.com/savannahga_historic
0.4 MILES

Courtyard By Marriott Savannah/Historic District
415 West Liberty Street
Savannah, Georgia 31401
P: 912-790-8287
www.courtyard.com/SAVDT
0.3 miles

SpringHill Suites Savannah Historic District
150 Montgomery St
Savannah, GA 31401
(912) 629-5300
www.marriott.com
0.5 miles

Expansion of drug take-back program coming next month, DEA announces
An expansion of the Drug Enforcement Administration's prescription drug take-back program, expected to take effect Oct. 9, would allow pharmacies and hospitals to accept returns of unused medications, including opioid painkillers. The new policy, announced by Attorney General Eric Holder, is part of an effort to stem the growth of prescription drug abuse. USA Today (9/8), The New York Times (tiered subscription model) (9/9) **Share:**

DEA Releases Final Prescription Drug Disposal Regulations

Yesterday the U. S. Drug Enforcement Administration's (DEA's) released its Final Rule for the Disposal of Controlled Substances, which implements the Secure and Responsible Drug Disposal Act of 2010,was made available online for preview by the Federal Register at https://s3.amazonaws.com/public-inspection.federalregister.gov/2014-20926.pdf. The Act, in an effort to curtail the prescription drug abuse epidemic, authorized DEA to develop and implement regulations that outline methods to transfer unused or unwanted pharmaceutical controlled substances to authorized collectors for the purpose of disposal. The Act also permits long-term-care facilities to do the same on behalf of residents or former residents of their facilities. The Final Rule will be officially published tomorrow and will take effect on October 9.

Prior to the passage of the Act, the Controlled Substances Act made no legal provisions for patients to rid themselves of unwanted pharmaceutical controlled substances except to give them to law enforcement, and banned pharmacies, doctors' offices, and hospitals from accepting them. Most people flushed their unused drugs down the toilet, threw them in the trash, or kept them in the house hold medicine cabinet.

Unused medications in homes create a public health and safety concern, because they are highly susceptible to accidental ingestion, theft, misuse, and abuse. Almost twice as many Americans (6.8 million) currently abuse pharmaceutical controlled substances than the number of those using cocaine, hallucinogens, heroin, and inhalants combined, according to the 2012 National Survey on Drug Use and

Health. Nearly 110 Americans die every day from drug-related overdoses, and about half of those overdoses are related to opioids, a class of drug that includes prescription painkillers and heroin. More than two-thirds (70 percent) of people who misuse prescription painkillers for the first time report obtaining the drugs from friends or relatives, including from the home medicine cabinet.
As a temporary measure, DEA began hosting National Prescription Drug Take-Back events in September 2010. Since then, the DEA has sponsored eight take-back days. Enormous public participation in those events resulted in the collection of more than 4.1 million pounds (over 2,100 tons) of medication at over 6,000 sites manned by law enforcement partners throughout all 50 states, the District of Columbia, and several U.S. territories.

The Final Rule authorizes certain DEA registrants (manufacturers, distributors, **reverse distributors,** narcotic treatment programs, retail pharmacies, and hospitals/clinics with an on-site pharmacy) to modify their registration with the DEA to become authorized collectors.

- All collectors may operate a collection receptacle at their registered location, **and collectors with an on-site means of destruction may operate a mail-back program.**
- Retail pharmacies and hospitals/clinics with an on-site pharmacy may operate collection receptacles at long-term care facilities.
- The public may find authorized collectors in their communities by calling the DEA Office of Diversion Control's Registration Call Center at 1-800-882-9539.
- Law enforcement continues to have autonomy with respect to how they collect pharmaceutical controlled substances from ultimate users, including holding take-back events. Any person or entity-DEA registrant or non-registrant-may partner with law enforcement to conduct take-back events.
- Patients also may continue to utilize the guidelines for the disposal of pharmaceutical controlled substances listed by the Food and Drug Administration on their website at http://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingOver-the-CounterMedicines/ucm107163.pdf.
- Any method of disposal that was valid prior to these new regulations being implemented continues to be valid.
The Final Rule is available at www.regulations.gov. It will also be available for viewing today on the DEA website at http://www.deadiversion.usdoj.gov.

Copy of the Federal Register regulation is filed in N:Drive under Returns Vendor/ Drug Disposal

Drug Disposal Links

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DEA Registrant Drug Disposal

Disposal of Controlled Substances; Final Rule (PDF) (September 9, 2014)
Letter to Registrants regarding Disposal of Controlled Substances; Final Rule (PDF) (September 9, 2014)
Registration for Disposal of Controlled Substances

- Modify eligible DEA registration to become a collector of unwanted pharmaceutical controlled substances
- Modify DEA registration to stop being a collector
- Modify existing collector registration information

Drug Disposal Fact Sheets

Disposal Regulations: Registrant Fact Sheet (PDF)
Disposal Act: General Public Fact Sheet (PDF)
Disposal Act: Long Term Care Facility Fact Sheet (PDF)

Non-DEA Registrant (General Public) Drug Disposal

Got Drugs? - National Prescription Drug Take-Back Day
FDA – How to Dispose of Unused Medicines (PDF)
FDA – Disposal of Unused Medicines
EPA – How to Dispose of Medicines Properly (PDF)
EPA – Disposal of Medical Sharps

Drug Disposal - Rulemaking

Secure & Responsible Drug Disposal Act of 2010 (PDF)
Public Meeting on Drug Disposal
Advance Notice of Proposed Rulemaking (ANPRM)
ANPRM Comments
Notice of Proposed Rulemaking (NPRM)
NPRM Comments

Pasted from <http://www.deadiversion.usdoj.gov/drug_disposal/index.html>