

Message

From: Nancy Baran [/O=ONETEAM/OU=FIRST ADMINISTRATIVE GROUP/CN=RECIPIENTS/CN=NBARAN]
Sent: 4/25/2012 4:12:27 PM
To: John Duff [/O=ONETEAM/OU=FIRST ADMINISTRATIVE GROUP/CN=RECIPIENTS/CN=JDUFF]; Kelly Smith [/O=ONETEAM/OU=FIRST ADMINISTRATIVE GROUP/CN=RECIPIENTS/CN=KSMITH]; Umesh Solanki [/O=ONETEAM/OU=FIRST ADMINISTRATIVE GROUP/CN=RECIPIENTS/CN=USOLANKI]; Rachelle Galant [/O=ONETEAM/OU=FIRST ADMINISTRATIVE GROUP/CN=RECIPIENTS/CN=RGALANT]; John LaRocca [/O=ONETEAM/OU=FIRST ADMINISTRATIVE GROUP/CN=RECIPIENTS/CN=JLAROCCA]; Michael Perfetto [/O=ONETEAM/OU=FIRST ADMINISTRATIVE GROUP/CN=RECIPIENTS/CN=MPERFETTO]; Michael Clarke [/O=ONETEAM/OU=FIRST ADMINISTRATIVE GROUP/CN=RECIPIENTS/CN=MCLARKE]
CC: Chris Young [/O=ONETEAM/OU=FIRST ADMINISTRATIVE GROUP/CN=RECIPIENTS/CN=CYOUNG]
Subject: FW: SOM Project Team Status/Upcoming Steering Committee Meeting

Although I have not published official minutes due to travel over the past 2 weeks, the project team has met on two occasions. Our meeting this afternoon was cancelled and will be rescheduled in the very near future. In the meantime, an outline of our current status and future direction can be found below:

➤ Compliance Agreement

- Compliance form has been finalized.
- List of all customers purchasing controlled drugs – (Complete – Nancy, Ara, Umesh)
- Kelly compiled the majority of all CEO contact names and provided to Nancy and John D.
- Nancy is reviewing with Sales – fill in any blanks and validating information (Due Date – May 1)
- John Duff/Paralegal support - working on filling in the “designated party.”
- Michael and/or John – working on a cover letter to accompany the compliance agreement
- Target date to have all letters mailed – on or before May 2nd meeting

➤ Direct and Indirect SOP's and Flow Chart

- Indirect SOP completed during 4/17 meeting. Plan is to give it a once over at next meeting at which time it will be considered complete.
- Flow Chart Process – to be continued during 4/25 meeting. Significant process has been made to date.
- Direct SOP – to be revisited and finalized by 5/2
- Site Survey has been finalized and will be modified as needed after being put into use.
- DEA reporting documents have been prepared – pending final review at which time, they will be considered complete.

➤ Cegedim conference

- Nancy and Kelly scheduled to attend conference from 4/18-4/20. Industry knowledge to be shared during next team meeting. In the meantime, a few points of confirmation/validation were received:

- ✓ Our SOM programs are accurately pending (holding) complete orders (all controlled drug lines) in the event 1 or more lines have attributes worthy on review = orders of interest.
- ✓ We are absolutely on the right track with our Indirect SOM initiative (also referred to as knowing your customers customer). The same question was asked repeatedly by manufacturers. Will manufacturers be held accountable for who their customers are selling to? The answer was yes. Purdue is currently



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the only pharmaceutical company with programs monitoring indirect sales. We were advised that Actavis is the only other manufacturer that has begun such an initiative. Therefore, we are on the right track. We have a plan in place – all we need to do now is to execute.

- ✓ Watson is currently in the process of contracting with Cegedim to implement a new or enhanced SOM process.
- ✓

➤ **Steering committee meeting – tentatively scheduled for Thursday, May 10th at 3:00pm (subject to availability).**

Tentative Agenda – *(one hour presentation – with 30 minutes for questions/discussion)*

- High level SOM Process Flow
 1. Steering Committee Role
 2. Legal/Regulatory Role
 3. DEA Intelligence
 4. SOM Direct business – Order Monitoring
 5. SOM Indirect business – Knowing your customer’s customer

- Know-Your-Customer Initiative
 1. Use of Compliance Agreements to validate and record customer efforts/programs related to SOM
 2. Overview of Site Survey and Site Visit Process – plans for 2012
 3. Customer license verification overview
 4. New customer process/customer termination process

- Direct SOM Process
 1. Process Flow
 2. SOP to support process
 3. Resource requirements
 4. Enhanced SOM model – statistics & sample reporting
 5. DEA Reporting process

- Indirect SOM Process
 1. Process Flow
 2. SOP to support process

- Miscellaneous
 1. Resource requirements – proposal
 2. Record-keeping
 3. Upcoming DEA visit
 4. Questions –general discussion.
 5. EXECUTE TO PLAN!

From: Nancy Baran
Sent: Friday, March 30, 2012 5:37 PM
To: Rachelle Galant; John Duff; Umesh Solanki; Kelly Smith; John LaRocca; Michael Clarke; Michael Perfetto
Cc: Ara Aprahamian RPh; Jinping McCormick
Subject: FW: Recap of SOM Meeting on Wednesday, March 21

*Minutes of 3/28/12 Weekly SOM Meeting –
In attendance: Nancy Baran, Rachelle Galant & Umesh Solanki*

Compliance Agreement Forms/Process –

- The content of the Compliance Agreement Form is still under review. Michael reviewed the form and provided some cosmetic changes prior to the meeting (see attached). Michael agrees that an appropriate customer letter to accompany this compliance agreement needs to be drafted. The letter should be narrow in focus, only dealing with the appropriate handling and distribution of our products, in accordance with DEA, FDA and state law prescribing requirements.
 - Compliance Agreement needs to be finalized. *(Owners – John & Michael with input from Beth? – to be confirmed. Can we complete by next meeting-: April 4th?)*
 - Cover letter to accompany agreement needs to be drafted *(same as above)*

- Michael suggests that we do not attempt to draw too broad a letter that opens up much of the general customer relationship. He suggests that we focus on this key risk area. If the rest of the team has no issue with this, we will proceed forward with plans on distributing a compliance agreement solely for confirming SOM compliance.
 - We need to designate a resource to research and document the appropriate CEO and “Notice Party” individuals.
 - Finalize comprehensive list of customers purchasing controls (combining list provided by Ara and IT – understanding is that it will include both direct and indirect). *(Nancy – to be complete by next meeting: April 4th)*

- *Carry-over from prior meeting as we didn't have the proper audience for discussion -*
Buying groups – there may need to be a provision within these contracts stating that Actavis has the right to discontinue sales to any individual member if they do not meet the requirements set forth in the compliance agreement.
 - Legal and Contracts team will need to agree upon our approach to buying groups. *Owner – TBD*
 - Legal and Contracts team will need to agree upon language to be included in all contracts supporting our SOM requirements (yearly signed compliance form & ability to visit customer locations to review/audit such processes as needed).

Know-your customer –

- Attached is a copy of the current **Customer Questionnaire Form** to be used to guide discussions and capture information during site visits.
 - DEA Log pending - used to record all suspicious order activity to the DEA (including the Actavis employee, initial phone contact information of DEA representative—who, when & results along with a record of the written communication/certified mailing). *(owner – Kelly Smith)*
 - Team to review the attached SOM Site Visit Questionnaire and provide final comments/remarks at next meeting. The goal would be to finalize this form at next meeting *(Owner – Project team, due April 4th)*
 - Site Visit/Tour is being planned with Cardinal to take place in late April/early May. Date is TBD. Doug Plassche is Elizabeth lead. *(Owner – Nancy is working with the customer to schedule and coordinate timing)*

DEA visit – *no change since last meeting (we will keep open in minutes for visibility)*

- Kelly has reached out to the DEA and let them know we are interested in meeting with them. Once Kelly hears back, she will continue to coordinate the visit as discussed previously.

- Participants targeted for this visit are Kelly, Michael, Chris & Nancy.

Indirect SOM Process –

- A copy of the updated Indirect SOM SOP is attached.
 - Review Indirect SOP in advance of our meeting on 4/4 (project team)
 - Target date for direct/indirect process flow completion – April 23

Direct SOM Process –

- Nancy & Rachelle worked together reviewing sample pending orders. This will continue to provide us with better confirmation regarding the various scenarios, complexity of each and time required to investigate.

Agenda for next meeting – (Wednesday, April 4th)

- 1) Review open items outlined above.
- 2) Finalize the updated Customer Questionnaire form.
- 3) Continue the review of our Indirect & Direct SOP's – work on charting out the process flow.
- 4) Nancy will provide an update on SOM Direct Production/Parallel testing – statistics.