
From: Napoli, Thomas
Sent: Wednesday, January 06, 2016 11:30 AM
To: Baran, Nancy
Cc: Woods, Mary; Simmons, William
Subject: RE: SOMS

Hi Nancy,
Teva has a proprietary automated system and will not be utilizing the cloud based solution. Allergan will be outsourcing CS distribution to UPS, who will be handling SOM. Therefore, the decision was made to discontinue the system upgrade project. I hope that this clarifies.
Thanks
Tom

From: Baran, Nancy
Sent: Wednesday, January 06, 2016 2:27 PM
To: Napoli, Thomas; Simmons, Sandra
Cc: Simmons, William; Lepore, Victoria; Woods, Mary
Subject: RE: SOMS

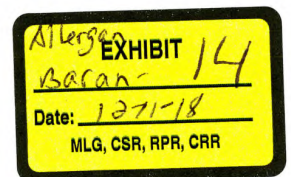
Thanks everyone for being so responsive. I think the one set of documents that I may still be missing are all the documents for the new program – requirement documents, test documents, etc..... so we can leverage these moving forward.

Nancy Baran
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From: Napoli, Thomas
Sent: Wednesday, January 06, 2016 1:28 PM
To: Simmons, Sandra
Cc: Simmons, William; Lepore, Victoria; Baran, Nancy; Woods, Mary
Subject: RE: SOMS

Hi Sandra,
I have attached a policy that is routing in Livelink that may be helpful as well as a process flow.
Thanks
Tom



From: Simmons, Sandra
Sent: Wednesday, January 06, 2016 12:31 PM
To: Lepore, Victoria; Baran, Nancy; Woods, Mary
Cc: Napoli, Thomas; Simmons, William
Subject: RE: SOMS

Hi Nancy,

I also copied Tom and Will for their comments.

Thanks

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From: Lepore, Victoria
Sent: Wednesday, January 06, 2016 12:01 PM
To: Baran, Nancy; Woods, Mary; Simmons, Sandra
Cc: Lepore, Victoria
Subject: RE: SOMS

Hi Nancy,

This is what we have in our License OPD which talks about the SOMS process. Let me know if you need the OPD. Thanks!

SOMS – Suspicious Order Monitoring System (Of Control Drugs Substances)

The Master Data Administrator (MDA) will be responsible to ensure that pending sales orders on hold due to suspicious order violations (SOMS) are investigated. The MDA will execute VA05 to determine the value and priority of the orders blocked due to SOMS violations. A MDA will print the SOMS form in a PDF file. The SOMS form contains Class of Trade (COT) averages and customer allowable/order and customer allowable/month. NOTE: A SOMS form **should not** be re- printed in the next month for a SOMS form printed from a previous month. Column values only show the current month and will no longer show the previous month's values when printed later and will not be accurate to properly evaluation an order.

The MDA will review the SOMS form to determine if customer contact is necessary. If customer contact is necessary, the MDA will contact the customer. If necessary, the customer contact information can be obtained from the CRA responsible for the account. The MDA will contact the customer to determine if the order should be considered an 'order of interest'. If the customer decides to cancel or reduce the quantity, they will need to provide a reason for the reduction or cancellation. All orders that require additional analysis should be communicated to the appropriate CRA and CRA Manager.

The following procedure is used to identify if the order is at or over the allowance Actavis gives the customer which will assist in determining the degree of analysis needed to release the order. Each order is evaluated and the best release code is applied to each order at that time.

Put the number that's in the "Order Quantity" column into the "Release Qty" column. Then, mathematically ADD the following columns "MTD Qty" plus the "Release Qty" to give you a total order quantity to date.

- The 'Pending Qty' column on the SOMS form shows other orders (not the one currently being viewed) that are on SOMS block for the same customer and product. This is to make the MDA aware of other order quantities in the system. The MDA should take the 'Pending Qty' into consideration when completing the analysis of the current order (the one being viewed).
- When releasing the order the MDA will use the most appropriate reason code for each order.
- If the "MTD Qty" plus the "Release Qty" is equal to or less than the "Customer allow/mth", then customer contact is not required.
- If the "MTD Qty" plus the "Release Qty" is greater than the "Customer Allow/mth", then further analysis is needed and SOMS form will need 2nd signature from management.

Some of the tools used during analysis:

- Current month call log.
 - 852 & 867 data if available.
 - Past shipping history; Year over Year (YOY) or Year to Date (YTD) comparison.
 - Contact internal departments (i.e. Marketing, Demand Management, and CRA) to verify if they had information to assist in the analysis (i.e. Updated forecast, special orders, short-date, etc...).
 - Customer contact.
 - Hana Report
- When contacting the customer via email, the following verbiage should be used.
 - Subject: "*Company Name*" Order(s) on Hold
 - Body of email:
 - *Hi (Addressee(s)), 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 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.*
 - *PO#*
 - *NDC#, Mat#, QTY*
 - *Please note the entire order is on hold. Your quick response will ensure your entire order will be released in a timely manner.*

Salutation

- The 'Release Qty' column on the SOMS form will need to be filled in by the MDA; this is the quantity that the MDA releases. Usually the 'Release Qty' is the same as the 'Order Qty', unless the customer requests to cancel the order or the MDA cancels the order with Management approval because the customer did not respond to the email sent by Master Data. ..
- If the customer decides to cancel the order, the MDA will request a reason for the cancellation of the order. Also, depending on the cancellation reason the MDA may forward the cancellation request to DEA Affairs for review. Please note: For IMA customers, if an increase is requested by the customer, the customer would need to be referred to the customer's CRA to have that request completed, and the increased order quantity will go through IMA again. (IMA stands for Inventory Management Agreement, IMA customers are customers that have agreed to share confidential sales activity with Actavis in order to streamline their inventory.)

- If the customer is contacted, the MDA will attach supporting documentation to the SOMS form which will include the customer contact name, phone number and/or email, reason for the increase, PO#, SD#, and date of order, and the SKU/Material number and description of the product released. If the same SKU/Material suspends again in the same month, the MDA will determine if the original resolution is appropriate for subsequent orders or if further analysis is needed.
- If the customer decides to cancel the order, then the order may come off of SOMS violation. The MDA will need to execute the VA05 again to verify the order is not on the VA05 list.
- The MDA group should make an effort to get to know the customers and their customers. With that said, if the customer's response is a general response, i.e. increase due to new customers; it is recommended the MDA try to obtain the name, city, & state in which the new customer is located. Please know, the customer has the right to deny this request.
- The MDA will release and sign any orders that are 50 or less. These type of requests does not need management signature.
- The MDA will release and sign any order that is 50 or less on product launches or first time buys with supporting documentation attached to the SOMS form. These type of requests does not need management signature.

Once this SOMS form is confirmed and verified, the MDA will release the SOMS violation block. Otherwise, the MDA will escalate the 'order of interest' (SOMS) to the DEA Affairs department for review and feedback. If DEA Affairs determines the 'order of interest' (SOMS) needs to be communicated to the DEA. Then DEA Affairs will contact the DEA.

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From: Baran, Nancy
Sent: Wednesday, January 06, 2016 11:49 AM
To: Woods, Mary; Simmons, Sandra
Cc: Lepore, Victoria
Subject: SOMS

Can someone please send me copies of any relevant documents speaking to our SOMS process?
 I am meeting with Teva and need to be able to speak accurately to all this. While I think I can speak pretty accurately about all this important team does, I want to be sure I speak correctly in terms of the process flow, systems, etc...

Thanks,
Nancy

Nancy Baran

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