

Customer Communication for SOMS

Wednesday, June 23, 2010

5:23 PM

Subject	Customer Communication for SOMS
From	Laura Pinti
To	#Master Data Group
Cc	Mary J Woods
Sent	Wednesday, June 23, 2010 1:23 PM

Effective today, please implement the following format for all SOMS orders that require additional information from the customer:

Dear Customer:

(Merge Tom's email, into this paragraph)

Thank you for your recent control substance order. This order is currently under review. In effort to complete the review process, please take a moment to complete the following questions below that will assist us in completing the necessary review process. Your immediate response is required to expedite the order review procedure.

In accordance with CFR (Tom's paragraph)

Reason For Increase: (Detailed explanation please)

New Contract:

1. Name of Customer
2. Identify affected products on order.

Promotion:

1. Timeline of promotion ?
2. Identify affected product on order?

New Customers:

1. What is the name of the new customer?
2. What is the class of trade of the new customer?
3. What is the location (if multiple, primary location) of the new customer?
4. Who was the new customer's previous supplier?
5. Does the new customer order products that are not controlled substances?

Adding Product to Product Line:

1. Identify affected product(s) on order?

Other Reason: (Detailed explanation please)

Please contact me direct with any questions that you may have.

Tie the 852 data to suspicious order monitoring.

Meeting - July 20, 2010 - Mary, Sandy, Tom, Lisa

1. Keep the paragraph at the top with the highlighted area.
2. Include the PO, product description, NDC, and qty ordered will be supplied



3. Create a form to send to the customer.
4. Sandy to have a member of her team check the PA report and send the market shortage issues to Tom and Lisa monthly
5. Have a preliminary set of questions documented on the form
6. Have a secondary set of questions, if we need to go back.
7. ~~Sandy supply New Account Procedure to Lisa~~
8. CSOP001-004 revisions by Lisa, Sandy will make changes, Mary, Tom, Molly (check the changes to make on the OPD's)
9. Change the OPD's that are affected by the CSOP001-004
10. ~~Tom supply verbiage for SOMS response to customer~~

Tom's Verbiage

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.

SOMs Agreement

Wednesday, June 23, 2010
10:31 PM

Subject	SOMs Agreement
From	Lisa A Scott
To	Victoria Lepore; Larry E Shaffer
Cc	Mary J Woods; Laura Pinti; Tom P Napoli; Lynn DaCunha; Ione M Graziosi
Sent	Wednesday, June 23, 2010 9:34 AM

FYI

As discussed during our 11:00 am EST meeting today, we have come to the following agreement.

Any order placed on June 21, 22 or 23 by ABC, Cardinal, McKesson or HD Smith that is held by the system pending on SOMs review, will not require customer contact for order justification and DEA Affairs review. These orders may be released.

This agreement applies specifically to these customers and order dates only.

Thank you.

Lisa Scott

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Office: 973.355.8265

RE: SOMS Table

Wednesday, June 23, 2010
10:50 PM

Subject	RE: SOMS Table
From	Larry E Shaffer
To	Mary J Woods; Laura Pinti; #Master Data Group
Cc	Judy L Callahan
Sent	Wednesday, June 23, 2010 5:39 AM

I just wanted to make mention that the multipliers they put in place the other day are lower than the multipliers we started SOMS with in 2004.

COT	STARTED WITH	CHANGED	RECENT (2010)	6/24/2010
CHAIN	3	6	1.5	3
DISTRIBUTOR	1.5	3	1.25	1.25
MAILORDER	1.5	3	1.25	1.25
MANUFACTURE	1.5	3	1.25	1.25
WHOLESALE	1.5	3	1.25	2

From: Mary J Woods
Sent: Tuesday, June 22, 2010 6:24 PM
To: Laura Pinti; Victoria Lepore; Larry E Shaffer; Mary Moskello; Lisa A Scott; Tom P Napoli
Cc: Sandra I Simmons; Judy L Callahan
Subject: SOMS Table

MD Team,
I did speak with Tom Napoli this afternoon regarding the amount of Order Pends based on the adjustments made to the table. He does feel that we can adjust for "COT Whsl." that based on the monitoring systems in place, and the extreme change we made, we can adjust to a multiplier of 2 vs. 1.25. He will have to make this change as soon as she comes in on Wednesday AM.
Tom, Thanks for the feedback. If I can take care of ASAP in the AM, this will show immediate progression for Wednesday's order validation process. Thank You.
Please let me know if you have any questions.
Thanks to this entire team for the effort and diligence this program relies on.
Best Regards,

Mary J. Woods
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