

Message

From: Michael Clarke [/O=ONETEAM/OU=FIRST ADMINISTRATIVE GROUP/CN=RECIPIENTS/CN=MCLARKE]
Sent: 9/25/2012 7:40:53 AM
To: Nancy Baran [/O=ONETEAM/OU=FIRST ADMINISTRATIVE GROUP/CN=RECIPIENTS/CN=NBARAN]; John Kaldes [/O=ONETEAM/OU=FIRST ADMINISTRATIVE GROUP/CN=RECIPIENTS/CN=JKALDES]; John Duff [/O=ONETEAM/OU=FIRST ADMINISTRATIVE GROUP/CN=RECIPIENTS/CN=JDUFF]; John LaRocca [/O=ONETEAM/OU=FIRST ADMINISTRATIVE GROUP/CN=RECIPIENTS/CN=JLAROCCA]; Rachelle Galant [/O=ONETEAM/OU=FIRST ADMINISTRATIVE GROUP/CN=RECIPIENTS/CN=RGALANT]; Michael Perfetto [/O=ONETEAM/OU=FIRST ADMINISTRATIVE GROUP/CN=RECIPIENTS/CN=MPERFETTO]
CC: Doug Plassche [/O=ONETEAM/OU=FIRST ADMINISTRATIVE GROUP/CN=RECIPIENTS/CN=DPLASSCHE]; Jason Chung [/O=ONETEAM/OU=FIRST ADMINISTRATIVE GROUP/CN=RECIPIENTS/CN=JCHUNG]
Subject: SOM meeting
Importance: High

Team,

This email will serve as my follow-up notes memorializing our September 24th SOM meeting:

1. Status of SOM direct and indirect process:
 - a. The internal team received training last week and has been monitoring direct customer orders. The expectation is that the process will go “live” between October 15 and 20.
 - b. The indirect process will include phone calls and visits to distributor customers, likely AmerisourceBergen and Walgreens, to discuss the DEA’s concerns about prescription drug diversion and our customers’ role in addressing those concerns. The discussions will include an overview of our indirect SOM process and the need for some level of secondary sales or distribution information from our customers about where Actavis product is going and may touch on termination of orders that cannot be justified as legitimate. Participants will be Clarke, Baran and possibly LaRocca.
 - i. There will need to be an advance review of our distributor contracts to determine whether any revision will be necessary to get secondary customer information and to terminate suspicious orders.
2. Elizabeth order monitoring issue:
 - a. There was discussion about the communications and documents provided to the DEA by Omar Plaza, who was not at the meeting to discuss his role. It is not clear what direction he was working under and why any communications to DEA continued after formation of the suspicious order monitoring group in Morristown.
 - b. A subgroup will meet with Plaza when he returns from vacation to discuss what direction he was given and the justification for his recent communications to the DEA.
 - c. The direction was given that any communications to or from the DEA regarding the commercial SOM process should go through Ethics and Compliance, in Morristown, not through Elizabeth.
3. Summary of phone call with Michael Smilek of the DEA’s Newark office:
 - a. Smilek agreed that any discussions about commercial suspicious orders should go through Ethics & Compliance and I gave him my contact information again.
 - b. He wants to proceed with an October meeting and is flexible as to the date, but would like to hear back this week on proposed dates in mid or late October. The meeting will cover:
 - i. An overview of the revised Actavis SOM process;
 - ii. The existence of any new SOPs and any employee training on the new process (Nancy, we need verification of who was on the phone during last Friday’s call and who was not on the call and needs to be captured); and
 - iii. The extent of our “trail through our distributors to our actual customers (pharmacies)”
 - c. Smilek referred to the 2007 DEA letter to registrants and how the agency had been waiting to hear from recipients and is now reaching out to determine the effectiveness of their diversion control processes.
 - d. Finally, he mentioned that he wants Actavis to be “ahead of the curve,” an industry model on diversion prevention and that he needs to keep up communications on our processes in case the agency director is

summoned to the Hill for testimony or for other reasons. Part of what DEA is seeking is for us to take the lead by reducing our quota, while keeping "legitimate" sales.

Please let me know if you have any comments or revisions to these notes.

Action Items:

1. Baran to schedule calls and meetings with ABC and Walgreens to discuss SOM efforts.
2. Plassche to set up a meeting with Omar Plaza and possibly Noemi Rebeco on their suspicious order efforts and to clarify the process going forward.
3. Clarke needs feedback on when we can schedule the DEA meeting with Smilek and his team by this Thursday.
4. Clarke and LaRocca to review the distributor contracts to assess our ability to get the additional secondary customer information and the impact of terminated orders and to determine what, if any, revisions are needed.

Regards,

Michael

Michael R. Clarke
Ethics & Compliance Officer- Americas



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