

Message

From: Spaulding, Eileen L. [Eileen.Spaulding@mallinckrodt.com]
Sent: 2/9/2015 1:52:27 PM
To: Harper, Karen [Karen.Harper@mallinckrodt.com]
Subject: FW: MK201502-0251 0252 0253 Suspected Tampering Elevated Issue

FYI – John was on original email.

Eileen

From: Besing, Margaret A
Sent: Friday, February 06, 2015 4:34 PM
To: Gillies, John V; Henson, Eldon; Horger, James; Hosna, Gary; Allen, Jim M (Hobart); Spaulding, Eileen L.
Cc: Noel, Jennifer L; Clark, Angela
Subject: FW: MK201502-0251 0252 0253 Suspected Tampering Elevated Issue

All,

Please see the attached reports involving product tampering with Morphine Sulfate Oral Solution. The customer is conducting an internal investigation with help from the local authorities. Per our SOP I am elevating this to your attention. Although the customer is stating that the issue is internal, we have sent the complaints to Hobart for investigation in order to have verification that the product was released within specifications.

Please let me know if you have any questions.

Thanks,
Margie

Margaret Besing, RPh, CMQ/OE | Director, Product Monitoring
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From: Noel, Jennifer L
Sent: Friday, February 06, 2015 2:42 PM
To: Besing, Margaret A; Clark, Angela
Subject: MK201502-0251 0252 0253 Suspected Tampering Elevated Issue

MK201502-0251, MK201502-0252, MK201502-0253

Morphine Sulfate Oral Solution 20mg per mL

Lot numbers: 8003X91880, 8003X90967, 8003X90965

Notification Date: 28Jan15; delay of entry due to pharmacy not providing details of investigation until they had the suspected bottles in their possession.

Event description: Partner's Pharmacy reported suspected tampering with Morphine Sulfate Oral Solution. The pharmacy provides nursing homes with the product. A nursing home noticed moisture/wetness on the outside of a bottle. When taking a closure look they discovered a pin hole in the black lettering on the bottle. The bottle would leak from the "pin hole" when turned upside down. The pharmacy stated the local police department has a nurse under

investigation for the tampering. The bottle is required for the police investigation and will not be returned for the manufacturing investigation. This occurred with a total of three bottles (three different lot numbers).

Sample return- The bottles are required for the police investigation and will not be returned for the manufacturing investigation.

Photo- not available