

[REDACTED]

From: Shamsi, Mutahar S
Sent: Monday, December 07, 2009 7:14 PM
To: [REDACTED]
Subject: FW: DrugInfo Comment Form FDA/CDER Site

Importance: High

Could you call Samia tomorrow when you get a chance. I tried today but forgot about the 3 hour time difference.

Mutahar

-----Original Message-----

From: Nasr, Samia
Sent: Monday, December 07, 2009 4:59 PM
To: Shamsi, Mutahar S; [REDACTED]
Cc: [REDACTED]; Nasr, Samia; Anderson, Kathleen R; Shukla, Sudha
Subject: RE: DrugInfo Comment Form FDA/CDER Site

Mutahar

Please contact me regarding the firm. Thanks

Samia

Samia M. Nasr, R.Ph., M.S.
Team Leader
Division of New Drugs and Labeling Compliance
Office of Compliance, CDER, FDA
10903 New Hampshire Avenue
Silver Spring, MD 20993
Bldg 51, room 5370

[REDACTED]

-----Original Message-----

From: Shamsi, Mutahar S
Sent: Monday, December 07, 2009 4:54 PM
To: [REDACTED]
Cc: [REDACTED]; Nasr, Samia
Subject: RE: DrugInfo Comment Form FDA/CDER Site

Thanks for the info. We are waiting for an assignment from CDER to go out and will follow up on this. Ameridose has been on our radar for quite some time.

Mutahar

-----Original Message-----

From: [REDACTED]
Sent: Monday, December 07, 2009 2:03 PM
To: Shamsi, Mutahar S; [REDACTED]
Subject: FW: DrugInfo Comment Form FDA/CDER Site

[REDACTED]

Here is a string of emails regarding a firm that was inspected and some issues that have recently been brought to the attention of CDER. Have you seen this yet?

I'm around to discuss if you need anything on my end.

Thanks,

-----Original Message-----

From: [REDACTED]
Sent: Monday, December 07, 2009 1:54 PM
To: [REDACTED]
Cc: [REDACTED]
Subject: FW: DrugInfo Comment Form FDA/CDER Site

[REDACTED]

We were forwarded the anonymous complaint below regarding a company in Massachusetts known as Ameridose from FDA's Division of Drug Information. I reviewed the company's website and it looks like they provide pharmacy outsourcing services, i.e. sterile admixing services and oral syringe repackaging services. I'm assuming this complaint may make its way to NEW-DO. Can you have someone check with the District Office to inquiry about the latest inspection of this facility and if they have plans to re-inspect? AIMS was negative for Ameridose.

Thank you [REDACTED]

-----Original Message-----

From: [REDACTED]
Sent: Monday, December 07, 2009 1:24 PM
To: [REDACTED]
Subject: FW: DrugInfo Comment Form FDA/CDER Site

See below information

-----Original Message-----

From: [REDACTED]
Sent: Monday, December 07, 2009 12:43 PM
To: [REDACTED]
Subject: FW: DrugInfo Comment Form FDA/CDER Site

This is an FYI from the Division of Drug Information.

Do you have an e-mail contact for future forwards that we should be using?

[REDACTED]

-----Original Message-----

From: [REDACTED]
Sent: Wednesday, October 28, 2009 3:44 PM
To: CDER DRUG INFO
Cc: [REDACTED]
Subject: FW: DrugInfo Comment Form FDA/CDER Site

Hello,

Please send this to OCI as FYI also.

Thanks,

-----Original Message-----

From: CDER DRUG INFO
Sent: Wednesday, October 28, 2009 8:42 AM
To: CDER DNDLC PM TRACK
Subject: FW: DrugInfo Comment Form FDA/CDER Site

