

[REDACTED]

From: [REDACTED]
Sent: Wednesday, July 14, 2010 8:56 AM
To: [REDACTED]
Cc: Nasr, Samia; Anderson, Kathleen R
Subject: RE: telecon

Hi [REDACTED]

Yes, the inspection scheduled for 7/26 should be put on hold for now. I think we need to resolve the nicardipine issue with the firm first before we do a full inspection. The [REDACTED] case is still being worked on at this time as well. Depending on what we decide to do with the firm's current issue will influence how we take the next step.

Thanks,
[REDACTED]

From: [REDACTED]
Sent: Wednesday, July 14, 2010 8:45 AM
To: [REDACTED]
Cc: Nasr, Samia
Subject: RE: telecon

[REDACTED]

Two Thursdays ago Samia said that the July 26, 2010 inspection of Ameridose may be pulled back to a later date because of [REDACTED]. Can you please tell me if the inspection is going to be pulled back to a later date or cancelled?

Thanks

[REDACTED]
*Compliance Officer
New England District*

From: [REDACTED]
Sent: Tuesday, July 13, 2010 2:32 PM
To: [REDACTED]
Cc: Nasr, Samia [REDACTED]; Anderson, Kathleen R
Subject: FW: telecon

Hi [REDACTED]

Thanks for the document. Samia will be out-of-office till next Friday. We looked into the USP general chapter 621 on HPLC that Ameridose claims to use and found that it has no specific method for potency testing. [REDACTED]

Please let us know what [redacted] finds out in regards

to the [redacted] telex. Thank you

[redacted]

From: [redacted]
Sent: Tuesday, July 13, 2010 1:52 PM
To: [redacted]
Cc: [redacted]
Subject: FW: telecon

Samia,

FYI

One of the Compliance Officers received a call from an informant in Ameridose.

[redacted]
*Compliance Officer
New England District*

From: [redacted]
Sent: Tuesday, July 13, 2010 10:35 AM
To: [redacted]
Cc: [redacted]
Subject: telecon

[redacted]

Please print out the following telecon, sign for me and distribute. Thanks.

<< File: Ameridose telecon 7.13.10.doc >>

[redacted]
*Compliance Officer
New England District Office
Food and Drug Administration*
[redacted]

[redacted]

