

[REDACTED]

From: Shamsi, Mutahar S
Sent: Monday, July 19, 2010 1:27 PM
To: [REDACTED]
Subject: FW: Ameridose discussion

Mutahar

From: [REDACTED]
Sent: Monday, July 19, 2010 12:37 PM
To: Costello, Gail T; Shamsi, Mutahar S
Cc: [REDACTED]
Subject: Ameridose discussion

Gail and Mo,

To follow up on our conversation this morning, we received repeated requests for assistance from the MA State Board of Pharmacy to follow up to a trade complaint that Ameridose is compounding various Nicardipine Injection products, the complaint alleged that the firm is labeling the product with a 75 hour shelf life (or use by date) when it actually has a shelf life of 24 hours. CDER requested that we obtain stability data/test results for these products for CDER review and also attempt to collect a sample of the product. We had previously received an assignment to inspect Ameridose on 4/28/2010, this assignment was subsequently placed on hold by CDER, the current inspection is limited to following up to the trade complaint. A physical sample was not able to be obtained at the firm, however NWE-DO is trying to obtain a physical sample of the Nicardipine Injection from one of the hospitals that Ameridose compounds these products for. NWE-DO returned to the firm on 7/15/10 and collected stability data which will be forwarded to CDER for review, NWE-DO will not be issuing a 483 for this inspection per instructions received from CDER.

[REDACTED]
Director Investigations Branch
FDA New England District Office
1 Montvale Ave
Stoneham MA 02180
[REDACTED]