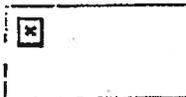


[REDACTED]

From: [REDACTED]
Sent: Monday, October 24, 2011 10:07 AM
To: Wardwell, Amber
Subject: RE: Confidential Informant Ameridose
Attachments: image001.jpg

Amber,

I just spoke with Tamera Ely from CDER. She said CDER is in the process of drafting guidance on compounding and manufacturing. She said we may start inspections the end of 2012. She said to interview the person and send the notes to her. We will not immediately follow-up but wait until the guidance is out, and then inspect as directed by CDER. She said no compounding facility is slated to be inspected in 2012.



U.S. Food and Drug Administration

[REDACTED]
Compliance Officer
New England District

From: Wardwell, Amber
Sent: Friday, October 21, 2011 11:22 AM
To: [REDACTED]
Cc: [REDACTED]
Subject: Confidential Informant Ameridose

FYI, OCI has sent over a referral for a informant at Ameridose in Westboro.

[REDACTED] please log this in as a complaint and set up an assignment (op 13 to interview)
[REDACTED] can you assist [REDACTED] with setting up the assignment Monday if necessary and can you sit in on the interview when it occurs?

Informant
Ameridose - Westboro

[REDACTED]

11/26/2012

[REDACTED]

[REDACTED]

- Alleging sales people in clean area filling product
- Continue repack "Avastatin" without FDA license

Amber Wardwell : Compliance Branch Director | New England District, USFDA | One Montvale Avenue | Stoneham, MA 02180 | p
[REDACTED]

11/26/2012