

[REDACTED]

From: [REDACTED]
Sent: Tuesday, August 17, 2010 10:42 AM
To: Nasr, Samia, [REDACTED]
Cc: [REDACTED]
Subject: RE: Ameridose complainant

Samia,

Yes, 2nd hand means he heard it from someone else which is unreliable.

Okay we will wait for the outcome of the [REDACTED] case.

[REDACTED]
*Compliance Officer
New England District*

From: Nasr, Samia
Sent: Tuesday, August 17, 2010 10:34 AM
To: [REDACTED]
Cc: [REDACTED]
Subject: RE: Ameridose complainant

Thanks [REDACTED] I am not sure about his complaint since he said that this information was second or third hand. What's this mean? he heard it from someone else? and I am wondering when he says manufacturing area, does he mean no prescriptions?

As I told you before, I like to do full inspection on Ameridose but I am waiting to see the outcome of our injunction with [REDACTED] first.

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 5174*

[REDACTED]

From: [REDACTED]
Sent: Tuesday, August 17, 2010 10:23 AM
To: [REDACTED]
Cc: [REDACTED]; Nasr, Sama; [REDACTED]
Subject: FW: Ameridose complainant

[REDACTED]

I am cc'ing this complaint to CDER.

Please do not follow-up at the firm at this time.

Thanks

[REDACTED]
Compliance Officer
New England District

From: [REDACTED]
Sent: Tuesday, August 17, 2010 8:02 AM
To: [REDACTED]
Cc: [REDACTED]
Subject: Ameridose complainant

[REDACTED]

I received a second call yesterday from a complainant at Ameridose. I initially spoke with him on 7/13/10 and understood that we may have had someone in the firm at the time. At the time, I discussed with [REDACTED] who are familiar with this firm and understood we were in recent contact with the state about this firm. I understood that FDA may not be in a position to follow-up at this time? Anyway, I wanted to make sure you had both copies of the following memos in your system. Is this information that you would also share with the state? Please let me know if you need any additional info. Thanks.

[REDACTED] any other suggestions?

<< File: Ameridose telecon 7.13.10.doc >> << File: Ameridose telecon 8.16.10.doc >>

[REDACTED]
Compliance Officer
New England District Office



MEMORANDUM OF TELECON

DATE: 8/16/10

BETWEEN: [REDACTED]

And

[REDACTED] CO, NWE-DO

SUBJECT: GMP Allegations at Ameridose, Westboro, MA

On 8/16/10 [REDACTED] called again to discuss allegations at Ameridose. He provided his cell # (b) (6) and home # (b) (6) and indicated if we had any additional questions, we can call him.

[REDACTED] he wanted to bring additional concerns to our attention. He discussed the following concerns:

- He indicated that personnel from their sales force were assisting in labeling operations in a clean room. He indicated that they had not been trained to perform such an operation. He did state that the drug product was sealed and that they received an additional QC check so he was not concerned with any serious product issues. He indicated that their firm was behind in orders and that this is why they needed additional personnel to assist in the manufacturing.
- On 8/5/10, he was aware that one of the 3 clean rooms had a positive result for mold growth. He was not sure of the location of the sample. He indicated that the room was used that day and that the managers performed a cleaning of the room in the evening. He indicated this cleaning was not documented. He stated that the following day, the firm performed another required monthly cleaning of the room. He stated that they routinely check drug products for growth and was not aware of any positive results in the product. He explained that he was concerned about the product made on that day; however, he was not sure of where the positive environmental sample was taken.
- He also indicated that when they take environmental samples, they clean the area first before taking the sample. He does not perform these operations.
- Approx 3-4 weeks ago, they were making a batch of cefazolin under the hood in a clean room. He explained that they typically manufacture 10-15 bags at a time and that sometimes one of the bags has a leak. Typically, when a bag leaks they either discard the product or they can filter the product to another bag. On this day the bag was discarded, outside of the hood into a waste / sharps container that was also located in the clean room. He stated that sometime later, a trainer observed the bag and contacted the director [REDACTED]. The contents of the bag was then refiltered into another bag and placed in inventory. He noted that

the bags have anywhere from 28-90 day shelf life. He indicated that the director, [REDACTED] was under pressure from manufacturing to make this type of decision and that he would not normally allow this.

I asked if he was aware of any complaints or illnesses related to drug products. He stated he was not aware of any, but that he would not be in a position to know this type of information. We did discuss that some of the events above, i.e., relabeling and handling positive environmental samples do occur in manufacturing operations. I asked if they had SOP's in place to handle such occurrences. He stated that he believed they did. He also stated that some of the information he provides is second or third hand but that he is still concerned.

I explained that FDA takes complaints such as his very seriously and that we would need to evaluate the information he provided. I asked if he was aware of any other issues that would cause a public health safety concern. He said no, but that he would contact us if he became aware of similar issues. I asked if he contacted any other offices such as the State of MA or the Board of Pharmacy. He stated he had not but would plan on doing so. We discussed that FDA is still seeking its jurisdiction over compounding pharmacies. He confirmed that they hold both retail and warehouse pharmacy licenses. He did confirm that he was available if we had any further questions. The telecom was then concluded.

[REDACTED]
Compliance Officer
New England District Office

Cc: [REDACTED]

MEMORANDUM OF TELECON

DATE: 7/13/10

BETWEEN: [REDACTED] at Ameridose)

And

[REDACTED] CO. NWE-DO

SUBJECT: GMP Allegations at Ameridose, Westboro, MA

On 7/8/10 [REDACTED] (no last name provided -Cell # [REDACTED]) left me a voicemail message indicating he was referred to our office by [REDACTED]. We finally spoke on the morning of 7/13/10.

[REDACTED] He explained that he recently became aware of some potential GMP issues and he wanted to bring them to our attention. He also thought that FDA was currently conducting an inspection at the plant. He stated that he was available for further discussion at the above cell number. He discussed the following concerns:

- Approx a week and a half ago, they were making a batch of succinylcholine. He explained that they pooled a number of vials to make a few batches of finished product. He stated that after a few lots, someone observed particulates in the bag. He stated that they determined the particulates to be "angel hair" and pieces of the bag itself. He stated that he was not sure if the previous lots made from the same batch were released. [REDACTED]

[REDACTED] He stated he was not directly involved with this lot, but was concerned about this product in the field.

- [REDACTED]
- [REDACTED]
- He explained that they recently limited the amount of finished product visual checks. He said they used to have a pharmacy check, a mfg check and a quality check. He stated that now, they are only routinely having QA check for the

proper label on the finished bag. He was not sure if the SOP has been changed to reflect this decreased inspection, but felt it was not right.

I explained that FDA takes complaints such as his very seriously and that we would need to evaluate the information he provided. I asked if he was aware of any other issues that would cause a public health safety concern. He said no, but that he would contact us if he became aware of similar issues. He did say he was available if we had any further questions and that we could leave a message on his voice mail and he would get back to us.

The telecom was then concluded.

[REDACTED]
Compliance Officer
New England District Office

Cc: [REDACTED]