

[REDACTED]

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From: [REDACTED]  
Sent: Wednesday, July 06, 2011 12:09 PM  
To: Blumberg, Enc  
Cc: [REDACTED]  
Subject: RE: Ameridose

Thanks. I don't think we know enough right now to know whether there are current serious problems that raise real safety issues. We'll have to make that assessment after the inspection and then act appropriately, though I agree we should have them gather what they'd need to to make seizure viable if the facts warrant.

[REDACTED]

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From: Blumberg, Enc  
Sent: Wednesday, July 06, 2011 11:39 AM  
To: [REDACTED]  
Cc: [REDACTED]  
Subject: RE: Ameridose

It is CDER's call, but if the problems are serious safety issues, why would we only issue a WL? Why not seize? (The inspectors should gather info about the viability of a seizure -- amount of articles on hand -- so it can make a decision on remedy, if necessary.)

[REDACTED]

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From: [REDACTED]  
Sent: Wednesday, July 06, 2011 10:20 AM  
To: Blumberg, Enc  
Cc: [REDACTED]  
Subject: Amendose

CDER's reasons for wanting to inspect Ameridose:

- Labeling
  - Most recently on 2/15/11, an email sent from [REDACTED] notified FDA that Ameridose was labeling IV bags that contained concentrated sodium chloride 23.4% with the statement "Caution Concentration: May Need to Dilute" The commercial product states that the product "Must Be Diluted" and under no circumstance would this product not need to be diluted. Ameridose changed the label after this incidence; however safety concerns about their labeling of other products remain.
- BUD
  - The 2010 inspection relating to Nicardipine products revealed that the firm put a BUD of 75 days. The manufactured product labeling states that "The Diluted Solution is Stable for 24 hours at room temperature." Test methods that Ameridose used with Dynalabs were sent to DPA lab for review. DPA reported back that the Dynalabs testing methods did not meet the necessary requirements to be accepted as a validated method. The sponsor of nicardipine and Ameridose has since settled amongst themselves.
  - On November 22, 2010, an inquiry from the State of California Department of Public Health notified FDA that hospital in San Diego had Succinylcholine syringes from Ameridose with a 90-day shelf life. The manufactured product labeling states that multi-dose vials are "stable for up to 14 days at room temperature without significant loss of potency."
- 797
  - Based on USP chapter 797, under the Determining BUD section, "the properties stabilized in the sterile vial for injection formulation usually cannot be expected to be carried over to the compounded or admixed preparation." Ameridose continually extends their BUDs of products for long periods of time. Based on the evaluation of the nicardipine from above, the testing method is not valid.
  - The firm has never been inspected under 797.

- Repackaging
  - Based on the 2008 inspection, Ameridose was involved in repackaging oral and injectable drug products. The 2010 inspection found the facility to repackage liquid RX and OTC drug products, however no longer repackaged tablets. The EIR states that "they use commercially available parenteral drug products to make various IV dosage products as requested by their customers."
  - The repackaging of sterile drug products would require an NDA, or prescriptions. Neither of the two currently does Ameridose possess.
- Registration and Listing
  - Ameridose is registered with FDA as a repacker; however none of their products are listed in eDRLs.
  - Also registered as a pharmacy with the state of Massachusetts and licensed in all states.
- Prescriptions
  - As stated above, Ameridose does not have patient-specific prescriptions for most of their products. The 2010 inspection revealed prescriptions only for dialysis products, but otherwise they did not have prescriptions for other products.

[REDACTED]  
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