

[REDACTED]

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**From:** Anderson, Kathleen R  
**Sent:** Saturday, January 24, 2009 7:53 AM  
**To:** Levy, Michael (CDER)  
**Cc:** Nasr, Samia; [REDACTED]  
**Subject:** Re: Ameridose Warning Letter

Yes, it appears to be a type of outsourcer, but Ameridose has several important differences.

We haven't brought new drug charges against outsourcers that are manipulating/reconstituting FDA approved drugs as a hospital pharmacy typically does and that are not making copies of FDA approved drugs.

Ameridose on the otherhand is using bulk APIs to make stock solutions of their own versions of drugs, including many that are copies of approved drugs.

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**From:** Levy, Michael  
**To:** Anderson, Kathleen R  
**Cc:** Nasr, Samia; [REDACTED]  
**Sent:** Fri Jan 23 22:21:36 2009  
**Subject:** RE: Ameridose Warning Letter

I have a few edits to these, but more important, a general question: is this a hospital outsourcer like CAPS? If so, haven't we avoided bringing new drug charges against these firms?

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**From:** Anderson, Kathleen R  
**Sent:** Friday, January 23, 2009 6:42 PM  
**To:** Levy, Michael  
**Cc:** Nasr, Samia; [REDACTED]  
**Subject:** FW: Ameridose Warning Letter

Mike - attached for your review are the Ameridose warning letter documents. Please let us know if you have any questions or concerns.

Thanks.

<< File: DRAFT WARNING LETTER NO.doc >> << File: WL Recommendation Memo.doc >>

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**From:** [REDACTED]  
**Sent:** Friday, January 09, 2009 5:20 PM  
**To:** Anderson, Kathleen R; Nasr, Samia  
**Subject:** Ameridose Warning Letter

Attached is the Ameridose, LLC Warning Letter and WL approval memo that I drafted for your review.

Attached below is DMPQ's revised Warning Letter and WL approval memo.

<< File: DMPQ Draft WL Ameridose FINAL.doc >> << File: Ameridose DMPQ Consult Memo.pdf >>

Attached below is District's Warning Letter and WL recommendation memo.

<< File: District's draft WL[1].pdf >> << File: Ameridose WL Recommendation[1].pdf >>

Thanks,

[REDACTED]

[REDACTED]