

[REDACTED]

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**From:** Saben, Alyson L  
**Sent:** Wednesday, September 02, 2009 12:11 PM  
**To:** Levy, Michael; Autor, Deborah; [REDACTED] Anderson, Kathleen R  
**Cc:** [REDACTED]; Stearn, Douglas; [REDACTED]  
**Subject:** FW: Compounding Pharmacy

Good Afternoon Mike -

As I recall from 1 or 2 recent ORA/CDER Wednesday calls, CDER was moving forward with developing a prioritized list of ongoing/open pharmacy compounding cases for which we are prepared to move forward/refresh the evidence in light of Dr. Sharfstein's decision to proceed with 503A. At that time, we discussed that CAPS, Pharmedium and Aptecure were on the short list.

Could you provide us with a status check on your current thinking and what this means for other cases such as Ameridose? Also, please let us know what OE can/might do to assist in the interim, prior to the Ad Hoc that is being planned.

Thanks so much.

Alyson L. Saben, Deputy Director  
Office of Enforcement  
15800 Crabbs Branch Way  
Rockville, MD 20855  
[REDACTED]

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**From:** Shamsi, Mutahar S  
**Sent:** Wednesday, September 02, 2009 11:52 AM  
**To:** ORA DCB Advisory Committee  
**Subject:** Compounding Pharmacy

If we have time, I'd like to discuss this today. NWE-DO spent a lot of time developing this case last year and having it "closed" for nebulous reasons is troubling. If you look this up in CMS CDER actually concurred with our rec back in Feb. So, I'm not sure what happened. This is quite frustrating since I thought we had a good WL. I've told our IB to not bother inspecting compounding pharmacies if we aren't going to act on the violations. Are you having the same experience?

Mo

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**From:** [REDACTED]  
**Sent:** Tuesday, September 01, 2009 11:27 AM  
**To:** Shamsi, Mutahar S  
**Subject:** FW: <CMS> Case # 40318 Has a Final Decision

It appears CDER closed the case. The activity notes say the WL case was put on hold due to conflicting court rulings related to Pharmacy Compounding and CDER is not proceeding with issuance of this WL because it has now been 1 year since the districts inspection of the firm.



Compliance Officer  
New England District

**From:** [Redacted]  
**Sent:** Tuesday, September 01, 2009 11:13 AM  
**To:** [Redacted]  
**Subject:** <CMS> Case # 40318 Has a Final Decision

**>> Go to CMS Case 40318**

Event List :

**The Final Decision for the Case has been set.**

<b>Case #</b> 40318	<b>Compliance Action:</b> Warning Letter	<b>Current Owner:</b> OCC
<b>Action Status:</b> Closed	<b>FDA Final Decision:</b> Disapproved	<b>CPLNC #</b> 37764
<b>Start Date:</b> 10/07/2008	<b>End Date:</b> 09/01/2009	
<b>Center Concurrence Required:</b> Yes <b>OCC Audit Program:</b> (Uncheck for ORA Direct Reference)		
<b>ORA Direct Reference:</b>		
<b>Blitz:</b>	<b>Combination Product:</b>	

<b>Firm</b>	<b>FEI #</b> 3005881167	<b>Firm Name:</b> Ameridose LLC
<b>District</b>	<b>Internal Status:</b> Closed	

<b>Team 1:</b> NWE Compliance Branch (HFR-NE240)	<b>Officer:</b> [Redacted] (Team Member)
<b>Team 2:</b> NWE Compliance Branch (HFR-NE240)	<b>Officer:</b> [Redacted] (Team Member)

**Center** **Center Name:** CDER **Internal Decision:** Concur

**Received:** 10/07/2008 **Due:** 10/29/2008 **Completed:** 02/05/2009

**Internal Status:** Completed

**Team 1:** CDER Pharmacy Compound Team (HFD-317) **Officer:** [Redacted] (Team Member)

**Team 2:** **Officer:**

<b>OCC</b>	<b>Internal Status</b> Waiting on Tasks	<b>Internal Decision:</b> No Decision
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**Type:** Requires Center Concurrence (District Generated)

<b>Received:</b> 02/06/2009	<b>Due:</b>	<b>Completed:</b>
<b>Team 1:</b> OCC Counselors - Drugs	<b>Attorney:</b> [Redacted] (Office Member)	

