

[REDACTED]

From: Levy, Michael
Sent: Wednesday, October 01, 2008 9:12 AM
To: Nasr, Samia; Anderson, Kathleen R
Subject: FW: Response letter to NECC

What is our plan with NECC? Thanks

From: Autor, Deborah
Sent: Wednesday, October 01, 2008 9:00 AM
To: Levy, Michael
Cc: Silverman, Steven
Subject: FW: Response letter to NECC

Please advise.

From: Shamsi, Mutahar S
Sent: Wednesday, October 01, 2008 8:19 AM
To: Autor, Deborah
Subject: FW: Response letter to NECC

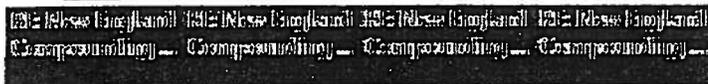
Hi Deb,

I would like to get our enforcement strategy for NECC understood. CDER sent a response to [REDACTED] but not to NECC even though there were similar issues. I'm wondering whether our lack of a response would hinder any further regulatory action against NECC (if OGC is reluctant to respond to a WL, how would they respond to an injunction request?) Shouldn't we make our position clear with NECC as we did with [REDACTED] I think we may be having a call with Samia today. Thanks.

PS [REDACTED] is the NWE-DO CO assigned to this. I've also asked OE [REDACTED] for clarification on this issue

Mo

From: Shamsi, Mutahar S
Sent: Wednesday, October 01, 2008 8:13 AM
To: [REDACTED]
Cc: [REDACTED]
Subject: RE: Response letter to NECC



I think these emails summarize our history with this response.

[REDACTED] - can you look this over and compare [REDACTED] response to that of NECC? I think they dispute the same issues

Mutahar

From: [REDACTED]

Sent: Wednesday, October 01, 2008 7:54 AM
To: Shamsi, Mutahar S
Subject: RE: Response letter to NECC

I think they had the same attorney at the beginning.

[REDACTED]
Compliance Officer
New England District

From: Shamsi, Mutahar S
Sent: Wednesday, October 01, 2008 7:49 AM
To: [REDACTED]
Subject: FW: Response letter to NECC

This is what CDER sent to [REDACTED]. I haven't had a chance to read it yet. Did they use the same lawyers as NECC? There may be a con call with Samia today. Stay tuned.

Mutahar

From: [REDACTED]
Sent: Tuesday, September 30, 2008 5:02 PM
To: Shamsi, Mutahar S
Cc: Nasr, Samia
Subject: Response letter to NECC

Hi Mo:

As per our phone conversation, attached is a scanned copy of the August 16, 2007, letter the Agency issued to [REDACTED] in reply to their Warning Letter response. Although it took seven months to issue, we did respond to them before we reinspected the firm. I believe that this letter is similar to the one issued to the other pharmacies that were part of the group of Warning Letters the Agency issued in 2006 who were involved in compounding [REDACTED] products. I am copying Samia with this e-mail and perhaps we can have a conference call to discuss the situation surrounding NECC.

Samia: do you know which attorney in OCC was assigned to reviewing NECC's response? I can contact them to see what happened to the response and believe, as does Mo, that the firm should be notified of the Agency's position before we conduct a reinspection. Let me know when you are available for a conference call and I will coordinate a call with everyone. Thanks.

[REDACTED]

<< File: Scanned WL Response JAN07.pdf >>

[REDACTED]
Compliance Officer
Division of Compliance Management and Operations
Office of Enforcement ORA

[REDACTED]