

[REDACTED]

From: [REDACTED]
Sent: Thursday, October 02, 2008 9:15 AM
To: Shamsi, Mutahar S
Subject: RE: Response letter to NECC

1. The lawyers pointed out in their 1/5/2007 response to the WL that from the end of the inspection to the issuance of the WL it took 684 days or 23 months. They also pointed out that some of the assertions (violations) no longer apply to NECC's operation, for example they no longer make trypan blue or 20% aminolevulinic acid. They also pointed out that FDA did not follow its WL procedures.
2. We received a response to the WL from the firm on 1/5/2007. We have not responded to the firm. Its been 1 year and 10 months since we received the response. It appears CDER and OCC cannot agree on a response to the firm.
3. If we re-inspect there is no second WL. Next step is to enjoin the firm. Have we given the firm the chance to voluntarily correct the deviations in the WL since we did not respond to the firm?
4. Injunctions have time frames and have to be processed quickly. If OCC and CDER cannot agree on a response letter can they agree on an injunction.
5. The firm pointed out in their WL response that they discontinued trypan blue 16 months ago and 20% aminolevulinic acid (ALA) 7 months ago. I am sure if we go for injunction we will go to court and the firm's attorneys will bring up all of these faults.

[REDACTED]
Compliance Officer
New England District

From: Shamsi, Mutahar S
Sent: Thursday, October 02, 2008 8:39 AM
To: [REDACTED]
Subject: RE: Response letter to NECC

No, I think we're stuck with this time. Let me know your concerns and I can forward them on.

Mutahar

From: Ota, Bruce R
Sent: Thursday, October 02, 2008 5:57 AM
To: Shamsi, Mutahar S
Subject: RE: Response letter to NECC

Mutahar,

I have a (b) (6) [REDACTED]. I most likely will not get out until after 4:00 pm and not home until 4:30 pm. Do you think we can make the call earlier or Friday.

[REDACTED]
Compliance Officer
New England District

From: Shamsi, Mutahar S
Sent: Wednesday, October 01, 2008 4:16 PM
To: [REDACTED] Nasr, Samia
Cc: [REDACTED]
Subject: RE: Response letter to NECC

(b) (6) [REDACTED]
Mutahar

From: [REDACTED]
Sent: Wednesday, October 01, 2008 3:58 PM
To: Nasr, Samia; Shamsi, Mutahar S
Cc: [REDACTED]
Subject: RE: Response letter to NECC

I will call everyone tomorrow at 4:00 P.M.. Can you be sure that you send me the numbers to call you all at?

[REDACTED]

From: Nasr, Samia
Sent: Wednesday, October 01, 2008 1:47 PM
To: Shamsi, Mutahar S; [REDACTED]
Cc: [REDACTED] Nasr, Samia
Subject: RE: Response letter to NECC

Great. [REDACTED] can you please conference us tomorrow. 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 5370*

[REDACTED]

From: Shamsi, Mutahar S
Sent: Wednesday, October 01, 2008 3:38 PM
To: Nasr, Samia; [REDACTED]
Cc: [REDACTED]
Subject: RE: Response letter to NECC

Tomorrow at 4pm EST is fine with me.

Mutahar

From: Nasr, Samia
Sent: Wednesday, October 01, 2008 3:29 PM
To: Shamsi, Mutahar S; [REDACTED]
Cc: [REDACTED]; Nasr, Samia
Subject: RE: Response letter to NECC
Importance: High

It seems that today will not work, I just spoke with [REDACTED] and we prefer to have the call tomorrow at 4:00 PM our time which is 2:00 PM your time. Please let me know if it is ok as soon as possible. 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 5370*

[REDACTED]

From: Shamsi, Mutahar S
Sent: Wednesday, October 01, 2008 12:35 PM
To: Nasr, Samia; [REDACTED]
Cc: [REDACTED]
Subject: RE: Response letter to NECC

[REDACTED] and I are available, but I don't think [REDACTED] is.

Mutahar

From: Nasr, Samia
Sent: Wednesday, October 01, 2008 12:29 PM
To: [REDACTED]
Cc: Shamsi, Mutahar S; [REDACTED]; Nasr, Samia
Subject: RE: Response letter to NECC

[REDACTED]

What about Mutahar and [REDACTED] are they available today at 3:30 PM ET?

*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
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[REDACTED]