

[REDACTED]

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From: Silverman, Steven  
Sent: Tuesday, January 17, 2006 11:20 AM  
To: [REDACTED]  
Cc: Nasr, Samia; [REDACTED]  
Subject: RE: NECC

[REDACTED],

Thanks for the update. This certainly is not a 320 lead. I'm passing this information on to Samia for her consideration of this matter in relation to the team's other enforcement priorities. As we discussed, NECC is a repeat player, so it might deserve attention that other operations wouldn't merit. But the team is caught up with a range of high-profile issues, so this may need to wait (especially absent reported injury).

Samia -- let me know if you have any questions or would like to discuss this matter. I defer to you about how to proceed. Thanks.

-- Steve

-----Original Message-----

From: [REDACTED]  
Sent: Tuesday, January 17, 2006 9:45 AM  
To: Silverman, Steven  
Subject: Fw: NECC

There may be one of two health concerns:

If the pharmacy compounds with a preservative, it has to be done carefully (preservatives are toxic), the right one in the right amount.

If the pharmacy compounds a multiple use vial we will expect to see addressed the issue of repeated use contamination (usually by including a preservative in the product design).

From the correspondence it seems like the first one above would be the concern.

Do you agree that the action needed is an investigation by the pharmacy compounding team to determine what kind of methotrexate product is being offered by NECC? [REDACTED]

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Sent from my BlackBerry Wireless Handheld

-----Original Message-----

From: Silverman, Steven [REDACTED]  
To: [REDACTED]  
Sent: Tue Jan 17 09:23:28 2006

Subject: RE: NECC

It looks like, as you suggested, this pharmacy is including the preservative for multiple-use MTX. If that's the case, am I right in understanding that the health concerns that we discussed this morning may not exist? Thanks.

-- Steve

-----Original Message-----

From: [REDACTED]  
Sent: Tuesday, January 17, 2006 7:39 AM  
To: Silverman, Steven  
Cc: [REDACTED]  
Subject: RE: NECC

Could this be an advertisement, for pharmacy compounding?

The name of the 'MTX without the needed preservative' is not given. Is/Are the 'main manufacturer(s)' [REDACTED]? I think they have preservative products approved?? Any more info available??

Methotrexate is a drug that requires application approval. The one referred to may have been approved without provision for multiple injections from the same vial. 211.160(b) is available for a specification change, but for drug products requiring approval we usually defer to the review divisions to get them right, but we should investigate. I suggest a pharmacy compounding team follow-up to [REDACTED] to ask some of these questions. [REDACTED]

-----Original Message-----

From: Silverman, Steven  
Sent: Monday, January 16, 2006 9:36 AM  
To: [REDACTED]  
Cc: [REDACTED]  
Subject: FW: NECC

[REDACTED]

FYI -- possible GMP associated with reusable MTX without necessary preservatives?

-- Steve

-----Original Message-----

From: [REDACTED]  
Sent: Saturday, January 14, 2006 6:49 PM  
To: Silverman, Steven; [REDACTED]  
Subject: NECC

Group Members:

I just became aware of an issue with injectable methotrexate ("MTX") that I want to make you aware of. I take oral MTX so this does not affect me, but I know we have many group members who do use injectable MTX for various reasons (instead of oral MTX).

I understand that the main manufacturer(s) of injectable MTX, for whatever reason, is currently only producing MTX without the needed preservative included to stop the growth of bacteria in the vial. In order for a vial of an injectable steroid, like MTX, to be punctured more than once it needs to contain a preservative to stop the growth of bacteria. Without the inclusion of the preservative, the vial (without preservative) should not be used again after the initial puncture. Because of this ongoing problem of getting injectable MTX with the preservative, I understand that many patients have been switched over to the oral version.

If you are having this problem, I have been made aware of one place where you can get injectable MTX with the preservative. This lab/pharmacy has MTX available for both clinic and outpatient use. In order to process an order they only need the physician's name and telephone number. They will speak with the physician and provide ordering information. **They do not need or desire to have the patients name.**

**</bold>**

In order to process such a request your physician could contact:

 Pharmacy Representative

New England Compounding Center

  
This was sent to my local group in the DFW/Ft Worth area.

