

[REDACTED]

From: Nasr, Samia
Sent: Thursday, March 02, 2006 6:05 AM
To: [REDACTED]
Cc: [REDACTED]; Anderson, Kathleen R; [REDACTED]
Subject: RE: New England Compounding Center Inspection Request - Avastin Repackaging and other potential Manufacturing Operations

I do not have any problem with the inspection, we will know what is going on. I think what we were thinking is that if we send a WL now (with the local anesthetic project!) then [REDACTED] will not be able to send a second one. I do not think OCC will allow us to do that, correct?

Samia

Samia M. Nasr, R.Ph., M.S.
Consumer Safety Officer
Division of New Drugs and Labeling Compliance HFD-317
Office of Compliance
Center for Drug Evaluation and Research, FDA
Phone: [REDACTED]
Fax: [REDACTED]
e-mail address: [REDACTED]

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

From: [REDACTED]
Sent: Wednesday, March 01, 2006 4:12 PM
To: [REDACTED]
Cc: [REDACTED]; Anderson, Kathleen R; [REDACTED]; Nasr, Samia
Subject: RE: New England Compounding Center Inspection Request - Avastin Repackaging and other potential Manufacturing Operations

Unless Kathy or Samia feel differently, please go ahead with the inspection assignment. Please send through review process.

Thanks.
[REDACTED]

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

From: [REDACTED]
Sent: Wednesday, March 01, 2006 9:30 AM
To: [REDACTED]
Cc: [REDACTED]; Anderson, Kathleen R; [REDACTED]
Subject: New England Compounding Center Inspection Request - Avastin Repackaging and other potential Manufacturing Operations

[REDACTED]

Because the proposed W/Ls to compounders of topical analgesics are being further delayed and in light of the new information suggesting that the scope of drug manufacturing operations at this firm are expanding, the issuance of the directed inspection request is appropriate.

Please advise.

Thanks.

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

From: [REDACTED]
Sent: Friday, February 24, 2006 1:08 PM

[REDACTED]

To: [REDACTED]
Cc: Nasr, Samia; [REDACTED]
Subject: RE: !!! Fwd: Avastin Promotion

One of the attachments is describing what sounds to be exactly like one of the things [REDACTED] was doing in the late 1980's that resulted in a court case and decision supporting the 505 requirements [REDACTED]. The policy outcome is written into CPG Sec. 446.100 Regulatory Action Regarding Approved New Drugs and Antibiotic Drug Products Subjected to Additional Processing or other Manipulations (CPG 7132c.06).

Since this company is already touting their products at National Ophthalmic Conventions we ought to move forward on the inspection without any additional delay. Note Frozen Antibiotics in the listing below. The scope of their manufacturing seems to be beyond the limited concern we have already identified with the Avasin manipulation!

Attn: Vitreous and Retina Physicians
Many Ophthalmologists are finding it difficult to obtain the medications they need because the manufactured products have been discontinued, are on prolonged backorder or are not available in the concentration, volume or dosage form best suited to your patient.

New England Compounding Center may be able to help by providing compounded medications on a patient-specific basis. Are you having trouble finding...?

- Triamcinolone P/F
- Frozen Antibiotics
- Examination Dilation Drops
- Hyaluronidase
- AvastinTM (single dose syringe)

New England Compounding Center has earned a national reputation as a provider of high quality compounded medications and excellent service to patients and prescribers. Please call today to discuss your patient's prescription needs:

-----Original Message-----
From: Anderson, Kathleen R
Sent: Friday, February 24, 2006 11:34 AM
To: Nasr, Samia; [REDACTED]
Subject: FW: !!! Fwd: Avastin Promotion

Samia/[REDACTED]

FYI - in case you did not get this. Thanks.

Kathy

-----Original Message-----
From: Silverman, Steven
Sent: Monday, January 16, 2006 9:38 AM
To: Anderson, Kathleen R
Subject: FW: !!! Fwd: Avastin Promotion

FYI

-----Original Message-----
From: Silverman, Steven

[REDACTED]

Sent: Monday, January 16, 2006 9:38 AM
To: Nasr, Samir; [REDACTED]
Subject: FW: !!! Fwd: Avastin Promotion

FYI

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

From: [REDACTED]
Sent: Saturday, January 14, 2006 6:15 PM
To: Silverman, Steven
Subject: !!! Fwd: Avastin Promotion

Begin forwarded message:

<excerpt><bold><color><param>0000,0000,0000</param>From:
</color></bold> [REDACTED]
<bold><color><param>0000,0000,0000</param>Date: </color></bold>January
14, 2006 11:40:44 AM CST
<bold><color><param>0000,0000,0000</param>To: </color></bold> [REDACTED]
<bold><color><param>0000,0000,0000</param>Subject: </color>FW: Avastin
</bold>

Dear [REDACTED] (if I may),

I received this from the New England Compounding Center. It looks like it is a pretty good company. Could you look over the inserts and let me know what you think? Thanks, [REDACTED]

From: [REDACTED]@neccrx.com]
Sent: Thu 1/12/2006 3:44 PM
To: [REDACTED]
Subject: Avastin

Dear [REDACTED]

Allow me to introduce New England Compounding Center. Attached for your review is information about the customized pharmacy services we provide to prescribers and their patients.

I wanted to let you know that we will be an exhibitor at the Squaw Valley Retina Symposium in Olympic Valley, CA in February. If you are attending this conference, I wanted to extend an invitation to visit our booth to further discuss our facility procedures and medications that we provide to retinal physicians now across the country. I am very confident that if you are looking for a compounding pharmacy that delivers the highest quality compounded medications and customer service, you will find New England Compounding Center the best value in the marketplace today.

Enclosed you will find some information on some of the compounded and repackaged medications that we provide to retinal specialists across the country.

Thank you again for your time and consideration and please do not hesitate to call me if you have any questions or want to place an order.

Best Regards,

[REDACTED]
National Director of Ophthalmic Division

New England Compounding Center

697 Waverly Street, Framingham, MA 01702

[REDACTED] phone

[REDACTED] fax

[REDACTED] cell

</excerpt>