

[REDACTED]

From: Nasr, Samia
Sent: Tuesday, September 14, 2010 2:48 PM
To: [REDACTED]
Cc: Nasr, Samia
Subject: FW: Drug Product Shortages Report - Amikacin

FYI

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 5174
[REDACTED]

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

From: Nasr, Samia
Sent: Tuesday, September 14, 2010 2:44 PM
To: [REDACTED]
Cc: [REDACTED] Nasr, Samia
Subject: RE: Drug Product Shortages Report - Amikacin

Yes, NECC is under our radar.

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 5174
[REDACTED]

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

From: [REDACTED]
Sent: Tuesday, September 14, 2010 1:43 PM
To: Nasr, Samia

Cc: [REDACTED]
Subject: FW: Drug Product Shortages Report - Amikacin

Hi Sam,
Here is a report of a compounding pharmacy at the bottom of this e-mail chain - don't know if there is anything that can be done but thought I would forward it on.
Thanks, [REDACTED]

[REDACTED]
Associate Director
CDER Drug Shortage Program, FDA
Building #22/Room 6202
10903 New Hampshire Avenue
Silver Spring, MD 20993
[REDACTED]

-----Original Message-----
From: [REDACTED]
Sent: Tuesday, September 14, 2010 1:19 PM
To: [REDACTED]

[REDACTED]

Subject: RE: Drug Product Shortages Report - Amikacin

We will go ahead and add our compounding information - I sincerely hope that we don't have any deaths due to poorly compounded product like we did during the betamethasone shortage....

-----Original Message-----
From: [REDACTED]
Sent: Tuesday, September 14, 2010 11:17 AM
To: Erin Fox

Cc: [REDACTED]

Subject: RE: Drug Product Shortages Report - Amikacin

[REDACTED]
We should definitely include warnings about compounding pharmacies in the posting.
[REDACTED] would you mind forwarding this report to the right area within FDA?
Thanks,
[REDACTED]

From: [REDACTED]@ashp.org>, [REDACTED]

[REDACTED]

[REDACTED]

Date: 09/14/2010 01:07 PM
Subject: RE: Drug Product Shortages Report - Amikacin

This is from a compounding pharmacy. In the past, we have posted information that pharmacies should consider before purchasing from a compounding pharmacy (eg the major risks, noted deaths due to compounded products etc). We can add this to the posting if helpful. The ASHP guidelines on managing shortages also discuss risks of using a compounded product.

[REDACTED]

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

From: [REDACTED]
Sent: Tuesday, September 14, 2010 11:01 AM
To: [REDACTED]
Subject: FW: Drug Product Shortages Report

From: [REDACTED]
Sent: Tuesday, September 14, 2010 11:00:36 AM
To: [REDACTED]

Subject: Drug Product Shortages Report
Auto forwarded by a Rule

Name of Drug Product: Amikacin

Drug Strength and Package Size: all

Drug Product's Manufacturer: [REDACTED]

Usual Supplier: [REDACTED]

[REDACTED]

E-mail Address of Person Submitting Information: [REDACTED]

State: NC

Length of time the product has been unavailable: just tried to order today

Projected availability of the product: Maybe later this week

Actions you have taken to obtain product and information: Below is a copy of an e-mail we received advertising amikacin availability. It is typical of e-mail and telephone solicitations we frequently receive. Are there any regulations regarding such practices? This makes it very difficult to receive meds through the proper channels and at reasonable prices.

Thanks,

[REDACTED]

NECC is providing Amikacin during the shortage (4ml of 250mg/ml).

The chemical we are sourcing is currently very expensive.

Minimum orders of #100 @ \$60/each (\$6,000).

Dating is 180 days Room Temp.

We can provide in 5ml syringes or 5ml vials.

Please don't hesitate to contact me with any questions or concerns.

Thank you,

[REDACTED]

Also Available at NECC:

Naloxone

Furosemide

Calcium Chloride

Sulphan Blue (Alternative to Lymphazurin®)

Irrigation Solutions (Bacitracin 60 days Refrigerated)

Methacholine "Challenge" Kits

L.E.T. Gel Syringes (Lidocaine/Epinephrine/Tetracaine)

Hyaluronidase (Wydase®)

[REDACTED]

Regional Sales Manager - Hospital Division

[REDACTED]

Representing: NECC

Direct Line: [REDACTED]

Cell Phone: [REDACTED]

Fax: [REDACTED]

[REDACTED]

www.Neccrx.com

NECC - A vital resource for sterile and non-sterile compounded medications

Alternative therapies your health care organization has considered and is using, if any: N/A

Prepare your institution for the Changing Landscape of Health Care at the premier conference on today's key pharmacy practice management topics! Attend the Fifteenth Annual ASHP Conference for Leaders in Health-System Pharmacy, October 18-19, 2010, at The Westin O'Hare, Chicago, IL. Register today at www.ashpadvantage.com/leaders.