



FDA Adverse Event Reporting System (FAERS)

Case Details - Preferred Terms

Case Information:

Case #: 8353780 Version: 1 Case Type: DIRECT eSub: Y HP: Y Country: USA Outcomes: LT
 FDA Rcvd Date: 25-Jan-2012 Init FDA Rcvd Date: 25-Jan-2012 Mfr Rcvd Date: MfrControl #: (A)NDA/BLA /

Patient Information:

Patient ID: (b) (6) Age (Yrs): 78 Sex: Female Weight: 70 KG DOB:

Suspect Products:

#	Product Name	Dose / Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date	Interval 1st Dose to Event	ReC	DeC
1	HEPARIN	/	IVDRP	20,000 units titrated	ATRIAL FIBRILLATION	20-Jan-2012	22-Jan-2012	2	NA	NA

#	Product Name	Lot#	Exp Date	NDC#	Labeler
1	HEPARIN	01062012@336			

Event Information:

MedDRA® PreferredTerm	Start Date	End Date	Outcomes	Highlighted Terms
PRODUCT COMPOUNDING QUALITY ISSUE				
PRODUCT QUALITY ISSUE				

Event / Problem Narrative :

We had a patient that the doctor had ordered a Heparin drip for. The patient had a bag and the labs came back that their level had not changed. They increased the drip and rechecked labs still no change. They changed the bag same processes and still not level. Pharmacy had lab test the lot number of the 2 bags on Tuesday and neither bag had any Heparin in the bags.

These bags were made by Ameridose, a compounding pharmacy in Framingham, MA. The lot number was pulled from all of the floors and kits and they were informed immediately. wilsonj: |*****| 2012-01-25-08.46.57 |*****|

USFDAMWVOLUNTARY_200153_13014_20120125.xml Route To: AERS : Electronic
 Route To: DQRS : Paper Compounding

Relevant Medical History:

Disease / Surgical Procedure	Start Date	End Date	Continuing?	Comment
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Medical History Products	Start Date	End Date	Indications	MedDRA® Preferred Term(s)
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Relevant Laboratory Data:

Test Date	Test Name	Result	Unit	Normal Low Range	Normal High Range	info Avail. Y/N
20-Jan-2012	HEPARIN ANTI-XA TESTS	<0.1	09:40			
21-Jan-2012		<0.1	02:55			
22-Jan-2012		<0.3	04:00			
23-Jan-2012		<0.3	03:40			
		<0.1	09:58			
		<0.1	19:15			
		<0.1	22:40			

Concomitant Products:

Product Name	Dose / Frequency	Route	Dosage text	Indication(s)	Start Date	End Date	Interval 1st Dose to Event
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Reporter Source:

Study Report	Study Name	Study Type	Sponsor Study	Protocol	IND #
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Literature Text:

Country of Event: USA

Reporter Name: (b) (6)

Reporter Org: [Redacted]

Reporter Street: [Redacted]

Reporter City: [Redacted]

Reporter Zip: [Redacted]

Health Prof.: Y

Occupation: HP

Sender MFR:

Reporter Type: Health Professional

Reporter Email: [Redacted]

Reporter State: (b) (6)

Reporter Country: USA

Sent To:

Identity Disclosed:

Reporter Phone: [Redacted]