



FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 10213469

Case Information:

Case Type: EXPEDITED (15-DAY) eSub: Y HP: Country: USA Outcomes: OT, (A)NDA/BLA: 021977 /

FDA Rcvd Date: 03-Jun-2014 Mfr Rcvd Date: 27-May-2014 Mfr Control #: US-SHIRE-US201402539

Patient Information:

Age: 10 YR Sex: Female Weight:

Suspect Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text			Indications(s)	Start Date	End Date
1	Vyvanse		Oral	UNK, Unknown			Attention deficit/hyperactivity disorder		

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	Vyvanse			U				SHIRE

Event Information:

Preferred Term (MedDRA 6 Version: 17.0) ReC

Homicide

Event/Problem Narrative:



(b) (6)



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(b) (6)

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?
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(b) (6)

Medical History Product(s)	Start Date	End Date	Indications	Events
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Relevant Laboratory Data:

Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail
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Concomitant Products:

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

Study Report?: No

Sender Organization: SHIRE

Literature Text: