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® Version: 17.0) **ReC**

Homicide

Event/Problem Narrative:

(b) (6)

[redacted]

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(b) (6)

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?
(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

Concomitant Products:

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

Reporter Source:

Study Report?: No **Sender Organization:** SHIRE

Literature Text: