FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report

Selection Criteria:

Product Name:	.;DELATESTRYL
Product Active Ingredient:	·
Active Ingredient	·
Active Moiety:	·
FDA Received Date:	From: 14-JAN-2010 To: 14-JAN-2015
MedDRA® Version* :	17.1
Total Cases**:	27
Number of Pages:	14

Disclaimer: Submission of a safety report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event. The information in these reports has not been scientifically or otherwise verified as to a cause and effect relationship and cannot be used to estimate the incidence of these events.

*. "MedDRA® Version" refers to the name and version of the dictionary in use at the time the cases were retrieved from the FDA Adverse Event Reporting System (FAERS). MedDRA Medical Dictionary for Regulatory Activities (MedDRA®) is a medical terminology developed under the support of the International Conference on Harmonization (ICH) and is a registered trademark of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA). MedDRA is used by FDA, other regulatory agencies, and pharmaceutical manufacturers to code adverse events, medication errors and other information associated with the use of medical products. A MedDRA® Preferred Term (PT) is used to standardize a "medical concept" in a report. For example, a report of "heart attack" or "myocardial infarct" are standardized to the same Preferred Term, "Myocardial Infarction". MedDRA is updated twice a year.

**. "Total Cases" reflects the number of individual patient case reports associated with the product of interest that were submitted to FDA within the specified time period. A case consists of an initial report and any follow-up reports submitted to FDA. Because FDA may receive reports on the same patient from more than one source, some of these cases may be duplicate patient reports.

The information in this report is generated from the FDA Adverse Event Reporting System (FAERS) by using a report query where suspect product(s) or active ingredients are selected from a standardized dictionary and a date range is specified as search criteria. The table below provides the definitions for field headings that are listed on the report.

FAERS data have limitations, including the following. There is no certainty that the reported event was actually due to the product. Reports are often incomplete - a blank field means that no data were provided. FDA does not receive reports on all adverse events that occur with a product. Many factors can influence whether or not an event will be reported, therefore, FAERS data cannot be used to compare products or calculate how frequently an event occurs in the U.S. population.

Field Heading	Definition
FDA Received Date	The date that FDA received the most recent information regarding a case, either as an initial report or follow-up report. The FDA Received Date may not be the same as the date that the event occurred. The event may have occurred days or even months (or years) before the report was sent to (and received by) FDA. Note the displayed date on the report may be later than the query date range if FDA received follow-up information for a case. FDA provides the most current case information available.
Case #	A unique number assigned by FDA that identifies a FAERS case. A case includes the information received in the initial report plus any additional information received in follow-up reports.
Case Type	There are three case types in FAERS: Expedited (15-Day): submitted to FDA by manufacturers; these are reports containing serious, unexpected adverse events Nonexpedited: submitted periodically to FDA by manufacturers; these are reports containing adverse events other than those qualifying for expedited (15-day) reporting Direct: submitted “directly” to FDA by healthcare professionals, patients and other consumers
Health Professional	Indicates whether the initial source who provided information about the event is a health professional (HP). Possible values are; Y - Yes, N – No or the field is blank if it was not reported
Outcomes	Based on FDA regulations, the reported outcome(s) determines whether a case is serious. The outcome categories include congenital anomaly/birth defect (CA), death (DE), disability (DS), hospitalization (HO), life-threatening (LT), other serious important medical event (OT), and required intervention to prevent permanent impairment/damage (RI). A case can have more than one outcome.
Manufacturer Control #	The Manufacturer Control Number is the manufacturer’s unique identifier associated with the case. Also referred to as the Company Report Number.
Age	The patient's age, with age unit, based on information provided in the report.
Sex	Patient sex (Male, Female, Unknown).
Country	The country where the event occurred. If not reported, then the country of the reporter. The International Organization for Standardization (ISO) 3166-1 alpha-3 country code is used as an abbreviation for the country.

Field Heading	Definition
Preferred Term	A Medical Dictionary for Regulatory Activities (MedDRA®) Preferred Term (PT) is used to standardize a “medical concept” in a report. For example, a report of “heart attack” or “myocardial infarct” are standardized to the same Preferred Term, “Myocardial Infarction”. MedDRA is a medical terminology developed under the support of the International Conference on Harmonization (ICH) and is a registered trademark of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA). MedDRA is used by FDA, other regulatory agencies, and pharmaceutical manufacturers to “code” adverse events, medication errors and other information associated with the use of medical products
Product	Name of a drug or therapeutic biologic in the case report. A product name can appear as either a brand name (trade name) or an active ingredient name, depending on what was reported.
Role	There are two roles for products listed on the cases. Suspect (S) identifies the product(s) that the initial reporter deemed most likely to be associated with the event. Concomitant (C) identifies products taken at the same time as the suspect product, but not deemed by the initial reporter as being associated with the event.
Route	Reported route of product administration (e.g., oral, topical, injection, sublingual, inhalation).
Dosage Text	Refers to the amount of the product that was taken or given to a patient, and the frequency of administration. For example, 20 mg twice daily.
Duration	The length of time the product was used. For example, if someone reported taking Drug A from January 1 to January 30, the duration would be 30 days.
Manufacturer	The manufacturer of the product, as indicated in the report.

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Feb-2010	7290583	EXPEDITED (15-DAY)	Y	OT	DELA20100002	34 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Drug dependence	DELATESTRYL	S				
Fatigue	OXYCONTIN (OXYCODONE HYDRCHLORIDE) (OXYCODONE HYDROCHLORIDE)	C				
Loss of libido	COCAINE (COCAINE) (COCAINE)	C				
Depressed mood						
Fear						
Gynaecomastia						
Total cholesterol/HDL ratio increased						

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-Mar-2010	7358461	EXPEDITED (15-DAY)	Y	HO	DELA20100004	30 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Oedema peripheral	DELATESTRYL	S	INTRAMUSCULAR	TWICE WEEKLY, INTRAMUSCULAR		
Blood pressure systolic increased	UNSPECIFIED INGREDIENT	S		5 DAYS PER WEEK		
Blood cholesterol increased	EPHEDRINE SULFATE	C				
Antinuclear antibody positive	CAFFEINE (CAFFEINE) (CAFFEINE)	C				
Nephrotic syndrome	INSULIN (INSULIN) (INSULIN)	C				
Focal segmental glomerulosclerosis	MULTI-VITAMIN	C				
Asthenia						
Depression						
Kidney fibrosis						
Libido decreased						
Nephropathy toxic						
Renal arteriosclerosis						
Renal injury						
Renal tubular atrophy						
Treatment noncompliance						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Dec-2011	8312193	EXPEDITED (15-DAY)	Y	LT	GB-ENDO PHARMACEUTICALS INC.-FORT20110117	56 YR	Male	GBR

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Scrotal swelling	FORTESTA	S		UNK		ENDO
Rash	DELATESTRYL	S		UNK		
	PENICILLIN V POTASSIUM	C		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Feb-2012	8420512	EXPEDITED (15-DAY)	Y	HO	NO-ENDO PHARMACEUTICALS INC.-FORT20120032		Male	NOR

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Glomerulonephritis	FORTESTA	S	TOPICAL	UNKNOWN		ENDO
Nephrotic syndrome	DELATESTRYL	S	INTRAMUSCULAR	UNKNOWN		
Scrotal oedema	NORDITROPIN	S	UNKNOWN	UNKNOWN		
Oedema peripheral	TRENBOLONE ACETATE	S	UNKNOWN	UNKNOWN		
Erysipelas	ANADROL	S	ORAL	UNKNOWN		
Hyperlipidaemia						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Aug-2012	8293332	EXPEDITED (15-DAY)	Y	DS	US-ENDO PHARMACEUTICALS INC.-DELA20110006	41 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Ischaemic stroke	DELATESTRYL	S	INTRAMUSCULAR	UNKNOWN		
Blindness unilateral	FLUDROCORTISONE ACETATE	C	UNKNOWN			
Deafness	PREDNISONE	C	UNKNOWN			
Meningioma benign	ARMOUR THYROID	C	ORAL			
Polycythaemia	CORTISOL	C	UNKNOWN	UNKNOWN		
	DEXAMETHASONE	C	UNKNOWN	UNKNOWN		
	ASACOL	C	UNKNOWN			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Sep-2012	8805044	EXPEDITED (15-DAY)	Y	HO,LT,OT	DELA20120002	33 YR	Male	DEU

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Rhabdomyolysis	DELATESTRYL	S				
	NANDROLONE	S				
Renal failure acute	METANDIENONE	S				
Multiple injuries	STANOZOLOL	S				
Road traffic accident	CLENBUTEROL	S				
Delirium						
Diaphragmatic rupture						
Drug abuse						
Haemodynamic instability						
Hyperthermia malignant						
Kidney rupture						
Multi-organ failure						
Neuroleptic malignant syndrome						
Pneumothorax						
Propofol infusion syndrome						
Respiratory disorder						
Restlessness						
Traumatic liver injury						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Dec-2012	8963656	EXPEDITED (15-DAY)		OT	IT-ENDO PHARMACEUTICALS INC.-DELA20120003		Male	ITA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Erythema multiforme	DELATESTRYL	S	UNKNOWN	UNK		
	FORTESTA	S	UNKNOWN	UNK		ENDO

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Mar-2013	9133747	NON-EXPEDITED			US-ENDO PHARMACEUTICALS INC.-DELA20110001		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Agitation	DELATESTRYL	S	INTRAMUSCULAR	UNKNOWN		
	XANAX	C	UNKNOWN	UNKNOWN		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Mar-2013	9133748	NON-EXPEDITED			US-ENDO PHARMACEUTICALS INC.-DELA20110004		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Blood testosterone decreased	DELATESTRYL	S	INTRAMUSCULAR			
Acne						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Mar-2013	9133749	NON-EXPEDITED			US-ENDO PHARMACEUTICALS INC.-DELA20110002	67 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Blood testosterone increased	DELATESTRYL	S	INTRAMUSCULAR			
Dry eye						
Dysphonia						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Mar-2013	9133751	NON-EXPEDITED			US-ENDO PHARMACEUTICALS INC.-DELA20110005	18 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Myalgia	DELATESTRYL	S	INTRAMUSCULAR			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Mar-2013	9133752	NON-EXPEDITED			US-ENDO PHARMACEUTICALS INC.-DELA20100009		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Overdose	DELATESTRYL	S		200 MG/ML		ENDO
Incorrect dose administered						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Mar-2013	9133754	NON-EXPEDITED			US-ENDO PHARMACEUTICALS INC.-DELA20110003		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Retinal migraine	DELATESTRYL	S	INTRAMUSCULAR	50 mg		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Apr-2013	9238821	DIRECT	Y	HO		76 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Lobar pneumonia	DELATESTRYL 100 MG/WEEK OR PLACEBO INTRAMUSCULARLY	S	INTRAMUSCULAR			
Oedema peripheral	HYDROCHLOROTHIAZIDE	C				
	FISH OIL	C				
Chronic obstructive pulmonary disease						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-Mar-2014	10037474	EXPEDITED (15-DAY)	Y	HO	DELA20140002	42 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Nausea	DELATESTRYL	S				
Vomiting	TESTOSTERONE ACETATE	S				
Diarrhoea	TESTOSTERONE CYPIONATE	S				
Dyspnoea	TESTOSTERONE DECANOATE	S				
Productive cough	TESTOSTERONE PROPIONATE	S				

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Hypoxia	TESTOSTERONE ISOCAPROATE	S				
Supraventricular tachycardia	TESTOSTERONE PHENYLPROPIONATE	S				
Acute respiratory distress syndrome						
Alanine aminotransferase increased						
Aspartate aminotransferase increased						
Atrial flutter						
Base excess decreased						
Blood bilirubin increased						
Blood glucose increased						
Blood lactic acid increased						
Blood pH decreased						
Blood potassium increased						
Continuous haemodiafiltration						
Fluid overload						
Haematocrit decreased						
Haemoglobin decreased						
Hepatic congestion						
Hepatic function abnormal						
Hypotension						
Multi-organ disorder						
Oedema						
Platelet count decreased						
Platelet count increased						
Pneumonia						
Renal failure acute						
Sepsis						
Systemic inflammatory response syndrome						
White blood cell count increased						

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Jul-2014	10277247	EXPEDITED (15-DAY)		OT	US-ENDO PHARMACEUTICALS INC-FORT20140151	59 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Aquagenic pruritus	DELATESTRYL	S	PARENTERAL			
Polycythaemia	DELATESTRYL	S	UNKNOWN			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
28-Jul-2014	10346038	EXPEDITED (15-DAY)		DE	CA-ENDO PHARMACEUTICALS INC.-DELA20140003		Male	CAN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Death	DELATESTRYL	S	UNKNOWN	UNKNOWN		
Acute myocardial infarction						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
21-Oct-2014	10530505	EXPEDITED (15-DAY)		HO,DS	US-ENDO PHARMACEUTICALS INC.-DELA20140004	63 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Cerebrovascular accident	DELATESTRYL	S	UNKNOWN	UNK		
	TESTOSTERONE CYPIONATE	S	UNKNOWN	UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Oct-2014	10533534	EXPEDITED (15-DAY)		HO,DS	US-ENDO PHARMACEUTICALS INC.-DELA20140005	77 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Cerebrovascular accident	DELATESTRYL	S	UNKNOWN	UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-Oct-2014	10542050	EXPEDITED (15-DAY)		HO,OT	US-PFIZER INC-2014291894		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Cerebrovascular accident	Depo-Testosterone	S		UNK, as directed		PFIZER
	DELATESTRYL	S		UNK, as directed		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Dec-2014	10640762	NON-EXPEDITED			US-ENDO PHARMACEUTICALS INC.-DELA20140001		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Diarrhoea	DELATESTRYL	S	UNKNOWN	UNK		
Abdominal pain						
Anxiety						
Drug ineffective						
Fatigue						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Dec-2014	10644602	EXPEDITED (15-DAY)		HO	US-ABBVIE-14P-163-1316422-00	51 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Myocardial infarction	ANDROGEL	S	TOPICAL			
Physical disability	DELATESTRYL	S	UNKNOWN			
Anxiety						
Economic problem						
Emotional disorder						
Impaired work ability						
Pain						
Partner stress						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-Dec-2014	10652522	EXPEDITED (15-DAY)		HO,DS	US-ENDO PHARMACEUTICALS INC.-DELA20140006	51 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Myocardial infarction	DELATESTRYL	S	UNKNOWN	UNK		
	ANDROGEL	S	TOPICAL	UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Dec-2014	10659487	EXPEDITED (15-DAY)		HO,DS,LT	US-ENDO PHARMACEUTICALS INC.-DELA20140007		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Myocardial infarction	DELATESTRYL	S	UNKNOWN	UNK		
	DEPO-TESTOSTERONE	S	UNKNOWN	UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Dec-2014	10659710	EXPEDITED (15-DAY)		HO,OT	US-PFIZER INC-2014345098	44 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Myocardial infarction	Depo-Testosterone	S		UNK, as directed		PFIZER
	DELATESTRYL	S		UNK, as directed		

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Jan-2015	10495293	EXPEDITED (15-DAY)		HO,OT	US-PFIZER INC-2014269053	62 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Deep vein thrombosis	Depo-Testosterone	S	INTRAMUSCULAR	1 ml, weekly		PFIZER
Thrombosis	Depo-Testosterone	S				PFIZER
Pulmonary embolism	Depo-Testosterone	S				PFIZER
Myocardial infarction	ANDROGEL	S		UNK, one pump daily		
Lung disorder	ANDROGEL	S				
Oedema peripheral	ANDROGEL	S				
	DELATESTRYL	S		UNK		
	DELATESTRYL	S				
	DELATESTRYL	S				
	BUPROPION	C		200 mg, UNK		
	CYCLOBENZAPRINE	C		10 mg, UNK		
	ABILIFY	C		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
07-Jan-2015	10696622	EXPEDITED (15-DAY)		DS	US-ENDO PHARMACEUTICALS INC.-DELA20140008	52 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Deep vein thrombosis	DELATESTRYL	S	UNKNOWN			
Myocardial infarction						

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