

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/01/00ISR Number: 3495314-6Report Type:Expedited (15-DaCompany Report #S00-USA-00571-01

Age:38 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Overdose	Health	Celexa (Citalopram Hydrobromide)	PS				
	Pulmonary Congestion	Professional	Clonazepam	SS				
	Pulmonary Oedema		Zolpidem	SS				
	Toxicologic Test Abnormal		Amitriptyline	SS				
			Mirtazepine	SS				
			Quetiapine (Quetiapine Fumarate)	SS				
			Amphetamine	SS				
			Cannabinoids	SS				
			Ethanol	SS				

Date:06/29/01ISR Number: 3750702-5Report Type:Expedited (15-DaCompany Report #2013170

Age:17 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Overdose	Health	Morphine Sulfate	PS				
	Toxicologic Test Abnormal	Professional	Oxycodone Hydrochloride	SS				
	Other		Quinine Sulfate	SS				
			Acetaminophen	SS				
			Cocaine	SS				
			Benzodiazepine	SS				
			Cannabinoids	SS				

Date:06/29/01ISR Number: 3750708-6Report Type:Expedited (15-DaCompany Report #2012671

Age:39 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Brain Oedema	Health	Morphine Sulfate	PS	Ab Generics Lp			
	Cardiomegaly	Professional	Opiates	SS				
	Drug Level Above Therapeutic	Other	Nicotine	SS				
	Eyelid Oedema		Caffeine	SS				
	Hepatic Steatosis		Cannabinoids	SS				
	Hepatomegaly		Benzodiazepines	SS				
	Pulmonary Congestion							
	Pulmonary Oedema							
	Toxicologic Test Abnormal							

Outcome PT
 Death Brain Oedema
 Cardiomegaly
 Coma
 Drug Level Above
 Therapeutic
 Eyelid Oedema
 Hepatic Steatosis

21-Jul-2006 12:29 PM

Page: 1

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Health	Morphine Sulfate					
Professional	(Similar To Nda					
Other	19-516)					
	Opiates				SS	
	Nicotine				SS	
	Caffeine				SS	
	Cannabinoids				SS	
	Benzodiazepines				SS	

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Health	Morphine Sulfate					
Professional	(Similar To Nda					
Other	19-516)					
	Oxycodone					
	Hydrochloride					
	(Similar To Nda					
	20-553)				SS	
	Quinine Sulfate				SS	
	Acetaminophen				SS	
	Cocaine				SS	
	Benzodiazepine				SS	
	Cannabinoids				SS	

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Health	Morphine Sulfate					
Professional	(Similar To Andas					
Other	74-769 And 74-862)				PS	
	Cocaine				SS	

Cannabinoids SS
 Codeine SS
 Ticlopidine
 Hydrochloride SS

Date:07/04/01ISR Number: 3752050-6Report Type:Expedited (15-DaCompany Report #2013161

Age:48 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Drug Toxicity	Health	Morphine Sulfate					
	Toxicologic Test Abnormal	Professional	(Similar To Nda					
	Other	19-516)	PS					
		Cocaine	SS					
		Codeine	SS					
		Ticlopidine						
		Hydrochloride	SS					
		Cannabinoids	SS					

21-Jul-2006 12:29 PM

Page: 2

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/10/01ISR Number: 3755900-2Report Type:Expedited (15-DaCompany Report #2013299

Age:33 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Drug Toxicity	Health	Ms Contin	PS	Purdue Frederick Co			
	Toxicologic Test Abnormal	Professional	Propoxyphene Hcl	SS				
	Other	Codeine	SS					
		Cocaine	SS					
		Cannabinoids	SS					
		Ethanol (Alcohol, Anhydrous)	SS					

Date:07/10/01ISR Number: 3756286-XReport Type:Expedited (15-DaCompany Report #2013298

Age:33 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accident	Health	Morphine Sulfate	PS	Ab Generics Lp			
	Blood Ethanol Increased	Professional	Propoxyphene Hcl	SS				
	Drug Level Above Therapeutic	Other	Codeine	SS				
	Drug Toxicity		Cocaine	SS				
	Toxicologic Test Abnormal		Cannabinoids	SS				
			Ethanol (Alcohol, Anhydrous)	SS				

Date:08/09/01ISR Number: 3774490-1Report Type:Expedited (15-DaCompany Report #2013732

Age:44 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Brain Oedema Coma Drug Toxicity Overdose Pulmonary Congestion Pulmonary Oedema Toxicologic Test Abnormal	Other	Morphine Sulfate(Similar To Andas 74-769 And 74-862) Diazepam Alprazolam Hydromorphone Hcl Oxazepam Temazepam Acetaminophen Hydrocodone Bitartrate Cannabinoids	PS SS SS SS	Abg Laboratories			

Date:09/19/01ISR Number: 3796445-3Report Type:Expedited (15-DaCompany Report #2013796 Age:17 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Animal Bite Excoriation Skull Fractured Base Toxicologic Test Abnormal	Health Professional Other	Ms Contin Tablets 30 Mg Cr (Morphine Sulfate) Amphetamine Methadone Cannabinoids Caffeine Anhydride Nicotine Diazepam	PS SS SS SS SS SS SS		ORAL	MG PO	

21-Jul-2006 12:29 PM

Page: 3

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/03/01ISR Number: 3804333-9Report Type:Expedited (15-DaCompany Report #2014348 Age:16 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide Drug Toxicity	Health Professional Other	Oxycodone Hydrochloride Hydrocodone Bitartrate Cannabinoids Methadone Carisoprodol Butalbital Alcohol Benzodiazepines	PS SS SS SS SS SS SS SS				

Date:10/03/01ISR Number: 3806060-0Report Type:Expedited (15-DaCompany Report #2014347

Age:25 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Road Traffic Accident	Health	Oxycodone					
		Professional	Hydrochloride	PS				
		Other	Hydrocodone					
			Bitartrate	SS				
			Amobarbital	SS				
			Pentobarbital	SS				
			Phenobarbital	SS				
			Secobarbital	SS				
			Chlordiazepoxide	SS				
			Diazepam	SS				
			Oxazepam	SS				
			Cannabinoids	SS				
			Cocaine	SS				
			Codeine	SS				
			Hydromorphone	SS				
			Meperidine	SS				
			Methadone	SS				
			Morphine	SS				
			Pentazocine	SS				
			Propoxyphene	SS				
			Methaqualone	SS				

Date:01/10/02ISR Number: 3850977-8Report Type:Expedited (15-DaCompany Report #2015458

Age:41 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Brain Oedema	Health	Oxycodone					
	Cerebral Arteriosclerosis	Professional	Hydrochloride	PS				
	Drug Toxicity	Other	Propoxyphene Hcl	SS				
	Nephrosclerosis		Naproxen	SS				
	Pulmonary Oedema		Lidocaine Hcl	SS				
	Toxicologic Test Abnormal		Nicotine	SS				
	Ventricular Hypertrophy		Alprazolam	SS				
			Valproic Acid	SS				
			Caffeine	SS				
			Cannabinoids	SS				

21-Jul-2006 12:29 PM

Page: 4

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/23/02ISR Number: 3859683-7Report Type:Expedited (15-DaCompany Report #2014978

Age:18 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
---------	----	---------------	---------	------	--------------	-------	------	----------

Death	Cardiac Failure Overdose Pulmonary Congestion Pulmonary Oedema Toxicologic Test Abnormal	Foreign Health Professional Company Representative Other	Oxycodone Hydrochloride (Similar To Nda 20-553) Alcohol Valium (Diazepam) Temazepam Citalopram Cannabinoids	PS SS SS SS SS SS SS	ORAL ORAL ORAL ORAL	MG PO MG PO MG PO MG PO
-------	--	---	---	--	------------------------------	----------------------------------

Date:01/31/02ISR Number: 3862963-2Report Type:Expedited (15-DaCompany Report #2014978 Age:18 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Failure Coma Overdose Pulmonary Congestion Pulmonary Oedema Toxicologic Test Abnormal	Foreign Health Professional Company Representative Other	Oxycodone Hydrochloride Valium (Diazepam) Temazepam Citalopram Cannabinoids	PS SS SS SS SS		ORAL ORAL ORAL ORAL	PO PO PO PO	

Date:02/13/02ISR Number: 3869394-XReport Type:Periodic Company Report #2013270 Age:36 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health Professional Other	Oxycodone Hydrochloride (Similar To Nda 20-553) Ethanol (Alcohol, Anhydrous) Cocaine Cannabinoids Carisoprodol Meprobamate	PS SS SS SS SS SS				

Date:02/13/02ISR Number: 3869418-XReport Type:Periodic Company Report #2013324 Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Overdose	Health Professional Other	Oxycodone Hydrochloride (Similar To Nda 20-553) Hydrocodone Bitartrate Diazepam Cocaine Meperidine Hcl Cannabinoids	PS SS SS SS SS SS SS				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/13/02ISR Number: 3869452-XReport Type:Periodic Company Report #2012631 Age:42 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health	Oxycodone					
		Professional	Hydrochloride	PS				
		Other	Nicotine	SS				
			Cocaine	SS				
			Caffeine	SS				
			Acetaminophen	SS				
			Carisoprodol	SS				
			Diazepam	SS				
			Ethanol	SS				
			Dilaudid					
			(Hydromorphone)	SS				
			Meprobamate	SS				
			Cannabinoids	SS				

Date:02/13/02ISR Number: 3869464-6Report Type:Periodic Company Report #2012183 Age:29 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health	Oxycodone					
		Professional	Hydrochloride					
		Other	(Similar To Nda					
			20-553)	PS				
			Ethanol	SS				
			Cannabinoids	SS				

Date:02/13/02ISR Number: 3869466-XReport Type:Periodic Company Report #2013192 Age:57 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health	Oxycodone					
		Professional	Hydrochloride					
		Other	(Similar To Nda					
			20-553)	PS				
			Ethanol	SS				
			Cannabinoids	SS				

Date:02/13/02ISR Number: 3869564-0Report Type:Periodic Company Report #2012419 Age:38 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health	Oxycodone					
		Professional	Hydrochloride					

Other (Similiar To Nda
 20-553) PS
 Hydrocodone
 Bitartrate SS
 Diazepam SS
 Oxazepam SS
 Temazepam SS
 Alprazolam SS
 Acetaminophen SS
 Ethanol SS
 Cannabinoids SS
 Tegretol
 (Carbamazepine) C

21-Jul-2006 12:29 PM

Page: 6

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/13/02ISR Number: 3869566-4Report Type:Periodic Company Report #2012421 Age:37 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health Professional Other	Oxycontin Cr Tablets, 10 Mg (Oxycodone Hydrochloride)				MG	
			Diazepam				SS	
			Cocaine				SS	
			Cannabinoids				SS	
			Temazepam				SS	

Date:02/13/02ISR Number: 3869571-8Report Type:Periodic Company Report #2012425 Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health Professional Other	Oxycodone Hydrochloride (Similar To Nda 20-553)				PS	
			Fluoxetine Hydrochloride				SS	
			Diphen (Diphenhydramine Hcl)				SS	
			Cannabinoids				SS	
			Acetaminophen				SS	

Date:02/13/02ISR Number: 3870502-5Report Type:Periodic Company Report #2012326 Age:22 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Overdose	Health Professional	Oxycodone Hydrochloride					

Other (Similar To Nda
 20-553) PS
 Oxazepam SS
 Alprazolam SS
 Carisoprodol SS
 Meprobamate SS
 Cannabinoids SS

Date:02/13/02ISR Number: 3870582-7Report Type:Periodic Company Report #2012642 Age:51 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health	Oxycodone					
		Professional	Hydrochloride					
		Other	(Similar To Nda 20-553) PS					
			Diphenhydramine SS					
			Caffeine SS					
			Nicotine SS					
			Methocarbamol SS					
			Alprazolam SS					
			Ethanol SS					
			Cannabinoids SS					
			Neurontin					

21-Jul-2006 12:29 PM

Page: 7

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

(Gabapentin) C
 Paxil (Paroxetine) C
 Mirtazapine C
 Diazepam C
 Divalproex Sodium C
 Dicyclomine Hcl C
 Dilantin (Phenytoin) C
 Lansoprazole C
 Docusate Sodium C
 Calcium Carbonate C
 Cyanobalamin C

Date:02/13/02ISR Number: 3870592-XReport Type:Periodic Company Report #2012566 Age:20 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Agitation	Health	Oxycontin Cr					
Other	Overdose	Professional	Tablets, 40 Mg					
		Other	(Oxycodone Hydrochloride) PS		ORAL	40 MG BID PO		
			Oxycontin Cr Tablets, 80 Mg (Oxycodone Hydrochloride) SS		ORAL	80 MG Q12H PO		

Oxyir Capsules (Oxycodone Hydrochloride)	SS	ORAL PRN PO	20 MG Q12H
Roxicodone (Oxycodone)	SS	ORAL PO	30 MG Q6H PRN
Alprazolam	SS	ORAL PO	2 MG Q6H PRN
Cannabinoids	SS		
Nicotine	SS		
Lidocaine	SS		
Hydrocodone Bitartrate	SS		
Paxil (Paroxetine)	C		

Date:02/13/02ISR Number: 3870602-XReport Type:Periodic Company Report #2013433 Age:21 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health	Oxycontin Cr Tablets	PS		ORAL	MG	PO
		Professional	Hydrocodone					
		Other	Bitartrate	SS				
			Diazepam	SS				
			Propoxyphene Hcl	SS				
			Acetaminophen	SS				
			Oxazepam	SS				
			Temazepam	SS				
			Caffeine Anhydride	SS				
			Nicotine	SS				
			Cannabinoids	SS				

21-Jul-2006 12:29 PM

Page: 8

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/13/02ISR Number: 3870608-0Report Type:Periodic Company Report #2013517 Age:36 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health	Oxycodone					
		Professional	Hydrochloride					
		Other	(Similar To Nda 20-553)	PS		ORAL	MG; PO	
			Hydrocodone Bitartrate	SS				
			Diazepam	SS				
			Cannabinoids	SS				
			Oxazepam	SS				

Nicotine SS
 Caffeine Amhydride SS
 Temazepam SS
 Acetaminophen C
 Ethanol (Alcohol,
 Anhydrous) C

Date:02/13/02ISR Number: 3870619-5Report Type:Periodic Company Report #2012271 Age:42 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health	Oxycodone					
		Professional	Hydrochloride					
		Other	(Similar To Nda					
			20-553)	PS	ORAL	PO		
			Alprazolam	SS	ORAL	PO		
			Ethyl Alcohol	SS	ORAL	PO		
			Cyclobenzaprine Hcl	SS				
			Mirtazepine	SS				
			Propoxyphene Hcl	SS				
			Cannabinoids	SS				

Date:02/13/02ISR Number: 3870620-1Report Type:Periodic Company Report #2012272 Age:42 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health	Oxycodone					
		Professional	Hydrochloride					
		Other	(Similar To Nda					
			20-553)	PS	ORAL	PO		
			Diazepam	SS				
			Oxazepam	SS				
			Temazepam	SS				
			Lorazepam	SS				
			Cannabinoids	SS				
			Diphenhydramine Hcl	SS				
			Gabapentin	SS				

Date:02/13/02ISR Number: 3870632-8Report Type:Periodic Company Report #2012264 Age:35 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health	Oxycodone					
		Professional	Hydrochloride					
		Other	(Similar To Nda					
			20-553)	PS				

Hydrocodone
 Bitartrate SS
 Ethyl Alcohol SS
 Cocaine SS
 Diazepam SS
 Cannabinoids SS
 Oxazepam SS
 Acetaminophen SS

Date:02/13/02ISR Number: 3870634-1Report Type:Periodic Company Report #2012266 Age:52 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health	Oxycodone					
		Professional	Hydrochloride					
		Other	(Similar To Nda					
			20-553)	PS				
			Diazepam	SS				
			Methadone	SS				
			Cocaine	SS				
			Amitriptyline	SS				
			Chlordiazepoxide	SS				
			Oxazepam	SS				
			Cannabinoids	SS				
			Temazepam	SS				
			Lidocaine Hcl	SS				

Date:02/13/02ISR Number: 3870636-5Report Type:Periodic Company Report #2012268 Age:46 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health	Oxycodone					
		Professional	Hydrochloride					
		Other	(Similar To Nda					
			20-553)	PS				
			Hydrocodone					
			Bitartrate	SS				
			Alprazolam	SS				
			Cocaine	SS				
			Cannabinoids	SS				
			Lidocaine	SS				
			Lorazepam	SS				
			Acetaminophen	SS				

Date:02/13/02ISR Number: 3871085-6Report Type:Periodic Company Report #2015032 Age:47 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health	Oxycontin Cr					
		Professional	Tablets, 20 Mg					
		Other	(Oxycodone					
			Hydrochloride)	PS		20 MG PO		
			Cannabinoids	SS				
			Nicotine	SS				

Caffeine Anhydride SS
Atropine SS

21-Jul-2006 12:29 PM

Page: 10

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/13/02ISR Number: 3871652-XReport Type:Periodic Company Report #2013429 Age:40 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health Professional Other	Oxycodone Hydrochloride (Similar To Nda 20-553) PS Hydrocodone Bitartrate SS Propoxyphene SS Venlafaxine SS Ethanol SS Caffeine SS Nicotine SS Cannabinoids SS					

Date:02/13/02ISR Number: 3871669-5Report Type:Periodic Company Report #2013508 Age:35 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health Professional Other	Oxycontin Cr Tablets, 80 Mg (Oxycodone Hydrochloride) PS Ethanol SS Meprobamate SS Carisoprodol SS Diazepam SS Cannabinoids SS					

Date:02/13/02ISR Number: 3871671-3Report Type:Periodic Company Report #2013514 Age:28 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health Professional Other	Oxycontin Cr Tablets, 80 Mg (Oxycodone Hydrochloride) PS Venlafaxine SS Caffeine SS Ibuprofen SS Hydroxyzine SS Valproic Acid SS					

Cannabinoids SS
Hydroxyzine C
Depakote (Divalproex Sodium) C

Date:02/13/02ISR Number: 3872296-6Report Type:Periodic Company Report #2014181 Age:36 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health Professional Other	Oxycodone Hydrochloride Hydrocodone Bitartrate Carisoprodol Meprobamate	PS				

21-Jul-2006 12:29 PM

Page: 11

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Amitriptyline SS
Cannabinoids SS

Date:02/13/02ISR Number: 3872398-4Report Type:Periodic Company Report #2014031 Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Dependence	Consumer Other	Oxycontin Cr Tablets, 10 Mg (Oxycodone Hydrochloride) Hydrocodone Bitartrate Alcohol Lorazepam Cannabinoids	PS	ORAL	MG PO		

Date:02/13/02ISR Number: 3872410-2Report Type:Periodic Company Report #2014837 Age:27 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health Professional Other	Oxycodone Hydrochloride (Similar To Nda 20-553) Hydromorphone Promethazine Cannabinoids	PS				

Date:02/13/02ISR Number: 3873170-1Report Type:Periodic Company Report #2012065 Age:44 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health	Oxycontin Cr					
		Professional Other	Tablets, 80 Mg (Oxycodone Hydrochloride)		ORAL	PO		
			Ethanol (Alcohol, Anhydrous)		ORAL	PO		
			Diazepam		ORAL	PO		
			Temazepam		ORAL	PO		
			Carisoprodol		ORAL	PO		
			Meprobamate		ORAL	PO		
			Cannabinoids					

Date:02/13/02ISR Number: 3873176-2Report Type:Periodic Company Report #2012650 Age:29 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health	Oxycodone					
		Professional Other	Hydrochloride (Similar To Nda 20-553)		PS			
			Cannabinoids		SS			
			Nicotine		SS			
			Caffeine Anhydride		SS			
			Ethanol		SS			

21-Jul-2006 12:29 PM

Page: 12

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/13/02ISR Number: 3873201-9Report Type:Periodic Company Report #2014225 Age:17 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Consumer	Oxycodone					
Other	Apnoea	Other	Hydrochloride	PS		NASAL NOSE	MG UNKNOWN	
	Drug Dependence		Alcohol					
			Cannabinoids					

Date:02/13/02ISR Number: 3875455-1Report Type:Periodic Company Report #2012979 Age:54 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Intentional Overdose	Health	Oxycodone					
		Professional Other	Hydrochloride (Similar To Nda 20-553)		PS			
			Hydrocodone Bitartrate		SS			
			Acetaminophen		SS			

Cannabinoids SS

Date:02/13/02ISR Number: 3875459-9Report Type:Periodic Company Report #2012968 Age:42 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health Professional Other	Oxycodone Hydrochloride (Similar To Nda 20-553) PS Ethanol (Alcohol, Anhydrous) SS Cannabinoids SS					

Date:02/13/02ISR Number: 3875465-4Report Type:Periodic Company Report #2012973 Age:45 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health Professional Other	Oxycontin Cr Tablets, 10 Mg (Oxycodone Hydrochloride) PS Carisoprodol SS Meprobamate SS Oxazepam SS Ethanol (Alcohol, Anhydrous) SS Cannabinoids SS Nicotine SS		ORAL	PO		

Date:02/13/02ISR Number: 3875496-4Report Type:Periodic Company Report #2012951 Age:28 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health Professional Other	Oxycodone Hydrochloride (Similar To Nda					

21-Jul-2006 12:29 PM

Page: 13

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

20-553) PS
Cocaine SS
Benzodiazepine SS
Cannabinoids SS

Date:02/13/02ISR Number: 3875530-1Report Type:Periodic Company Report #2013117 Age:23 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
---------	----	---------------	---------	------	--------------	-------	------	----------

Death Accidental Overdose Health Oxycontin Cr
 Professional Tablets, 10 Mg
 Other (Oxycodone
 Hydrochloride) PS ORAL PO
 Amitriptyline SS
 Olanzapine SS
 Trihexyphenidyl Hcl SS
 Alprazolam SS
 Cannabinoids SS
 Atropine SS

Date:02/13/02ISR Number: 3875575-1Report Type:Periodic Company Report #2012189 Age:46 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health	Oxycontin Cr					
		Professional	Tablets, 20 Mg					
		Other	(Oxycodone Hydrochloride)	PS		ORAL		PO
			Hydrocodone Bitartrate	SS				
			Alprazolam	SS				
			Cannabinoids	SS				
			Triclosan	SS				
			Caffeine Anhydride	SS				
			Nicotine	SS				

Date:02/13/02ISR Number: 3876148-7Report Type:Periodic Company Report #2012316 Age:41 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Overdose	Health	Oxycodone					
		Professional	Hydrochloride					
		Other	(Similar To Nda 20-553)	PS		ORAL		PO
			Tramadol Hydrochloride	SS		ORAL		PO
			Propoxyphene	SS		ORAL		PO
			Caffeine	SS				
			Cannabinoids	SS				

Date:02/13/02ISR Number: 3876158-XReport Type:Periodic Company Report #2010782 Age:21 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health	(Oxycodone					
		Professional	Hydrochloride)					
		Other	(Similar To Nda 20-553)	PS				

Freedom Of Information (FOI) Report

Heroin SS
 Xanax (Alprazolam) SS
 Cocaine SS
 Cannabinoids SS
 Hydrocodone SS
 Propoxyphene Hcl SS
 Acetaminophen SS

Date:02/13/02ISR Number: 3876169-4Report Type:Periodic Company Report #2013015 Age:21 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Intentional Overdose	Health	Oxycodone					
		Professional	Hydrochloride					
		Other	(Similar To Nd					
			20-553)	PS	MG			
			Hydrocodone					
			Bitartrate	SS				
			Diazepam	SS	MG			
			Cannabinoids	SS				
			Caffeine	SS				
			Temazepam	SS				
			Oxazepam	SS				

Date:02/13/02ISR Number: 3876195-5Report Type:Periodic Company Report #2010775 Age:41 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health	Oxycodone					
		Professional	Hydrochloride					
		Other	(Similar To Nda					
			20-553)	PS				
			Propoxyphene Hcl	SS				
			Diazepam	SS				
			Temazepam	SS				
			Cannabinoids	SS				

Date:02/13/02ISR Number: 3876252-3Report Type:Periodic Company Report #2012529 Age:29 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health	Oxycodone					
		Professional	Hydrochloride					
		Other	(Similar To Nda					
			20-553)	PS				
			Diazepam	SS				
			Temazepam	SS				
			Acetaminophen	SS				
			Fluoxetine					
			Hydrochloride	SS				
			Cannabinoids	SS				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/13/02ISR Number: 3876278-XReport Type:Periodic Company Report #2013067 Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Overdose	Health Professional Other	Oxycodone Hydrochloride (Similar To Nda 20-553) PS Thioridazine SS Cannabinoids SS					

Date:02/13/02ISR Number: 3876301-2Report Type:Periodic Company Report #2012071 Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health Professional Other	Oxycodone Hydrochloride (Similar To Nda 20-553) PS Diazepam SS Cannabinoids SS Ethanol (Alcohol, Anhydrous) SS		ORAL ORAL	PO MG; PO		

Date:02/13/02ISR Number: 3876715-0Report Type:Periodic Company Report #2013976 Age:30 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health Professional Other	Oxycodone Hydrochloride (Similar To Nda 20-553) PS Diazepam SS Meprobamate SS Cocaine SS Atropine SS Cannabinoids SS					

Date:02/13/02ISR Number: 3876722-8Report Type:Periodic Company Report #2013951 Age:38 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health	Oxycodone					
		Professional	Hydrochloride					
		Other	(Similar To Nda					
			20-553)	PS	ORAL	MG PO		
			Acetaminophen	SS				
			Cannabinoids	SS				
			Alcohol	SS				

Date:02/13/02ISR Number: 3876727-7Report Type:Periodic Company Report #2013968 Age:37 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health	Oxycontin Cr					
		Professional	Tablets, 40 Mg					
		Other	(Oxycodone					
			Hydrochloride)	PS				

21-Jul-2006 12:29 PM

Page: 16

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Propoxyphene SS
Cannabinoids SS

Date:02/13/02ISR Number: 3876777-0Report Type:Periodic Company Report #2012202 Age:24 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health	Oxycodone					
		Professional	Hydrochloride					
		Other	(Similar To Nda					
			20-553)	PS				
			Promethazine	SS				
			Diazepam	SS				
			Methylene					
			Dioxymethamphetamine	SS				
			Cannabinoids	SS				
			Ethanol (Alcohol,					
			Anhydrous)	SS				

Date:02/13/02ISR Number: 3876795-2Report Type:Periodic Company Report #2012669 Age:21 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Intentional Overdose	Health	Oxycodone					
		Professional	Hydrochloride					
		Other	(Similar To Nda					
			20-553)	PS				
			Hydrocodone					

Bitartrate	SS		MG
Dihydrocodeine			
(Similar To Anda			
88-584)	SS		MG
Tramadol			
Hydrochloride	SS	ORAL	MG PO
Alprazolam	SS		MG
Propoxyphene Hcl	SS		MG
Ephedrine	SS		
Pseudoephedrine Hcl	SS		
Caffeine	SS		
Cannabinoids	SS		
Nicotine	SS		
Acetaminophen	SS		

Date:02/13/02ISR Number: 3876802-7Report Type:Periodic Company Report #2012662 Age:21 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health	Oxycodone					
		Professional	Hydrochloride					
		Other	(Similar To Nda					
			20-553)					
			Diazepam					
			Cocaine					
			Carisoprodol					
			Cannabinoids					

21-Jul-2006 12:29 PM

Page: 17

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/13/02ISR Number: 3877707-8Report Type:Periodic Company Report #2013712 Age:40 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health	Oxycodone					
		Professional	Hydrochloride					
		Other	(Similar To Nda					
			20-553)					
			Benzodiazepine		UNKNOWN			
			Cannabinoids		UNKNOWN			
			Methadone		UNKNOWN			
			Darvon					
			(Propoxyphene)		UNKNOWN			

Date:02/13/02ISR Number: 3877724-8Report Type:Periodic Company Report #2013092 Age:35 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
---------	----	---------------	---------	------	--------------	-------	------	----------

Death Overdose

Oxycodone
Hydrochloride
(Similar To Nds
20-553) PS
Cannabinoids SS
Diazepam SS
Chlordiazepoxide SS
Oxazepam SS
Fentanyl SS
Carisoprodol SS
Meprobamate SS
Ethynol (Alcohol,
Anhydrous) SS

Date:02/13/02ISR Number: 3877739-XReport Type:Periodic Company Report #2013024 Age:21 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Overdose	Health	Oxycontin Cr Tablets	PS		ORAL	10 MG PO	
		Professional Other	Oxycontin Cr Tablets, 20 Mg (Oxycodone Hydrochloride)	SS		ORAL	20 MG PO	
			Doxepin Hcl	SS			10 MG	
			Cyclobenzaprine Hcl	SS			10 MG	
			Carisoprodol	SS			350 MG	
			Meprobamate	SS				
			Dextromethorphan	SS				
			Acetaminophen	SS				
			Cannabinoids	SS				
			Ephedrine	SS				
			Pseudoephedrine Hcl	SS				

Date:02/13/02ISR Number: 3877743-1Report Type:Periodic Company Report #2013033 Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Overdose	Health	Oxycodone					
		Professional	Hydrochloride	PS		ORAL	MG PO	
			Ethanol (Alcohol, Anhydrous)	SS				

21-Jul-2006 12:29 PM

Page: 18

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Acetaminophen SS
Methadone SS
Nordiazepam SS
Cannabinoids SS
Oxazepam SS
Temazepam SS

Promethazine Hcl SS

Date:02/13/02ISR Number: 3877751-0Report Type:Periodic Company Report #2013034 Age:39 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Overdose	Health	Oxycontin Cr					
		Professional	Tablets, 10 Mg					
		Other	(Oxycodone					
			Hydrochloride)	PS				
			Ethanol (Alcohol,					
			Anhydrous)	SS				
			Alprazolam	SS				
			Oxazepam	SS				
			Propoxyphene Hcl	SS				
			Cannabinoids	SS				

Date:02/13/02ISR Number: 3877767-4Report Type:Periodic Company Report #2013985 Age:45 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Overdose	Health	Oxycodone					
		Professional	Hydrochloride	PS				
			Butalbital Compound	SS				
			Cannabinoids	SS				

Date:02/13/02ISR Number: 3878361-1Report Type:Periodic Company Report #2011723 Age:33 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Other	Oxycodone					
			Hydrochloride					
			(Similar To Nda					
			20-553)	PS				
			Carisoprodol	SS				
			Vicodin					
			(Hydrocodone/Acetami					
			nophen)	SS				
			Cocaine	SS				
			Acetaminophen	SS				
			Diphenhydramine Hcl	SS				
			Phenylpropanolamine					
			Hcl	SS				
			Cannabinoids	SS				

Date:02/13/02ISR Number: 3878370-2Report Type:Periodic Company Report #2012188 Age:31 YR Gender:Male I/FU:I

Outcome	PT	Report Source
Death	Accidental Overdose	Health
		Professional

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Other

Product	Role	Manufacturer	Route	Dose	Duration
Oxycodone Hydrochloride (Similar To Nda 20-553)	PS				
Cocaine	SS				
Methadone	SS				
Cannabinoids	SS				
Caffeine Anhydride	SS				
Nicotine	SS				

Date:02/13/02ISR Number: 3878817-1Report Type:Periodic Company Report #2010949 Age:21 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Overdose	Consumer	Oxycodone Hydrochloride (Similar To Nda 20-553)	PS				
		Other	Methadone	SS				
			Cannabinoids	SS				
			Ranitidine	SS				
			Benzodiazepine	SS				

Date:02/13/02ISR Number: 3879481-8Report Type:Periodic Company Report #2012897 Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Intentional Overdose	Health Professional	Oxycodone Hydrochloride (Similar To Nda 20-553)	PS				
		Other	Hydrocodone Bitartrate	SS				
			Dihydrocodeine (Similar To Anda 88-584)	SS				
			Diphenhydramine Hcl	SS				
			Cannabinoids	SS				
			Alprazolam	SS				
			Diazepam	SS				

Date:02/28/02ISR Number: 3878163-6Report Type:Expedited (15-DaCompany Report #USA-2002-0000101 Age:19 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
---------	----	---------------	---------	------	--------------	-------	------	----------

Death	Alcohol Interaction	Health	Oxycodone					
	Asphyxia	Professional	Hydrochloride					
	Aspiration	Other	(Similar To Nda					
	Drug Level Above		20-553) (Oxycodone					
	Therapeutic		Hydrochloride)	PS	ORAL		UNK MG, ORAL	
	Drug Toxicity		Ethanol(Ethanol)	SS	ORAL		UNK L, ORAL	
	Overdose		Benzodiazepines(Benz					
	Pulmonary Congestion		odiazepines)	SS	ORAL		ORAL	
	Toxicologic Test Abnormal		Cannabinoids(Cannabi					
		noids)	SS		ORAL		ORAL	

21-Jul-2006 12:29 PM

Page: 20

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Nicotine(Nicotine) SS ORAL ORAL

Date:03/15/02ISR Number: 3885016-6Report Type:Expedited (15-DaCompany Report #2015386

Age:21 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Coma	Consumer	Morphine Sulfate					
	Drug Toxicity	Health	(Similar To Andas					
	Pulmonary Oedema	Professional	74-769 And 74-862)	PS				
	Toxicologic Test Abnormal	Other	Morphine Sulfate					
			(Similar To Nda					
			19-516)	SS			MG	
			Tramadol					
			Hydrochloride	SS	ORAL		MG PO	
			Citalopram	SS				
			Diazepam	SS				
			Alpha-Hydroxyalprazo					
			lam	SS				
			Cannabinoids	SS			MG	
			Oxazepam	SS			MG	
			Temazepam	SS			MG	
			Paroxetine	SS			MG	

Date:04/24/02ISR Number: 3907396-5Report Type:Expedited (15-DaCompany Report #2013363

Age:34 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Anxiety	Health	Oxycontin Tablets					
Initial or Prolonged	Arthralgia	Professional	(Oxycodone					
Other	Bone Pain	Other	Hydrochloride) Cr					
Required	Cardiomegaly		Tablet	PS		ORAL	MG, SEE TEXT,	
Intervention to	Chest Pain					ORAL		
Prevent Permanent	Chronic Obstructive		Amitriptyline					
Impairment/Damage	Pulmonary Disease		(Amitriptyline)	SS				
	Coma		Acetaminophen					
	Delirium		(Paracetamol)	SS				
	Drug Dependence		Cannabinoids ()	SS				

Drug Toxicity	Tylox (Oxycodone
Dyspepsia	Terephthalate) C
Dyspnoea	Ativan (Lorazepam) C
Erectile Dysfunction	Xanax (Alprazolam) C
Hypertonia	Vioxx (Rofecoxib) C
Hypoaesthesia	Pamelor
Joint Stiffness	(Nortriptyline
Legal Problem	Hydrochloride) C
Muscular Weakness	Ultram C
Nocturia	Skelaxin
Overdose	(Metaxalone) C
Pain In Extremity	Buspar (Buspirone
Paraesthesia	Hydrochloride) C
Pollakiuria	Tenormin (Atenolol) C
Stridor	Narcan (Naloxone
Toxicologic Test Abnormal	Hydrochloride) C
Urinary Incontinence	Ambien (Zolpidem
Wheezing	Tartrate) C
	Haldol (Haloperidol) C
	Cogentin
	(Benzatropine
	Mesilate) C

21-Jul-2006 12:29 PM

Page: 21

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/02/02ISR Number: 3943810-7Report Type:Expedited (15-DaCompany Report #2013363

Age:34 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Abnormal Behaviour	Health	Oxycontin Tablets 20					
Hospitalization - Initial or Prolonged	Aggression	Professional	Mg(Oxycodone					
Other	Anxiety	Other	Hydrochloride) Cr					
	Arthralgia		Tablet PS			ORAL	20 MG / ORAL	
	Back Pain		Oxycontin Tablets					
	Bone Pain		40mg (Oxycodone					
	Cardiomegaly		Hydrochloride) Cr					
	Chest Pain		Tablet SS			ORAL	40 MG / ORAL	
	Chronic Obstructive Pulmonary Disease		Hydrocodone /Apap					
	Coma		(Paracetamol,					
	Delirium		Hydrocodone					
	Disorientation		Bitartrate) SS			ORAL	10 MG, SEE	
	Drug Dependence		Cannabinoids ()	SS				1229 DAY
	Drug Effect Decreased		Acetaminophen					
	Drug Toxicity		(Paracetamol)	SS				1229 DAY
	Dyspepsia		Amitriptyline					
	Dyspnoea		(Amitriptyline)	SS				1229 DAY
	Erectile Dysfunction		Tylox (Oxycodone					
	Hypertonia		Terephthalate) C					
	Hypoaesthesia		Ativan (Lorazepam)	C				
	Joint Stiffness		Xanax (Alprazolam)	C				
	Muscular Weakness		Vioxx (Rofecoxib)	C				
	Mydriasis		Pamelor					

Nocturia	(Nortriptyline	
Overdose	Hydrochloride)	C
Pain In Extremity	Ultram	C
Paraesthesia	Skelaxin	
Pollakiuria	(Metaxalone)	C
Pupillary Reflex Impaired	Buspar (Buspirone	
Sexual Dysfunction	Hydrochloride)	C
Somnolence	Tenormin (Atenolol)	C
Speech Disorder	Narcan (Naloxone	
Stridor	Hydrochloride)	C
Toxicologic Test Abnormal	Ambien (Zolpidem	
Urinary Incontinence	Tartrate)	C
Vomiting	Haldol (Haloperidol)	C
Wheezing	Cogentin	
	(Benzatropine	
	Mesilate)	C
	Narcan (Naloxone	
	Hydrochloride)	C
	Diazepam (Diazepam)	C
	Baclofen (Baclofen)	C

Date:07/17/02ISR Number: 3951458-3Report Type:Expedited (15-DaCompany Report #2013363

Age:34 YR Gender:Male I/FU:F

Outcome PT
 Death Accidental Overdose
 Hospitalization - Aggression
 Initial or Prolonged Arthralgia
 Other Bone Pain
 Bronchitis
 Cardiomegaly
 Chest Pain
 Chronic Obstructive

21-Jul-2006 12:29 PM

Page: 22

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Pulmonary Disease							
Coma							
Cough							
Delirium	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Diarrhoea	Health	Oxycontin	PS		ORAL	20 MG, ORAL	
Disorientation	Professional	Oxycontin Tablets					
Drug Toxicity	Other	(Oxycodone					
Drug Withdrawal Syndrome		Hydrochloride) Cr					
Dyspepsia		Tablet	SS		ORAL	40 MG, ORAL	
Dyspnoea		Hydrocodone/Apap					
Enuresis		(Paracetamol,					
Fall		Hydrocodone					
Hypoaesthesia		Bitartrate) Unknown	SS		ORAL	10 MG, SEE	
Joint Stiffness					TEXT, ORAL		
Muscular Weakness		Amitriptyline					
Pain In Extremity		(Amitriptyline)	SS			100 MG, NOCTE	1229 DAY

Paraesthesia	Acetaminophen	
Pollakiuria	(Paracetamol)	SS
Pupillary Reflex Impaired	Cannabinoids	SS
Pyrexia	Xanax (Alprazolam)	C
Sexual Dysfunction	Vioxx (Rofecoxib)	C
Somnolence	Pamelor	
Urinary Incontinence	(Nortriptyline	
Vomiting	Hydrochloride)	C
Wheezing	Ultram	C
	Skelaxin	
	(Metaxalone)	C
	Buspar (Buspirone	
	Hydrochloride)	C
	Tenormin (Atenolol)	C
	Narcan	C
	Ambien (Zolpidem	
	Tartrate)	C
	Haldol (Haloperidol)	C
	Cogentin	
	(Benzatropine	
	Mesilate)	C
	Narcan	C
	Diazepam (Diazepam)	C
	Baclofen (Baclofen)	C
	Lorcet	C
	Toradol (Ketorolac	
	Tromethamine)	C
	Phenergan	
	(Promethazine	
	Hydrochloride)	C
	E-Mycin	
	(Erythromycin)	C
	Flovent (Fluticasone	
	Propionate)	C
	Theo-Dur	C
	Prednisone	
	(Prednisone)	C
	Soma (Carisoprodol)	C
	Proventil Inhaler	
	(Salbutamol)	C
	Tylox	C
	Ativan	C

1229 DAY
1229 DAY

21-Jul-2006 12:29 PM

Page: 23

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/06/02ISR Number: 3959200-7Report Type:Expedited (15-DaCompany Report #2013363

Age:34 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
---------	----	---------------	---------	------	--------------	-------	------	----------

Death	Accidental Overdose	Health	Oxycontin Tablets 20			
Hospitalization -	Arthralgia	Professional	Mg (Oxycodone			
Initial or Prolonged	Bone Pain	Other	Hydrochloride) Cr			
Other	Bronchitis		Tablet PS	ORAL	20 MG, ORAL	
	Cardiomegaly		Oxycontin Tablets 40			
	Chest Pain		Mg (Oxycodone			
	Chronic Obstructive		Hydrochloride) Cr			
	Pulmonary Disease		Tablet SS	ORAL	40 MG, ORAL	
	Coma		Hydrocodone / Apap			
	Cough		(Paracetamol,			
	Delirium		Hydrocodone			
	Diarrhoea		Bitartrate) Unknown	ORAL	10 MG, SEE	
	Disorientation			TEXT, ORAL		
	Drug Abuser		Amitriptyline			
	Drug Dependence		(Amitriptyline)		100 MG, NOCTE	1229 DAY
	Drug Screen Positive		Acetaminophen			
	Drug Toxicity		(Paracetamol)		1229 DAY	
	Drug Withdrawal Syndrome		Cannabinoids ()		1229 DAY	
	Dyspepsia		Tylox (Oxycodone			
	Dyspnoea		Terephthalate)			
	Erectile Dysfunction		Ativan (Lorazepam)			
	Fall		Xanax (Alprazolam)			
	Hypertonia		Vioxx (Rofecoxib)			
	Hypoaesthesia		Pamelor			
	Joint Stiffness		(Nortriptyline			
	Muscular Weakness		Hydrochloride)			
	Mydriasis		Ultram			
	Nocturia		Skelaxin			
	Pain		(Metaxalone)			
	Pain In Extremity		Buspar (Buspirone			
	Paraesthesia		Hydrochloride)			
	Pollakiuria		Tenormin (Atenolol)			
	Pyrexia		Narcan			
	Sluggishness		Ambien (Zolpidem			
	Somnolence		Tartrate)			
	Stridor		Haldol (Haloperidol)			
	Urinary Incontinence		Cogentin			
	Vomiting		(Benzatropine			
	Wheezing		Mesilate)			
			Narcan			
			Diazepam (Diazepam)			
			Baclofen (Baclofen)			
			Lorcet			
			Toradol (Ketorolac			
			Tromethamine)			
			Phenergan			
			(Promethazine			
			Hydrochloride)			
			E-Mycin			
			(Erythromycin)			
			Flovent (Fluticasone			
			Propionate)			
			Theo-Dur			
			Prednisone			
			(Prednisone)			
			Soma (Carisoprodol)			
			Proventil Inhaler			

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/14/02ISR Number: 3963773-8Report Type:Expedited (15-DaCompany Report #2013363

Age:34 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Abnormal Behaviour	Health	Oxycontin Tablets 20					
Hospitalization - Initial or Prolonged	Accidental Overdose Aggression	Professional Other	Mg (Oxycodone Hydrochloride) Cr					
Other	Arthralgia		Tablet PS			ORAL	20 MG, ORAL	
	Bone Pain		Oxycontin Tablets 40					
	Bronchitis		Mg (Oxycodone Hydrochloride) Cr					
	Cardiomegaly		Tablet SS			ORAL	40 MG, ORAL	
	Chest Pain		Hydrocodone/Apap (Paracetamol, Hydrocodone Bitartrate)	SS		ORAL	10 MG, SEE TEXT, ORAL	
	Chronic Obstructive Pulmonary Disease							
	Coma							
	Cough							
	Delirium							
	Diarrhoea		Amitriptyline (Amitriptyline)	SS				
	Disorientation						100 MG, NOCTE	1229 DAY
	Drug Abuser		Acetaminophen (Paracetamol)	SS				1229 DAY
	Drug Dependence							
	Drug Effect Decreased		Cannabinoids()	SS				1229 DAY
	Drug Toxicity		Tylox (Oxycodone Terephthalate)	C				
	Drug Withdrawal Syndrome							
	Dyspepsia		Ativan (Lorazepam)	C				
	Dyspnoea		Xanax (Alprazolam)	C				
	Erectile Dysfunction		Vioxx (Rofecoxib)	C				
	Fall		Pamelor (Nortriptyline Hydrochloride)	C				
	Hypertonia							
	Hypoaesthesia							
	Mydriasis		Ultram	C				
	Nocturia		Skelaxin (Metaxalone)	C				
	Pain In Extremity							
	Paraesthesia		Buspar (Buspirone Hydrochloride)	C				
	Pollakiuria							
	Pupillary Disorder		Tenormin (Atenolol)	C				
	Pyrexia		Narcan	C				
	Somnolence		Ambien (Zolpidem Tartrate)	C				
	Speech Disorder							
	Stridor		Haldol (Haloperidol)	C				
	Suicidal Ideation		Cogentin (Benzatropine Mesilate)	C				
	Urinary Incontinence							
	Urine Analysis Abnormal							
	Vomiting		Narcan	C				
	Wheezing		Diazepam (Diazepam)	C				
			Baclofen (Baclofen)	C				
			Lorcet	C				
			Toradol (Ketorolac Tromethamine)	C				

Phenergan
(Promethazine
Hydrochloride) C
E-Mycin
(Erythromycin) C
Flovent (Fluticasone
Propionate) C
Theo-Dur C
Prednisone
(Prednisone) C
Soma (Carisoprodol) C
Proventil Inhaler
(Salbutamol) C

21-Jul-2006 12:29 PM

Page: 25

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Percocet Tablet C
Penicillin V-K
(Phenoxymethylpenicil
lin Potassium) C

Date:09/11/02ISR Number: 3974501-4Report Type:Expedited (15-DaCompany Report #2013363

Age:34 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health	Oxycontin Tablets					
Hospitalization - Initial or Prolonged	Aggression Anxiety	Professional Other	20mg (Oxycodone Hydrochloride) Cr					
Other	Arthralgia		Tablet PS			ORAL	20 MG, ORAL	
	Bone Pain		Oxycontin Tablets 40					
	Bronchitis		Mg (Oxycodone					
	Cardiomegaly		Hydrochloride) Cr					
	Chest Pain		Tablet SS			ORAL	40 MG, ORAL	
	Chronic Obstructive Pulmonary Disease		Hydrocodone/Apap (Paracetamol,					
	Coma		Hydrocodone					
	Cough		Bitartrate) SS			ORAL	10, MG, SEE	
	Delirium						TEXT, ORAL	
	Diarrhoea		Amitriptyline					
	Disorientation		(Amitriptyline) SS					1229 DAY
	Drug Abuser		Acetaminophen					
	Drug Dependence		(Paracetamol) SS					1229 DAY
	Drug Toxicity		Cannabinoids() SS					1229 DAY
	Drug Withdrawal Syndrome		Tylox (Oxycodone					
	Dyspepsia		Terephthalate) C					
	Dyspnoea		Ativan (Lorazepam) C					
	Erectile Dysfunction		Xanax (Alprazolam) C					
	Fall		Vioxx (Rofecoxib) C					
	Hypertonia		Pamelor					
	Hypoaesthesia		(Nortriptyline					
	Mydriasis		Hydrochloride) C					

Nocturia	Ultram	C
Pain In Extremity	Skelaxin	
Pollakiuria	(Metaxalone)	C
Pyrexia	Buspar (Buspirone	
Somnolence	Hydrochloride)	C
Stridor	Tenormin (Atenolol)	C
Toxicologic Test Abnormal	Narcan (Naloxone	
Urinary Incontinence	Hydrochloride)	C
Vomiting	Ambien (Zolpidem	
Wheezing	Tartrate)	C
	Haldol (Haloperidol)	C
	Cogentin	
	(Benzatropine	
	Mesilate)	C
	Narcan (Naloxone	
	Hydrochloride)	C
	Diazepam (Diazepam)	C
	Baclofen (Baclofen)	C
	Lorcet	C
	Toradol (Ketorolac	
	Tromethamine)	C
	Phenergan	
	(Promethazine	
	Hydrochloride)	C
	E-Mycin	

21-Jul-2006 12:29 PM

Page: 26

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

(Erythromycin)	C
Flovent (Fluticasone	
Propionate)	C
Theo-Dur	C
Prednisone	
(Prednisone)	C
Soma (Carisoprodol)	C
Proventil Inhaler	
(Salbutamol)	C
Percocet Tablet	C
Penicillin V-K	
(Phenoxymethylpenici	
llin Potassium)	
Tablet	C

Date:12/31/02ISR Number: 4037850-XReport Type:Expedited (15-DaCompany Report #L02-AUS-03493-06

Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Drug Toxicity	Foreign	Citalopram					
		Literature	(Citalopram					
		Health	Hydrobromide)				PS	
		Professional	Alcohol				SS	
		Other	Propranolol				SS	

Diazepam SS
 Methamphetamine SS
 Cannabinoids
 (Cannabis) SS

Date:02/27/03ISR Number: 4068349-2Report Type:Expedited (15-DaCompany Report #2013363

Age:34 YR Gender:Male I/FU:F

Outcome PT
 Death Abnormal Behaviour
 Hospitalization - Accidental Overdose
 Initial or Prolonged Aggression
 Other Arthralgia
 Bronchitis
 Cardiomegaly
 Chest Pain
 Chronic Obstructive
 Pulmonary Disease
 Coccydynia
 Coma
 Delirium
 Diarrhoea
 Disorientation
 Drug Abuser
 Drug Dependence
 Drug Screen Positive
 Drug Toxicity
 Drug Withdrawal Syndrome
 Dyspepsia
 Dyspnoea
 Erectile Dysfunction
 Fall
 Hypertonia
 Hypoaesthesia
 Imprisonment
 Muscular Weakness

21-Jul-2006 12:29 PM

Page: 27

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Mydriasis	Nocturia	Overdose	Pain In Extremity	Pollakiuria	Pupillary Reflex Impaired	Sexual Dysfunction	Somnolence	Speech Disorder	Toxicologic Test Abnormal	Urinary Incontinence	Vomiting
Report Source	Product	Role	Manufacturer	Route	Dose	Duration					
Health	Oxycontin Tablets										
Professional	20mg (Oxycodone Hydrochloride) Cr										
Other	Tablet PS			ORAL	20 MG, UNK;						
				ORAL							
	Oxycontin Tablets 40 Mg (Oxycodone Hydrochloride) Cr										
	Tablet SS			ORAL	40 MG, UNK;						

Wheezing

ORAL

Hydrocodone/Apap
(Paracetamol,
Hydrocodone
Bitartrate) Unknown SS

ORAL 10 MG, SEE
TEXT; ORAL

Amitriptyline
(Amitriptyline) SS

100 MG, NOCTE 1229 DAY

Acetaminophen(Parace
tamol) SS

1229 DAY

Cannabinoids () SS

1229 DAY

Xanax (Alprazolam) C

Vioxx (Rofecoxib) C

Pamelor

(Nortriptyline

Hydrochloride) C

Ultram C

Skelaxin

(Metaxalone) C

Buspar (Buspirone

Hydrochloride) C

Tenormin (Atenolol) C

Narcan C

Ambien (Zolpidem

Tartrate) C

Haldol (Haloperidol) C

Cogentin

(Benzatropine

Mesilate) C

Narcan C

Diazepam (Diazepam) C

Baclofen C

Lorcet C

Toradol (Ketorolac

Tromethamine) C

Phenergan

(Promethazine

Hydrochloride) C

E-Mycin

(Erythromycin) C

Flovent (Fluticasone

Propionate) C

Theo-Dur C

Prednisone C

Soma (Carisoprodol) C

Proventil Inhaler

(Salbutamol) C

Percocet C

Penicillin V-K

Ilin Potassium) C
 Tylox C
 Ativan C

Date:05/29/03ISR Number: 4120281-1Report Type:Expedited (15-DaCompany Report #USA-2003-0006619 Age:38 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Aspiration	Literature	Oxycontin Tablets					
	Cardiac Failure	Health	(Oxycodone					
	Collapse Of Lung	Professional	Hydrochloride) Cr					
	Drug Interaction		Tablet PS					
	Nervous System Disorder		Lonopin (Clonzaepam)	SS				
	Overdose		Trazodone					
	Respiratory Depression		(Trazodone)	SS				
			Cannabinoids ()	SS				
			Nicotine (Nicotine)	SS				

Date:06/18/03ISR Number: 4132626-7Report Type:Expedited (15-DaCompany Report #USA-2003-0006619 Age:38 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Literature	Oxycontin Tablets					
	Aspiration	Health	(Oxycodone					
	Atelectasis	Professional	Hydrochloride) Cr					
	Collapse Of Lung	Other	Tablet PS		ORAL		40 MG, ORAL	
	Depressed Level Of		Klonopin					
	Consciousness		(Clonazepam)	SS				
	Drug Interaction		Trazodone					
	Pupils Unequal		(Trazodone)	SS				
	Respiratory Depression		Cannabinoids ()	SS				
	Shock		Nicotine (Nicotine)	SS				
	Toxicologic Test Abnormal							

Date:12/03/03ISR Number: 4246672-6Report Type:Expedited (15-DaCompany Report #USA-2003-0010940 Age:20 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Health	Oxycodone					
	Drug Level Above	Professional	Hydrochloride					
	Therapeutic	Other	(Similar To Nda					
	Gun Shot Wound		20-553) (Oxycodone					
			Hydrochloride)	PS			UNK, MG,	
							UNKNOWN	
			Acetaminophen					
			(Paracetamol)	SS			UNK, MG,	
							UNKNOWN	
			Cannabinoids()	SS			UNK MG,	
							UNKNOWN	
			Caffeine (Caffeine)	SS			UNK, MG,	
							UNKNOWN	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/17/03ISR Number: 4270326-3Report Type:Periodic Company Report #2015388 Age:30 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health	Oxycodone Hcl Cr					
		Professional	Tablets (Similar To					
		Other	Nda 20-553)					
			(Oxycodone					
			Hydrochloride)	PS				
			Ethanol (Ethanol)	SS	ORAL	ORAL		
			Diazepam (Diazepam)	SS	ORAL	ORAL		
			Cannabinoids	SS	ORAL	ORAL		
			Oxazepam (Oxazepam)	SS	ORAL	ORAL		
			Temazepam					
			(Temazepam)	SS	ORAL	ORAL		
			Cocaine (Cocaine)	SS				

Date:06/21/04ISR Number: 4396103-0Report Type:Periodic Company Report #USA-2003-0011033 Age:15 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health	Oxycontin Tablets					
		Professional	(Oxycodone					
		Other	Hydrochloride)	PS		MG		
			Nicotine (Nicotine)	SS		MG		
			Citalopram					
			(Citalopram)	SS		MG		
			Cannabinoids	SS		MG		

Date:06/21/04ISR Number: 4399085-0Report Type:Periodic Company Report #2012529 Age:29 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Multiple Drug Overdose	Consumer	Oxycontin Tablets					
	Accidental	Health	(Oxycodone					
		Professional	Hydrochloride)	PS				
		Other	Diazepam (Diazepam)	SS				
			Temazepam					
			(Temazepam)	SS				
			Acetaminophen					
			(Paracetamol)	SS				
			Fluoxetine					
			Hydrochloride					
			(Fluoxetine)					

Hydrochloride) SS
 Cannabinoids SS
 Valium C

Date:08/13/04ISR Number: 4428302-3Report Type:Expedited (15-DaCompany Report #USA-2004-0016259

Age:44 YR Gender:Male I/FU:I

Outcome PT
 Death Accident
 Accidental Overdose
 Arteriosclerosis
 Cardiomegaly
 Drug Toxicity
 Injection Site
 Discolouration

21-Jul-2006 12:29 PM

Page: 30

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Injection Site Induration
 Pulmonary Congestion
 Pulmonary Oedema

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Health	Oxycodone					
Professional	Hydrochloride	PS				
Other	Alprazolam					
	(Alprazolam)	SS				
	Cannabinoids	SS				
	Promethazine					
	(Promethazine)	SS				
	Salicylic Acid					
	(Salicylic Acid)	SS				
	Oxazepam (Oxazepam)	SS				

Date:12/27/04ISR Number: 4541579-9Report Type:Expedited (15-DaCompany Report #USA-2004-0018072

Age:41 YR Gender:Male I/FU:I

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Morphine Sulfate					
Literature	(Morphine Sulfate)	PS				
Health	Duragesic					
Professional	(Fentanyl)	SS				
Other	Ethanol					
	(Ethanol)	SS	ORAL	ORAL		
	Amfetamine					
	(Amfetamine)	SS				
	Cannabinoids	SS				

Date:03/02/05ISR Number: 4596404-7Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20050205883

Age:42 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Drug Exposure During Pregnancy		Ibuprofen	PS				
	Drug Level Below Therapeutic		Subutex	SS		SUBLINGUAL		
	Multiple Drug Overdose		Diazepam	SS		OROPHARINGEAL		
			Oxazepam	SS				
			Cocaine	SS		intermittentl		
			Cannabinoids	SS	y			

Date:04/05/05ISR Number: 4627495-2Report Type:Expedited (15-DaCompany Report #USA-2004-0018113 Age:17 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Death	Consumer	Oxycontin Tablets					
Other	Anoxic Encephalopathy	Health	(Oxycodone					
	Cardiac Arrest	Professional	Hydrochloride)Cr					
	Foreign Body Aspiration	Other	Tablet	PS				
	General Physical Health Deterioration		Alcohol (Ethanol)	SS				
	Multiple Drug Overdose		Alprazolam					
	Accidental		(Alprazolam)	SS				
	Polysubstance Abuse		Oxymorphone					
	Respiratory Arrest		(Oxymorphone)	SS				
			Lidocaine					
			(Lidocaine)	SS				
			Cocaine (Cocaine)	SS				
			Cannabinoids	SS				

21-Jul-2006 12:29 PM

Page: 31

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/27/05ISR Number: 4648651-3Report Type:Expedited (15-DaCompany Report #PAR_0008_2005 Age:15 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Anuria	Foreign	Verapamil	PS		ORAL	7.2 G ONCE PO	
Hospitalization - Initial or Prolonged	Atrioventricular Block First Degree	Literature Health	Paroxetine	SS		ORAL PO	240 MG ONCE	
Required Intervention to Prevent Permanent Impairment/Damage	Blood Creatinine Increased	Professional Other	Sertraline	SS			DF	
	Blood Phosphorus Decreased		Cannabinoids	SS			DF	
	Blood Pressure Systolic Decreased							
	Cardiac Arrest							
	Cardiomyopathy							
	Confusional State							
	Corneal Light Reflex Test Abnormal							
	Electromechanical Dissociation							
	Grand Mal Convulsion							
	Heart Rate Decreased							

Lung Infiltration
 Multiple Drug Overdose
 Pupil Fixed
 Respiratory Distress
 Rhabdomyolysis
 Serotonin Syndrome
 Sinus Tachycardia
 Troponin I Increased

Date:04/28/05ISR Number: 4650264-4Report Type:Expedited (15-DaCompany Report #KII-2005-0016092 Age:20 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Blood Glucose Increased Body Temperature Increased Coma Drug Abuser Pneumonia Aspiration Troponin Increased Vomiting	Study Health Professional Other	Oxycodone Hydrochloride (Oxycodone Hydrochloride) Benzodiazepine Derivatives () Cannabinoids ()	PS		ORAL ORAL ORAL	SEE TEXT, ORAL ORAL	

Date:05/26/05ISR Number: 4675013-5Report Type:Expedited (15-DaCompany Report #2013363 Age:34 YR Gender:Male I/FU:F

Outcome	PT
Death Hospitalization - Initial or Prolonged Other	Abnormal Behaviour Alcoholism Anxiety Arthralgia Asthenia Bone Pain Borderline Mental Impairment Bronchitis Cardiomegaly Chronic Obstructive Pulmonary Disease

21-Jul-2006 12:29 PM

Page: 32

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Delinquency Delirium Depressed Level Of Consciousness Diarrhoea Drug Abuser Drug Dependence Drug Toxicity Drug Withdrawal Syndrome		Consumer Health Professional Other	Oxycontin Tablets 20 Mg (Oxycodone Hydrochloride)Cr Tablet Oxycontin Tabelets 40 Mg(Oxycodone	PS		ORAL	20 MG, ORAL	

Dyspepsia	Hydrochloride)Cr			
Emotional Distress	Tablet	SS	ORAL	40 MG, ORAL
Fall	Hydrocodone/Apap			
Generalised Anxiety Disorder	(Paracetamol, Hydrocodone			
Hand Fracture	Bitartrate)	SS	ORAL	10 MG, SEE
Hypertension				TEXT, ORAL
Hypoaesthesia	Amitriptyline			
Inadequate Analgesia	(Amitriptyline)	SS		100 MG, NOCTE
Learning Disability	Acetaminophen			
Major Depression	(Paracetamol)	SS		
Male Sexual Dysfunction	Cannabinoids	SS		
Musculoskeletal Stiffness	Tylox (Oxycodone			
Nocturia	Terephthalate)	C		
Obesity	Ativan (Lorazepam)	C		
Overdose	Xanax (Alprazolam)	C		
Pain In Extremity	Vioxx (Rofecoxib)	C		
Paraesthesia	Pamelor			
Pneumoconiosis	(Nortriptyline			
Pollakiuria	Hydrochloride)	C		
Pyrexia	Ultram	C		
Somnolence	Skelaxin			
Speech Disorder	(Metaxalone)	C		
Spinal Osteoarthritis	Buspar (Buspirone			
Suicidal Ideation	Hydrochloride)	C		
Tooth Extraction	Tenormin (Atenolol)	C		
Urinary Incontinence	Narcan	C		
Vomiting	Ambien (Zolpidem			
	Tartrate)	C		
	Haldol (Haloperidol)	C		
	Cogentin			
	(Benzatropine			
	Mesilate)	C		
	Narcan	C		
	Diazepam (Diazepam)	C		
	Baclofen (Baclofen)	C		
	Lorcet	C		
	Toradol (Ketorolac			
	Tromethamine)	C		
	Phenergan			
	(Promethazine			
	Hydrochloride)	C		
	E-Mycin			
	(Erythromycin)	C		
	Flovent (Fluticasone			
	Propionate)	C		
	Theo-Dur	C		
	Prednisone			
	(Prednisone)	C		
	Soma (Carisoprodol)	C		
	Proventil Inhaler			
	(Salutamol)	C		

Freedom Of Information (FOI) Report

Percocet Tablet C
Penicillin V-K
(Phenoxymethylpeni-
illin Potassium)
Tablet C

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Summary report for FOI selections:

Selection by inexact search of active ingredient:

CANNABINOIDS%

Selection by inexact search of Tradename/Verbatim:

CANNABINOIDS%

Total number of reports: 96

From: 01-NOV-1997 To: 30-JUN-2005

21-Jul-2006 12:29 PM

Page: 35