

FDA Adverse Event Reporting System (AERS)
 Freedom Of Information (FOI) Report

Date: 03/20/2000 ISR Number: 3478290-1 Report Type: Expedited (15-Day) Company Report Number: 97850 Age: 14 YR Gender: Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Life-Threatening	Abdominal Pain Upper	Consumer	Accutane Capsules (Isotretinoin) 40 Mg	PS		ORAL		
Hospitalization - Initial or Prolonged	Abnormal Behaviour Nos	Health Professional	Aleve (Naproxen Sodium)	C				
	Acne Aggravated	Other	Ibuprofen (Ibuprofen)	C				
	Alopecia		Tylenol (Acetaminophen)	C				
	Anaemia Nos							
	Anger							
	Anxiety Nec							
	Appetite Decreased							
	Arthralgia							
	Back Pain							
	Belligerence							
	Blood Calcium Decreased							
	Bulimia Nervosa							
	Cold Intolerance							
	Crying							
	Depression Nec							
	Dermatitis Nos							
	Dizziness (Exc Vertigo)							
	Dry Skin							
	Ecchymosis							
	Fatigue							
	Hand Fracture							
	Hypersomnia							
	Intentional Self-Injury							
	Irritability							
	Irritable Bowel Syndrome							
	Lip Dry							
	Localised Exfoliation							
	Mood Alteration Nos							
	Mouth Haemorrhage							
	Personality Change							
	Pressure Of Speech							
	Proteinuria Present							
	Pyrexia							
	Rigors							
	Skin Discolouration							
	Skin Hypopigmentation							
	Sore Throat Nos							
	Suicide Attempt							
	Thinking Abnormal Nec							

FDA Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report

Date:	ISR Number:	Report Type:	Company Report Number:	Age:	Gender:			
03/22/2000	3479072-7	Expedited (15-Day)	231514	52 YR	Female			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Abnormal Behaviour Nos Aggression Vein Disorder Nos	Foreign Other	Rosacutane (Isotretinoin)	PS		ORAL		
03/28/2000	3480831-5	Expedited (15-Day)	97850	14 YR	Female			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Life-Threatening	Abnormal Behaviour Nos	Consumer	Accutane Capsules (Isotretinoin) 40 Mg	PS		ORAL		
Hospitalization - Initial or Prolonged	Acne Aggravated Aggression Alcoholism Anaemia Nos Antisocial Behaviour Anxiety Nec Appetite Decreased Arthralgia Back Pain Belligerence Binge Eating Body Image Disorder Bulimia Nervosa Cheilitis Cold Intolerance Condition Aggravated Crying Depression Nec Dizziness (Exc Vertigo) Drug Abuse Dysthymic Disorder Eating Disorder Nec Fear, Focus Nec Haemorrhage Nos Headache Nos Hypersomnia Injury Nos Intentional Self-Injury Irritability Inritable Bowel Syndrome Lip Dry Mood Alteration Nos Mood Disorder Nos	Health Professional Other	Aleve (Naproxen Sodium) Ibuprofen (Ibuprofen) Tylenol (Acetaminophen) Effexor (Venlafaxine Hydrochloride) Prozac (Fluoxetine Hydrochloride)	C C C C C				

FDA Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report

Date:	ISR Number:	Report Type:	Company Report Number:	Age:	Gender:			
03/30/2000	3482155-9	Expedited (15-Day)	232009	15 YR	Male			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Hospitalization - Initial or Prolonged	Abnormal Behaviour Nos Increased Activity Mania Psychotic Disorder Nos	Consumer	Accutane Capsules (Isotretinoin) 40 Mg	PS		ORAL		
03/30/2000	3482168-7	Expedited (15-Day)	205301	17 YR	Female			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Ankylosing Spondylitis Antinuclear Factor Positive Appetite Decreased Arthralgia Arthritis Nos Blood Alkaline Phosphatase Nos Decreased Depression Nec Dermatitis Nos Dry Mouth Dry Skin Erythrocyte Sedimentation Rate Increased Fatigue Herpes Simplex Joint Stiffness Joint Swelling Myalgia Nausea Polyarthritits Acute Pyrexia Rash Erythematous Red Blood Cell Count Decreased Rigors Skin Irritation Sore Throat Nos Sweating Increased Synovitis Upper Respiratory Tract Infection Nos Weight Decreased	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL		

FDA Adverse Event Reporting System (AERS)
 Freedom Of Information (FOI) Report

Date: 03/31/2000	ISR Number: 3482861-6	Report Type: Expedited (15-Day)	Company Report Number: 231204	Age: 21 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Anxiety Nec Hypertension Nos Liver Function Tests Nos Abnormal Transaminase Nos Increased	Consumer Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL		
Date: 03/31/2000	ISR Number: 3482872-0	Report Type: Expedited (15-Day)	Company Report Number: 227877	Age: 16 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Collapse Delirium Dyspnoea Nos Stridor Vocal Cord Disorder Nos	Consumer	Accutane Capsules (Isotretinoin) 40 Mg	PS		ORAL		
Date: 04/04/2000	ISR Number: 3483866-1	Report Type: Direct	Company Report Number:	Age: 15 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Drug Toxicity Nos Mania Psychotic Disorder Nos		Accutane 40mg /(Roche)	PS	Roche			
Date: 04/03/2000	ISR Number: 3484059-4	Report Type: Expedited (15-Day)	Company Report Number: 210608	Age: 16 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Upper Activated Partial Thromboplastin Time Shortened	Other	Accutane Capsules (Isotretinoin)	PS		ORAL		
Required Intervention to Prevent Permanent Impairment/Damage	Back Pain Bipolar Disorder Nec Cheilitis Coma Nec Conjunctivitis Nec Crying Cystitis Acute Nos Depression Nec Dermatitis Exfoliative Nos Dysarthria Dyspepsia Dysuria Fatigue Fibula Fracture Gait Abnormal Nos		Paxil (Paroxetine) Differin (Adapalene) Oral Contraceptive Nos Claritin (Loratadine) Nasacort (Triamcinolone Acetonide)	C C C C C				

08/03/2000

FD-302 (Rev. 1-27-2003) (Continued)
 Part B - Adverse Event Reporting System (AERS)
 Program Of Information (POI) Report

Date: 04/03/2000 ISR Number: 3484073-9 Report Type: Expedited (15-Day) Company Report Number: 232350 Age: 18.YR Gender: Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Anger Delusion Nos Depression Nec Neurotransmitter Level Altered Paranoia Short-Term Memory Loss Thinking Abnormal Nec	Consumer	Accutane Capsules (Isotretinoin)	PS		ORAL		

Date: 04/03/2000 ISR Number: 3484074-0 Report Type: Expedited (15-Day) Company Report Number: 205301 Age: 17.YR Gender: Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Antinuclear Factor Positive Appetite Decreased Arthralgia Blood Alkaline Phosphatase Nos Decreased Depression Nec Dermatitis Nos Dna Antibody Nos Positive Dry Mouth Dry Skin Erythrocyte Sedimentation Rate Increased Fatigue Herpes Simplex Joint Stiffness Joint Swelling Myalgia Nausea Polyarthritits Acute Pyrexia Rash Erythematous Rigors Skin Irritation Sore Throat Nos Synovitis Tenderness Nos Upper Respiratory Tract Infection Nos Weight Decreased White Blood Cell Count Decreased	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL		

FDA Adverse Event Reporting System (AERS)
Freedom Of Information FOI Report

Date: 04/06/2000	ISR Number: 3484609-8	Report Type: Expedited (15-Day)	Company Report Number: 231514	Age: 52 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Abnormal Behaviour Nos Physical Assault Vein Disorder Nos	Foreign Other	Roaccutane (Isotretinoin)	PS		ORAL		
Date: 04/06/2000	ISR Number: 3484858-9	Report Type: Expedited (15-Day)	Company Report Number: 232575	Age: 16 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Bulimia Nervosa Depression Nec Emotional Disturbance Nos Fatigue Personality Change Suicidal Ideation	Consumer Other	Accutane Capsules (Isotretinoin) Oral Contraceptive Nos	PS C		ORAL		
Date: 04/07/2000	ISR Number: 3485896-2	Report Type: Expedited (15-Day)	Company Report Number: 227877	Age: 16 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Acne Aggravated Collapse Delirium Dyspnoea Nos Stridor Vocal Cord Disorder Nos	Consumer	Accutane Capsules (Isotretinoin) 40 Mg	PS		ORAL		
Date: 04/11/2000	ISR Number: 3486850-7	Report Type: Expedited (15-Day)	Company Report Number: 227868	Age: 18 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec Fatigue Oedema Upper Limb Skin Discolouration Venous Thrombosis Nos	Health Professional	Accutane Capsules (Isotretinoin) 40 Mg	PS		ORAL		
Date: 04/11/2000	ISR Number: 3486893-3	Report Type: Expedited (15-Day)	Company Report Number: 232009	Age: 15 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Abnormal Behaviour Nos Acute Psychosis Bipolar I Disorder Drug Induced Psychosis Increased Activity Mania	Consumer Health Professional	Accutane Capsules (Isotretinoin) 40 Mg	PS		ORAL		

08/03/2000

FDA Adverse Event Reporting System (AERS)
 Freedom Of Information (FOI) Report

Date: 04/13/2000		ISR Number: 3488405-7		Report Type: Expedited (15-Day)		Company Report Number: 228372		Age: 17 YR		Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Other	Arthralgia	Foreign	Accutane	PS		ORAL					
	Blood Creatine Phosphokinase Increased	Consumer									
	C-Reactive Protein Increased	Health Professional									
	Decreased Activity										
	Erythema Nec										
	Erythema Nodosum										
	Erythrocyte Sedimentation Rate Increased										
	Feeling Hot										
	Headache Nos										
	Influenza Like Illness										
	Leucopenia Nos										
	Liver Function Tests Nos Abnormal										
	Myalgia										
	Oedema Lower Limb										
	Panniculitis										
	Pyrexia										
	Rash Maculo-Papular										
	Rigors										
	Skin Disorder Nos										
	Sore Throat Nos										
	Vasculitis Necrotising										
Date: 04/13/2000		ISR Number: 3488406-9		Report Type: Expedited (15-Day)		Company Report Number: 232575		Age: 16 YR		Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Other	Bulimia Nervosa	Consumer	Accutane (Isotretinoin)	PS		ORAL					
	Depression Nec	Other	Oral Contraceptive	C							
	Emotional Disturbance Nos										
	Fatigue										
	Personality Change										
	Suicidal Ideation										
Date: 04/13/2000		ISR Number: 3488412-4		Report Type: Expedited (15-Day)		Company Report Number: 231302		Age: 19 YR		Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Other	Asthenia	Foreign	Roaccutane (Isotretinoin)	PS		ORAL					
	Cheilitis	Health Professional									
	Diarrhoea Nos										
	Haemorrhage Nos										

FDA Adverse Event Reporting System (FAERS)
Freedom of Information (FOI) Report

Date: 04/14/2000 ISR Number: 3488425-2 Report Type: Direct Company Report Number: Age: 29 YR Gender: Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Life-Threatening	Abrasion Nos		Accutane	PS		ORAL		
Disability	Arthralgia							
Other	Back Pain							
Required Intervention to Prevent Permanent Impairment/Damage	Blister							
	Blood Glucose Increased							
	Bone Pain							
	Burning Sensation Nos							
	Cheilitis							
	Dermatitis Nos							
	Dry Eye Nec							
	Dry Skin							
	Dysphonia							
	Eczema Nos							
	Eye Disorder Nos							
	Eye Pain							
	Eyelid Disorder Nos							
	Fatigue							
	Gingival Bleeding							
	Gingivitis Infection Nos							
	Hoarseness							
	Hypercholesterolaemia							
	Hypertriglyceridaemia							
	Impaired Healing							
	Increased Tendency To Bruise							
	Inflammation Nos							
	Keratitis Nec							
	Localised Exfoliation							
	Low Density Lipoprotein Increased							
	Menstrual Disorder Nos							
	Mucosal Dryness Nos							
	Muscle Spasms							
	Myalgia							
	Neoplasm Nos							
	Neuralgia Nos							
	Osteoarthritis Nos							
	Periodontal Disorder Nos							
	Photophobia							
	Photosensitivity Reaction Nos							
	Scab							

FDA Adverse Event Reporting System (AERS)
Summary of Individual Case Reports

Date: 04/18/2000		ISR Number: 3489907-X		Report Type: Expedited (15-Day)		Company Report Number: 232009		Age: 15 YR		Gender: Male	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>			
Hospitalization - Initial or Prolonged	Abnormal Behaviour Nos Acute Psychosis Bipolar I Disorder Increased Activity Mania	Consumer Health Professional	Accutane Capsules (Isotretinoin) 40 Mg	PS		ORAL					
Date: 04/21/2000		ISR Number: 3490971-2		Report Type: Expedited (15-Day)		Company Report Number: 229463		Age: 39-YR		Gender: Female	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>			
Other	Constipation Depression Nec Menstrual Disorder Nos Premature Menopause	Consumer Other	Accutane Capsules (Isotretinoin) Birth Control Pill (Oral Contraceptive Nos)	PS C		ORAL					
Date: 04/21/2000		ISR Number: 3491282-1		Report Type: Expedited (15-Day)		Company Report Number: 233882		Age: 20 YR		Gender: Female	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>			
Other	Condition Aggravated Obsessive-Compulsive Disorder	Foreign Health Professional	Roaccutane (Isotretinoin)	PS		ORAL					
Date: 04/26/2000		ISR Number: 3493498-7		Report Type: Expedited (15-Day)		Company Report Number: 232575		Age: 16 YR		Gender: Female	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>			
Other	Bulimia Nervosa Depression Nec Eating Disorder Nec Emotional Disturbance Nos Fatigue Personality Change Suicidal Ideation	Consumer Other	Accutane Capsules (Isotretinoin) Oral Contraceptives Nos (Oral Contraceptive Nos)	PS C		ORAL					
Date: 04/27/2000		ISR Number: 3493659-7		Report Type: Expedited (15-Day)		Company Report Number: PRIUSA2000001841		Age: 35 YR		Gender: Female	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>			
Hospitalization - Initial or Prolonged	Anxiety Nec Blood Creatine Phosphokinase Increased Blood Creatine Phosphokinase Mb Increased Cardiac Enzymes Increased Chest Pain Coronary Artery Disease Nos Myocardial Infarction	Consumer	Ortho Tri-Cyclen (Tablet) (Norgestimate/Ethinylestradiol) Accutane (Isotretinoin)	PS SS		ORAL ORAL					

08/03/2000

FDA Adverse Event Reporting System (FAERS)
Freedom Of Information (FOI) Report

Date: 05/05/2000		ISR Number: 3496981-3		Report Type: Expedited (15-Day)		Company Report Number: 232575		Age: 16 YR		Gender: Female	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>			
Other	Bulimia Nervosa	Consumer	Accutane Capsules (Isotretinoin)	PS		ORAL					
	Depression Nec	Health Professional	Oral Contraceptive Nos	C							
	Emotional Disturbance Nos	Other									
	Fatigue										
	Lip Dry										
	Personality Change										
	Suicidal Ideation										
Date: 05/05/2000		ISR Number: 3497056-X		Report Type: Expedited (15-Day)		Company Report Number: 234968		Age: 35 YR		Gender: Female	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>			
Other	Agitation	Consumer	Accutane Capsules (Isotretinoin)	PS		ORAL					
	Anxiety Nec		Loestrin (Ethinyl Estradiol / Norethindrone Acetate)	C							
	Blood Pressure Increased										
	Blood Thyroid Stimulating Hormone Decreased										
	Congenital Pyloric Stenosis										
	Dry Skin										
	Dyspnoea Nos										
	Headache Nos										
	Hyperthyroidism										
	Muscle Cramps										
	Pregnancy Nos										
	Rash Pruritic										
	Tachycardia Nos										
	Tri-Iodothyronine Increased										
	Weakness										
Date: 05/05/2000		ISR Number: 3497185-0		Report Type: Direct		Company Report Number:		Age: 12 YR		Gender: Female	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>			
Hospitalization - Initial or Prolonged	Agitation		Accutane	PS							
	Anger		Erythromycin	C							
	Disorientation										
	Hallucination Nos										
	Psychotic Disorder Nos										
Date: 05/08/2000		ISR Number: 3498104-3		Report Type: Expedited (15-Day)		Company Report Number: PRIUSA2000001841		Age: 35 YR		Gender: Female	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>			
Hospitalization - Initial or Prolonged	Anxiety Nec	Consumer	Ortho Tri-Cyclen	PS	Rw Johnson Pharmaceutical Research Institute Div Ortho Pharm	ORAL					
	Arterial Disorder Nos										
	Blood Creatine Phosphokinase										

08/03/2000

FDA Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report

Date	ISR Number	Report Type	Company Report Number	Age	Gender			
05/08/2000	3498235-8	Expedited (15-Day)	234822	44 YR	Female			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Disability	Amnesia Nec Bipolar I Disorder Feeling Abnormal Irritability Seborrhoea Suicidal Ideation	Consumer	Accutane Capsules (Isotretinoin)	PS		ORAL		
05/08/2000	3498539-9	Expedited (15-Day)	232412	21 YR	Female			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Disability	Crying Depression Nec Disturbance In Attention Nec Sedation	Health Professional Other	Accutane Capsules (Isotretinoin) Birth Control Pill (Oral Contraceptive Nos)	PS C		ORAL		
05/08/2000	3498541-7	Expedited (15-Day)	213686	30 YR	Female			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Required Intervention to Prevent Permanent Impairment/Damage	Cerebrovascular Disorder Nos Hypoesthesia Memory Impairment Paraesthesia Nec Visual Disturbance Nos	Health Professional	Accutane Capsules	PS	Hlr Technology	ORAL		
05/08/2000	3498542-9	Expedited (15-Day)	92720	16 YR	Female			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Hospitalization - Initial or Prolonged Disability Required Intervention to Prevent Permanent Impairment/Damage	Benign Intracranial Hypertension Blindness Nec Blood Triglycerides Increased Decreased Activity Haemorrhage Nos Headache Nos Hypertiglyceridaemia Migraine Nos Nausea Papilloedema Retinal Haemorrhage Swelling Nos Tension Headaches Tinnitus Vision Blurred	Health Professional	Accutane Capsules (Isotretinoin) Triphasil (Ethinyl Estadiol/Levonorgestrel) Maxair (Firbuterol Acetate) Tylenol (Acetaminophen)	PS C C C	Hlr Technology	ORAL		

08/03/2000

FDA Adverse Event Reporting System (FAERS)
 Patient Information (PI) Report

Date: 05/08/2000		ISR Number: 3498543-0		Report Type: Expedited (15-Day)		Company Report Number: 209062		Age: 42 YR		Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Other	Condition Aggravated	Consumer	Accutane Capsules (Isotretinoin)	PS		ORAL					
	Deafness Nos	Health Professional	Birth Control Pills (Oral Contraceptive Nos)	C							
	Dry Eye Nec	Other	Calcium Supplement (Calcium Nos)	C							
	Localised Exfoliation		Zinc (Bisoprolol Fumarate/Hydrochlorothiazide)	C							
	Paranoia		Potassium (Potassium)	C							
	Red Eye		Zantac (Ranitidine)	C							
Date: 05/08/2000		ISR Number: 3498544-2		Report Type: Expedited (15-Day)		Company Report Number: 223642		Age: 16 YR		Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Hospitalization - Initial or Prolonged	Abdominal Pain Nos	Consumer	Accutane Capsules (Isotretinoin)	PS		ORAL					
Required Intervention to Prevent Permanent Impairment/Damage	Back Pain	Other									
	Blister										
	Decreased Activity										
	Depression Nec										
	Fatigue										
	Gastritis Nos										
	Gastrointestinal Disorder Nos										
	Lip Dry										
	Malaise										
	Markedly Reduced Food Intake										
	Mouth Haemorrhage										
	Myalgia										
	Ovarian Cyst										
	Ovarian Neoplasm Nos										
	Pain Nos										
	Weight Decreased										
Date: 05/10/2000		ISR Number: 3498976-2		Report Type: Expedited (15-Day)		Company Report Number: 235209		Age: 40 YR		Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Other	Aspartate Aminotransferase Increased	Consumer	Accutane Capsules (Isotretinoin)	PS		ORAL					
	Blood Alkaline Phosphatase Nos Increased		Depo-Provera (Medroxyprogesterone Acetate)	C							
	Blood Carbon Dioxide Decreased										
	Blood Triglycerides Increased										
	Depression Nec										
	Dyspnoea Nos										

FDA Adverse Event Reporting System (AERS)
 Division of Information (DID) Report

Date: 05/10/2000 ISR Number: 3498990-7 Report Type: Expedited (15-Day) Company Report Number: 231499 Age: 15 YR Gender: Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged Disability	Abdominal Pain Nos Appetite Disorder Nos Crohn'S Disease	Health Professional	Accutane Capsules (Isotretinoin) 40 Mg	PS		ORAL		
Required Intervention to Prevent Permanent Impairment/Damage	Gastrointestinal Disorder Nos Gastrointestinal Necrosis Haematemesis Ileal Stenosis Ileus Intestinal Ischaemia Malaise Mallory-Weiss Syndrome Oedema Nos Scar Small Intestinal Obstruction Nos Vomiting Nos							

Date: 05/10/2000 ISR Number: 3498996-8 Report Type: Expedited (15-Day) Company Report Number: 222459 Age: Gender: Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Congenital Anomaly	Anomaly Of External Ear Congenital Nos	Consumer	Accutane Capsules (Isotretinoin)	PS		ORAL		
Required Intervention to Prevent Permanent Impairment/Damage	Apnoea Atelectasis Blindness Congenital Cardiac Disorder Nos Complications Of Maternal Exposure To Therapeutic Drugs Congenital Central Nervous System Anomaly Nos Congenital Heart Disease Nos Convulsions Nos Crying Cyanosis Nos Deafness Conductive (Exc Otosclerosis) Disorder Neonatal Nos Erythema Nec Extraocular Muscle Paresis Eye Deformity Congenital Nos Eye Movement Disorder Nos Facial Dysmorphism Feeding Disorder Of Infancy Or	Health Professional Other						

Adverse Event Reporting System (AERS)
Freedom of Information (FOI) Report

Date: 05/10/2000 ISR Number: 3498999-3 Report Type: Expedited (15-Day) Company Report Number: 223654 Age: 32 YR Gender: Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Abdominal Distension	Consumer	Accutane Capsules (Isotretinoin) 10 Mg	PS		ORAL		
	Abdominal Pain Nos		Imitrex (Sumatriptan Succinate)	C				
	Depression Nec							
	Ovarian Cyst							
	Ovarian Cyst Ruptured							
	Scar							

Date: 05/11/2000 ISR Number: 3499626-1 Report Type: Expedited (15-Day) Company Report Number: 202578 Age: Gender: Male

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Congenital Anomaly	Antepartum Haemorrhage	Consumer	Accutane	PS	Hlr Technology	ORAL		
	Appetite Decreased	Health Professional						
	Bladder Disorder Nos							
	Bronchiolitis							
	Cervical Incompetence							
	Chorioamnionitis							
	Complications Of Maternal							
	Exposure To Therapeutic Drugs							
	Congenital Ureteric Anomaly							
	Nos							
	Cough							
	Crying							
	Disorder Neonatal Nos							
	Feeding Disorder Nos							
	Hydroureter							
	Insomnia Nec							
	Irritability							
	Nasal Congestion							
	Pharyngitis Streptococcal							
	Pregnancy Nos							
	Pyrexia							
	Rash Papular							
	Renal Disorder Nos							
	Rhinorrhoea							
	Scarlet Fever							
	Sleep Disorder Nos							
	Tonsillitis Nos							
	Twin Pregnancy							
	Ultrasound Scan Nos Abnormal							
	Umbilical Cord Vascular							
	Disorder							
	Ureteric Obstruction							

FDA Adverse Event Reporting System (AERS)
Freedom of Information (FOI) Report

Date: 05/12/2000		ISR Number: 3500100-4		Report Type: Expedited (15-Day)		Company Report Number: 231006		Age:		Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Other	Back Pain	Consumer	Accutane	PS	HlrTechnology	ORAL					
	Blood Cholesterol Increased										
	Blood Triglycerides Increased		Zoloft (Sertraline Hydrochloride)	SS		ORAL					
	Chest Pain		Tenormin (Atenolol)	C							
	Condition Aggravated										
	Cyst Nos										
	Dry Skin										
	Dysphonia										
	Irritability										
	Nervousness										
	Panic Attack										
Date: 05/16/2000		ISR Number: 3501251-0		Report Type: Expedited (15-Day)		Company Report Number: 235626		Age: 10 YR		Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Hospitalization - Initial or Prolonged	Amnesia Nec	Consumer	Accutane	PS	HlrTechnology	ORAL					
	Anger	Health Professional									
	Catatonia										
	Confusion										
	Crying										
	Depression Nec										
	Emotional Disturbance Nos										
	Hallucination, Auditory										
	Irritability										
	Malaise										
	Mood Swings										
	Suicidal Ideation										
	Violence-Related Symptom										
Date: 05/16/2000		ISR Number: 3501257-1		Report Type: Expedited (15-Day)		Company Report Number: 234803		Age: 15 YR		Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Other	Accident Nos	Health Professional	Accutane	PS	HlrTechnology	ORAL					
	Benign Intracranial Hypertension										
	Blindness Night										
	Csf Pressure Increased										
	Dysarthria										
	Head Injury										
	Headache Nos										
	Hypoesthesia										

FDA Adverse Event Reporting System (AERS)
Freedom of Information (FOI) Report

Date:	ISR Number:	Report Type:	Company Report Number:	Age:	Gender:			
05/16/2000	3501281-9	Expedited (15-Day)	230859	13 YR	Male			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Hospitalization - Initial or Prolonged	Abnormal Behaviour Nos Acne Aggravated Blood Alkaline Phosphatase Nos Increased Diabetes Mellitus Nos Hyperglycaemia Nos Hypertiglyceridaemia	Health Professional	Accutane	PS	HlrTechnology	ORAL		
05/19/2000	3502063-4	Expedited (15-Day)	235788	17 YR	Male			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Hospitalization - Initial or Prolonged	Abnormal Behaviour Nos Bacterial Infection Nos Csf Abnormal Nos Csf Protein Increased Encephalitis Nos Headache Nos Hearing Impaired Herpes Simplex Mastoiditis Nos Neck Stiffness Nuclear Magnetic Resonance Imaging Abnormal Otitis Media Nos Sinusitis Acute Nos Syncope Toxicology Nos Abnormal Tympanic Membrane Disorder Nos	Health Professional	Accutane	PS	HlrTechnology	ORAL		
05/19/2000	3502073-7	Expedited (15-Day)	222246		Male			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Appetite Decreased Complication Of Delivery Nos Complications Of Maternal Exposure To Therapeutic Drugs Constipation Depression Nec Disorder Neonatal Nos Fatigue Feeding Problem In Newborn Gastrointestinal Motility	Health Professional Other	Accutane Oral Contraceptive Pill (Oral Contraceptive Nos) Vitamins (Multivitamin Nos)	PS C C	HlrTechnology	ORAL		

08/03/2000

FDA Adverse Event Reporting System (AERS)
 Part of Ocular (PO) Report

Date: 05/19/2000 ISR Number: 3502086-5 Report Type: Expedited (15-Day) Company Report Number: 233962 Age: 25 YR Gender: Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Abdominal Pain Nos	Foreign	Accutane	PS	Hlr Technology	ORAL		
	Asthenia	Health Professional	Doxigram (Doxycycline Hyclate) 100 Mg	SS				
	Constipation							
	Drug Interaction Nos							
	Headache Nos							
	Nausea							
	Smear Cervix Abnormal							
	Vaginal Infection Nos							
	Visual Acuity Reduced							
	Vomiting Projectile							

Date: 05/17/2000 ISR Number: 3502346-8 Report Type: Expedited (15-Day) Company Report Number: 223642 Age: 15 YR Gender: Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Nos	Consumer	Accutane	PS	Hlr Technology	ORAL		
Required Intervention to Prevent Permanent Impairment/Damage	Anorexia	Health Professional						
	Appendicitis	Other						
	Back Pain							
	Blister							
	Decreased Activity							
	Depression Nec							
	Dermoid Cyst Of Ovary							
	Dysmenorrhoea							
	Epistaxis							
	Fatigue							
	Gastritis Nos							
	Gastrointestinal Disorder Nos							
	Lip Dry							
	Malaise							
	Mouth Haemorrhage							
	Myalgia							
	Nausea							
	Ovarian Cyst							
	Pain Nos							
	Pelvic Pain Nos							
	Teratoma Nos							
	Weight Decreased							

FDA Adverse Event Reporting System (AERS)
 Freedom of Information (FOI) Report

Date: 05/17/2000 ISR Number: 3502356-0 Report Type: Expedited (15-Day) Company Report Number: 235549 Age: 18 YR Gender: Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Life-Threatening	Abdominal Pain Upper	Consumer	Accutane	PS	Hlr Technology	ORAL		
	Abnsion Nos	Health Professional						
	Acute Circulatory Failure	Other						
	Alopecia							
	Anxiety Nec							
	Appetite Decreased							
	Blood Cholesterol Increased							
	Collapse							
	Convulsions Nos							
	Depression Nec							
	Diarrhoea Nos							
	Dizziness (Exc Vertigo)							
	Dry Eye Nec							
	Dry Skin							
	Dyspnoea Nos							
	Epistaxis							
	Face Oedema							
	Fatigue							
	Gastrointestinal Disorder Nos							
	Haemorrhage Nos							
	Heart Rate Increased							
	Hot Flashes Nos							
	Hyperventilation							
	Hypoglycaemia Nos							
	Ingrowing Nail							
	Loss Of Consciousness Nec							
	Migraine Nos							
	Mood Alteration Nos							
	Muscle Disorder Nos							
	Musculoskeletal Pain							
	Nail Disorder Nos							
	Nausea							
	Nervousness							
	Pain In Limb							
	Pallor							
	Petit Mal Epilepsy							
	Post-Traumatic Stress Disorder							
	Protein Total Decreased							
	Pruritus							
	Rash Erythematous							

FDA Adverse Event Reporting System (AERS)
Division Of Information (DID) Report

Date: 05/17/2000		ISR Number: 3502403-6		Report Type: Expedited (15-Day)		Company Report Number: 235886		Age: 29 YR		Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Other	Blepharitis Depression Nec	Foreign Health Professional	Accutane	PS	Hlr Technology	ORAL					
Date: 05/17/2000		ISR Number: 3502405-X		Report Type: Expedited (15-Day)		Company Report Number: 228163		Age: 83 YR		Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Death	Dementia Nos Aggravated	Foreign	Tasmar	PS	Hoffmann La Roche Inc	ORAL					
Hospitalization - Initial or Prolonged	Pneumonia Nos	Health Professional	Madopar Dr (Benserazide/Levodopa) Ferrum Hausmann Voltaren (Diclofenac Sodium) Lasix (Furosemide)	C C C C							
Date: 05/17/2000		ISR Number: 3502858-7		Report Type: Expedited (15-Day)		Company Report Number: 235909		Age: 33 YR		Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Other	Acne Aggravated Chest Pain Dry Skin Dysphagia Erythema Nec Markedly Reduced Food Intake Oesophageal Ulcer Weight Decreased	Consumer	Accutane Capsules (Isotretinoin) 20 Mg Imitrex (Sumatriptan Succinate) Carafate (Sucralfate)	PS C C	Hlr Technology	ORAL					
Date: 05/22/2000		ISR Number: 3503147-7		Report Type: Expedited (15-Day)		Company Report Number: 236020		Age: 16 YR		Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Other	Delirium	Foreign Consumer	Accutane	PS	Hlr Technology	ORAL					
Date: 05/23/2000		ISR Number: 3503849-2		Report Type: Expedited (15-Day)		Company Report Number: 224469		Age: 32 YR		Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Disability	Cerebrovascular Accident Nos Headache Nos Hemiparesis Memory Impairment Speech Disorder Nec Vertigo Nec	Consumer	Accutane	PS	Hlr Technology	ORAL					

U.S. Adverse Event Reporting System (AERS)
 Freedom Of Information (FOI) Report

Date:	ISR Number:	Report Type:	Company Report Number:	Age:	Gender:			
05/25/2000	3504227-2	Direct		17 YR	Male			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Required Intervention to Prevent Permanent Impairment/Damage	Arthralgia Back Pain Bone Pain Decreased Activity Dermatitis Nos Difficulty In Walking Dry Skin Headache Nos Pain Nos Rash Erythematous Rash Pruritic Scar Subcutaneous Haematoma		Accutane	PS				
05/26/2000	3505623-X	Periodic	234231	57 YR	Male			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Difficulty In Walking Fall Gait Abnormal Nos Headache Nos Insomnia Nec Weakness	Consumer Health Professional	Tasmart Sinemet (Carbidopa/Levodopa) Paramax (Acetaminophen/Metoclopramide Hydrochloride)	PS C C	Hoffmann La Roche Inc	ORAL		
05/30/2000	3506397-9	Expedited (15-Day)	236836	16 YR	Male			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Aggression Mental Disorder Nec Sedation	Foreign Study Health Professional	Accutane	PS	Hlr Technology	ORAL		
05/30/2000	3506399-2	Expedited (15-Day)	920500422001	17 YR	Male			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Death Life-Threatening	Asthenia Completed Suicide Drug Maladministration Mental Disorder Nec Thinking Abnormal Nec	Foreign Literature Health Professional	Accutane	PS	Hlr Technology	ORAL		

FDA Adverse Event Reporting System (AERS)
 Freedom Of Information (FOI) Report

Date: 05/31/2000		ISR Number: 3506617-0		Report Type: Expedited (15-Day)		Company Report Number: 235788		Age: 17 YR		Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Hospitalization - Initial or Prolonged	Abnormal Behaviour Nos Bipolar Disorder Nec Condition Aggravated Cof Abnormal Nos Cof Protein Increased Drug Abuse Ear Disorder Nos Encephalitis Nos Headache Nos Hearing Impaired Herpes Simplex Mastoiditis Nos Neck Stiffness Nuclear Magnetic Resonance Imaging Abnormal Otitis Media Nos Sinusitis Acute Nos Syncope	Health Professional	Accutane	PS	Hlr Technology	ORAL					
Date: 06/02/2000		ISR Number: 3507781-X		Report Type: Expedited (15-Day)		Company Report Number: 229463		Age: 39 YR		Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Other	Constipation Depression Nec Dry Eye Nec Epimenorrhoea Menstrual Disorder Nos Premature Menopause	Consumer Other	Accutane Birth Control Pill (Oral Contraceptive Noc)	PS C	Hlr Technology	ORAL					
Date: 06/02/2000		ISR Number: 3507783-3		Report Type: Expedited (15-Day)		Company Report Number: 236836		Age: 16 YR		Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Other	Aggression Insomnia Nec Irritability Mental Disorder Nec Sedation	Foreign Study Health Professional	Accutane	PS	Hlr Technology	ORAL					
Date: 06/02/2000		ISR Number: 3508083-8		Report Type: Expedited (15-Day)		Company Report Number: JACGER2000000746		Age: 67 YR		Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Hospitalization - Initial or Prolonged	Drug Maladministration Extrapyramidal Disorder Nec	Foreign	Halidol	PS	Rw Johnson Pharmaceutical Research	INTRAVEN OUS DRIP					

08/03/2000

FDA Adverse Event Reporting System (AERS)
Freedom of Information Act Report

Date: 06/02/2000		ISR Number: 3508083-8		Report Type: Expedited (15-Day)		Company Report Number: 200000466		Route	Dose/Unit	Duration
PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Drug Maladministration	Health Professional	Haldol	PS	Rw Johnson Pharmaceutical Research Institute	INTRAVEN OUS DRIP					
Extrapyramidal Disorder Nec		Alosil (Isopromethazine Hydrochloride)	SS		INTRAVEN OUS DRIP					
Psychotic Disorder Nos		Tasmar (Tolcapone)	SS		ORAL					
Sedation		Dopergin (Lisuride Maleate)	SS		ORAL					
		Amantadin (Amantadine Hydrochloride)	SS		ORAL					
		Striaton (Sinemet)	SS		ORAL					
Date: 06/05/2000		ISR Number: 3508628-8		Report Type: Expedited (15-Day)		Company Report Number: 229463		Age: 39 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration		
Other	Constipation	Consumer	Accutane	PS	Hlr Technology	ORAL				
	Depression Nec	Health Professional	Birth Control Pill (Oral Contraceptive Nos)	C						
	Dry Eye Nec	Other								
	Menstrual Disorder Nos									
	Premature Menopause									
Date: 06/07/2000		ISR Number: 3509554-0		Report Type: Direct		Company Report Number:		Age: 52 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration		
Disability	Arthralgia		Accutane	PS	Hoffmann-La Roche Inc					
	Decreased Activity		Advil	C						
	Dermatitis Nos									
	Difficulty In Walking									
	Pigmentation Disorder Nos									
Date: 06/08/2000		ISR Number: 3510578-8		Report Type: Expedited (15-Day)		Company Report Number: 236644		Age: 71 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration		
Hospitalization - Initial or Prolonged	Activated Partial Thromboplastin Time Prolonged	Foreign	Tasmar	PS	Hoffmann La Roche Inc					
Required Intervention to Prevent Permanent Impairment/Damage	Atioventricular Block First Degree	Health Professional	Madopar Dr (Benserazide / Levodopa) 250 Mg	SS		ORAL				
	Atioventricular Block Nos		Permax (Pergolide Mesylate)	C						
	Confusion		Motilium (Domperidone)	C						
	Depression Nec		Gutron (Midodrine Hydrochloride)	C						
	Disorientation		Importal (Lactitol)	C						
	Dizziness Postural									
	Dystonia									
	Erythropenia									
	Haematocrit Decreased									

FDA - Adverse Event Reporting System (AERS)
 Division of Information (DID) Report

Date: 06/08/2000		ISR Number: 3511041-0		Report Type: Expedited (15-Day)		Company Report Number: 235886		Age: 18 YR		Gender: Male	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>			
Other	Blepharitis Depression Nec Irritability	Foreign Health Professional	Accutane	PS	Hlr Technology	ORAL					
Date: 06/12/2000		ISR Number: 3512002-8		Report Type: Expedited (15-Day)		Company Report Number: 235626		Age: 10 YR		Gender: Female	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>			
Hospitalization - Initial or Prolonged	Amnesia Nec Anger Catatonia Confusion Crying Depression Nec Emotional Disturbance Nos Fear, Focus Nec Hallucination, Auditory Irritability Malaise Mood Swings Suicidal Ideation Violence-Related Symptom	Consumer Health Professional	Accutane	PS	Hlr Technology	ORAL					
Date: 06/12/2000		ISR Number: 3512005-3		Report Type: Expedited (15-Day)		Company Report Number: 233882		Age: 19 YR		Gender: Female	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>			
Other	Condition Aggravated Depression Nec Fatigue Obsessive-Compulsive Disorder	Foreign Health Professional Other	Accutane Cycleane 20 (Desogestrel/Ethinyl Estradiol) Rhinathiol(Carbocysteine) Agram Oral (Amoxicillin) Ponstyl (Mefenamic Acid)	PS C C C C	Hlr Technology	ORAL					
Date: 06/12/2000		ISR Number: 3512007-7		Report Type: Expedited (15-Day)		Company Report Number: 237445		Age: 40 YR		Gender: Female	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>			
Other	Agoraphobia Anxiety Nec Crying Panic Attack	Foreign Health Professional Other	Accutane	PS	Hlr Technology	ORAL					

08/03/2000

FDA Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report

Date: 06/12/2000

ISR Number: 3512119-8

Report Type: Expedited (15-Day)

Company Report Number: 235549

Age: 18 YR

Gender: Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Life-Threatening	Abdominal Pain Upper	Consumer	Accutane	PS	Hlr Technology	ORAL		
	Acute Circulatory Failure	Health Professional						
	Alopecia	Other						
	Anxiety Nec							
	Appetite Decreased							
	Blood Cholesterol Increased							
	Collapse							
	Convulsions Nos							
	Depression Nec							
	Dermatitis Nos							
	Diarhoea Nos							
	Dizziness (Exc Vertigo)							
	Dry Eye Nec							
	Dry Skin							
	Dyspnoea Nos							
	Electroencephalogram Abnormal							
	Epistaxis							
	Face Oedema							
	Fatigue							
	Gastrointestinal Disorder Nos							
	Haemorrhage Nos							
	Heart Rate Increased							
	Hot Flashes Nos							
	Hyperventilation							
	Hypoglycaemia Nos							
	Lip Dry							
	Loss Of Consciousness Nec							
	Migraine Nos							
	Mood Swings							
	Muscle Injury Nos							
	Musculoskeletal Pain							
	Nail Disorder Nos							
	Nausea							
	Nervousness							
	Fallor							
	Palpitations							
	Petit Mal Epilepsy							
	Post-Traumatic Stress Disorder							
	Protein Total Decreased							
	Pruritus							

08/03/2000

FDA Adverse Event Reporting System (AERS)
Freedom of Information (FOI) Report

Date:	ISR Number:	Report Type:	Company Report Number:	Age:	Gender:			
06/12/2000	3512123-X	Expedited (15-Day)	232009	15 YR	Male			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Hospitalization - Initial or Prolonged	Abnormal Behaviour Nos Bipolar I Disorder Depression Nec Educational Problem Increased Activity Mania Psychotic Disorder Nos	Consumer Health Professional	Accutane	PS	Hlr Technology	ORAL		
06/12/2000	3512126-5	Expedited (15-Day)	234822	44 YR	Female			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Disability	Amnesia Nec Bipolar I Disorder Condition Aggravated Decreased Activity Feeling Abnormal Irritability Seborrhea Suicidal Ideation	Consumer Other	Accutane Klonopin Tablets (Clonazepam) Lupron Depot (Leuprolide Acetate) 3.75 Mg Neurontin (Gabapentin) Seronoel (Quetapine Fumarate) Allegra (Fexofenadine Hydrochloride) Primrose Oil (Evening Primrose Oil) Coenzyme Q10 (Ubidecarenone) Gadlic (Gadlic) Chromium Picolinate (Chromium Picolinate) Vitamin C (Ascorbic Acid) Vitamin E (Vitamin E) Vitamin B6 (Pyridoxine Hydrochloride) Vitamin B12 (Cyanocobalamin) Ginkoba (Ginkgo)	PS SS SS C C C C C C C C C C C C	Hlr Technology	ORAL ORAL INTRAMUSCULAR OCULAR		
06/13/2000	3512660-8	Expedited (15-Day)	PRJUSA2000001841	35 YR	Female			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Hospitalization - Initial or Prolonged	Anxiety Nec Blood Creatine Phosphokinase Increased Blood Creatine Phosphokinase Mb Increased Blood Triglycerides Increased Cardiac Disorder Nos Cardiac Enzymes Increased	Consumer	Ortho Tri-Cyclen Accutane (Isotretinoin)	PS SS	Rw Johnson Pharmaceutical Research Institute Div Ortho Pharm	ORAL ORAL		

FDA Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report

Date: 06/09/2000	ISR Number: 3513145-5	Report Type: Periodic	Company Report Number: 204596			Age: 17 YR	Gender: Male		
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>	
Other	Anxiety Nec Crying Depression Nec	Health Professional	Accutane	PS	Hlr Technology	ORAL			
Date: 06/09/2000	ISR Number: 3513154-6	Report Type: Periodic	Company Report Number: 204749			Age: 34 YR	Gender: Female		
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>	
Other	Abnormal Dreams Alopecia Eczema Seborrheic Lip Dry Sleep Disorder Nos Urinary Frequency	Consumer	Accutane	PS	Hlr Technology	ORAL			
Date: 06/09/2000	ISR Number: 3513157-1	Report Type: Periodic	Company Report Number: 204805			Age: 17 YR	Gender: Male		
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>	
Other	Appetite Decreased Depression Nec Lip Dry Mood Alteration Nos	Other	Accutane	PS	Hlr Technology	ORAL			
Date: 06/09/2000	ISR Number: 3513160-1	Report Type: Periodic	Company Report Number: 204840			Age: 20 YR	Gender: Male		
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>	
Other	Decreased Activity Headache Nos Sweating Increased	Other	Accutane	PS	Hlr Technology	ORAL			
Date: 06/09/2000	ISR Number: 3513255-2	Report Type: Periodic	Company Report Number: 218266			Age:	Gender:		
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>	
Other	Irritable Bowel Syndrome	Literature Consumer	Accutane	PS	Hlr Technology	ORAL			
Date: 06/09/2000	ISR Number: 3513268-0	Report Type: Periodic	Company Report Number: 204310			Age: 15 YR	Gender: Male		
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>	
Other	Abdominal Pain Nos Diarrhoea Nos Epistaxis Face Oedema Glossodynia Lethargy	Health Professional Other	Accutane	PS	Hlr Technology	ORAL			

08/03/2000

FDA - Adverse Event Reporting System (AERS)
 Division of Information (DID) Report

Date: 06/09/2000	ISR Number: 3513448-4	Report Type: Periodic	Company Report Number: 204302			Age: 17 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Dry Skin Epistaxis Personality Change Sleep Disorder Nos	Other	Accutane Minocin (Minocycline Hydrochloride)	PS C	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3513453-8	Report Type: Periodic	Company Report Number: 204310			Age: 15 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Abdominal Pain Nos Diarrhoea Nos Epistaxis Face Oedema Glossodynia Lethargy Myalgia	Health Professional Other	Accutane	PS	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3513460-5	Report Type: Periodic	Company Report Number: 204495			Age: 19 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Anxiety Nec Dyspnoea Nos Urticaria Nos	Health Professional	Accutane Contraceptive (Contraceptive Nos)	PS C	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3513462-9	Report Type: Periodic	Company Report Number: 204559			Age: 26 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec Libido Decreased	Consumer Health Professional	Accutane	PS	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3513479-4	Report Type: Periodic	Company Report Number: 206298			Age: 23 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec Dry Skin Hyperkeratosis Localised Exfoliation	Consumer Health Professional	Accutane Birth Control Pill (Oral Contraceptive Nos)	PS C	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3513490-3	Report Type: Periodic	Company Report Number: 206506			Age:	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec Panic Attack	Other	Accutane	PS	Hlr Technology	ORAL		

Adverse Event Reporting System (AERS)
Freedom of Information (FOI) Report

Date: 06/09/2000	ISR Number: 3513495-2	Report Type: Periodic	Company Report Number: 206634			Age: 18 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Ejaculation Disorder Nos Erectile Disturbance	Health Professional	Accutane	PS	HlrTechnology	ORAL		
Date: 06/09/2000	ISR Number: 3513524-6	Report Type: Periodic	Company Report Number: 205601			Age: 27 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Alopecia Dyspareunia Nec Libido Decreased	Consumer	Accutane Ortho Tri Cyclen (Ethinyl Estradiol/Norgestimate)	PS C	HlrTechnology	ORAL		
Date: 06/09/2000	ISR Number: 3513539-8	Report Type: Periodic	Company Report Number: 205961			Age: 35 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Anxiety Nec Blood Pressure Increased Chest Tightness Cyanosis Nos Dizziness (Exc Vertigo) Dry Skin Flushing Paresthesia Nec Tachycardia Nos	Consumer	Accutane	PS	HlrTechnology	ORAL		
Date: 06/09/2000	ISR Number: 3513559-3	Report Type: Periodic	Company Report Number: 207889			Age: 17 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Abnormal Behaviour Nos Depression Nec	Health Professional	Accutane	PS	HlrTechnology	ORAL		
Date: 06/09/2000	ISR Number: 3513567-2	Report Type: Periodic	Company Report Number: 208021			Age: 46 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Blood Triglycerides Increased Burning Sensation Nos Depression Aggravated Erythema Nec	Consumer Other	Accutane Zoloft (Sertraline Hydrochloride)	PS C	HlrTechnology	ORAL		
Date: 06/09/2000	ISR Number: 3513618-5	Report Type: Periodic	Company Report Number: 206849			Age: 16 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Abnormal Behaviour Nos Appetite Decreased Depression Nec	Health Professional	Accutane	PS	HlrTechnology	ORAL		

08/03/2000

USA Adverse Event Reporting System (AERS)
 Freedom of Information (FOI) Report

Date: 06/09/2000		ISR Number: 3513619-7		Report Type: Periodic		Company Report Number: 206881		Age: 18 YR		Gender: Female	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>			
Other	Burns Nos Depression Nec Dermatitis Nos Dry Eye Nec	Other	Accutane	PS	Hlr Technology	ORAL					
Date: 06/09/2000		ISR Number: 3513623-9		Report Type: Periodic		Company Report Number: 206924		Age: 25 YR		Gender: Female	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>			
Other	Anaemia Nos Anxiety Nec Back Pain Depression Nec Influenza Like Illness Lymphadenopathy Sensation Of Pressure Nos Skin Lesion Nos Urinary Frequency Urinary Tract Infection Nos Uterine Contractions Weight Gain Poor	Other	Accutane	PS	Hlr Technology	ORAL					
Date: 06/09/2000		ISR Number: 3513625-2		Report Type: Periodic		Company Report Number: 206942		Age: 21 YR		Gender: Male	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>			
Other	Alopecia Depression Nec Dermatitis Nos Dry Eye Nec Lip Dry Photophobia Urticaria Nos Vision Blurred	Other	Accutane	PS	Hlr Technology	ORAL					
Date: 06/09/2000		ISR Number: 3513630-6		Report Type: Periodic		Company Report Number: 207098		Age: 15 YR		Gender: Male	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>			
Other	Acne Nos Emotional Disturbance Nos Tenderness Nos	Health Professional	Accutane	PS	Hlr Technology	ORAL					

FDA Adverse Event Reporting System (AERS)
Freedom of Information (FOI) Report

Date: 06/09/2000	ISR Number: 3513680-X	Report Type: Periodic	Company Report Number: 208856			Age:	Gender: Female	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Aggression Mood Alteration Nos Personality Change	Other	Accutane	PS	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3513683-5	Report Type: Periodic	Company Report Number: 208864			Age: 28 YR	Gender: Female	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Irritability Mood Swings	Consumer Health Professional Other	Accutane Birth Control Pill	PS C	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3513687-2	Report Type: Periodic	Company Report Number: 209045			Age: 40 YR	Gender: Female	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Acne Aggravated Condition Aggravated Depression Nec Fatigue Menorrhagia Scar	Consumer	Accutane Progesterone (Progesterone)	PS C	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3513704-X	Report Type: Periodic	Company Report Number: 209083			Age: 22 YR	Gender: Female	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Appetite Decreased Dry Skin Fatigue Lip Dry Mood Swings Photosensitivity Reaction Nos	Other	Accutane Birth Control Pill	PS C	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3513727-0	Report Type: Periodic	Company Report Number: 209491			Age: 32 YR	Gender: Female	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Alopecia Depression Nec Lip Disorder Nos Localised Exfoliation Pruritus Rash Scaly Sleep Disorder Nos	Consumer	Accutane Capsules Phentermine (Phentermine)	PS C	Hlr Technology	ORAL		

FDA Adverse Event Reporting System (AERS)
Freedom of Information (FOI) Report

Date: 06/09/2000	ISR Number: 3513680-X	Report Type: Periodic	Company Report Number: 208856			Age:	Gender: Female	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Aggression Mood Alteration Nos Personality Change	Other	Accutane	PS	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3513683-5	Report Type: Periodic	Company Report Number: 208864			Age: 28 YR	Gender: Female	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Irritability Mood Swings	Consumer Health Professional Other	Accutane Birth Control Pill	PS C	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3513687-2	Report Type: Periodic	Company Report Number: 209045			Age: 40 YR	Gender: Female	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Acne Aggravated Condition Aggravated Depression Nec Fatigue Menorrhagia Scar	Consumer	Accutane Progesterone (Progesterone)	PS C	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3513704-X	Report Type: Periodic	Company Report Number: 209083			Age: 22 YR	Gender: Female	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Appetite Decreased Dry Skin Fatigue Lip Dry Mood Swings Photosensitivity Reaction Nos	Other	Accutane Birth Control Pill	PS C	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3513727-0	Report Type: Periodic	Company Report Number: 209491			Age: 32 YR	Gender: Female	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Alopecia Depression Nec Lip Disorder Nos Localised Exfoliation Pruritus Rash Scaly Sleep Disorder Nos	Consumer	Accutane Capsules Phentermine (Phentermine)	PS C	Hlr Technology	ORAL		

FDA Adverse Event Reporting System (AERS)
 Freedom of Information (FOI) Report

Date: 06/09/2000		ISR Number: 3513762-2		Report Type: Periodic		Company Report Number: 210173		Age: 26 YR		Gender: Female	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>			
Other	Mood Swings Nightmare Sleep Disorder Nos	Health Professional	Accutane Ambien (Zolpidem Tartrate)	PS C C	Hlr Technology	ORAL					
Date: 06/09/2000		ISR Number: 3513771-3		Report Type: Periodic		Company Report Number: 210578		Age: 30 YR		Gender: Female	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>			
Other	Mood Disorder Nos Nausea Nervousness	Health Professional Other	Accutane Birth Control Pills (Oral Contraceptive Nos)	PS C	Hlr Technology	ORAL					
Date: 06/09/2000		ISR Number: 3513773-7		Report Type: Periodic		Company Report Number: 210666		Age: 14 YR		Gender: Male	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>			
Other	Decreased Interest Depression Nec Malaise Personality Change	Health Professional	Accutane	PS	Hlr Technology	ORAL					
Date: 06/09/2000		ISR Number: 3513781-6		Report Type: Periodic		Company Report Number: 210793		Age: 22 YR		Gender: Female	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>			
Other	Acne Aggravated Appetite Decreased Back Pain Dry Skin Lip Dry Mood Disorder Nos Skin Hypopigmentation Weight Decreased	Consumer	Accutane Birth Control Pills (Oral Contraceptive Nos)	PS C	Hlr Technology	ORAL					
Date: 06/09/2000		ISR Number: 3514043-3		Report Type: Periodic		Company Report Number: 210963		Age: 41 YR		Gender: Female	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>			
Other	Blood Cholesterol Increased Blood Triglycerides Increased Disturbance In Attention Nec Dry Skin Fatigue Memory Impairment Myalgia Short-Term Memory Loss	Consumer Health Professional	Accutane Cod Liver Oil Birth Control Pill	PS C C	Hlr Technology	ORAL					

FDA Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report

Date: 06/09/2000	ISR Number: 3514049-4	Report Type: Periodic	Company Report Number: 211055		Age: 13 YR	Gender: Male
Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose/Unit Duration
Other	Haemorrhage Nos Hypertrophic Scar Insomnia Nec Skin Disorder Nos Skin Ulcer Nos	Health Professional	Accutane	PS	Hlr Technology	ORAL
Date: 06/09/2000	ISR Number: 3514053-6	Report Type: Periodic	Company Report Number: 211070		Age: 40 YR	Gender: Female
Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose/Unit Duration
Other	Costochondritis Insomnia Nec Musculoskeletal Pain	Consumer	Accutane Claritin Continuing (Loratadine)	PS C C	Hlr Technology	ORAL
Date: 06/09/2000	ISR Number: 3514063-9	Report Type: Periodic	Company Report Number: 211742		Age: 13 YR	Gender: Male
Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose/Unit Duration
Other	Acne Aggravated Depression Aggravated Granuloma Nos Scar	Health Professional	Accutane Paxil Acne Medication	PS C C	Hlr Technology	ORAL
Date: 06/09/2000	ISR Number: 3514066-4	Report Type: Periodic	Company Report Number: 211787		Age: 17 YR	Gender: Female
Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose/Unit Duration
Other	Depressed Mood Ear Infection Nos Flat Affect Lethargy Mood Disorder Nos		Accutane Ortho Tri-Cyclen (Ethinyl Estradiol/Norgestimate)	PS C C	Hlr Technology	ORAL
Date: 06/09/2000	ISR Number: 3514074-3	Report Type: Periodic	Company Report Number: 212259		Age: 21 YR	Gender: Female
Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose/Unit Duration
Other	Anxiety Nec Chellitis Dry Skin Headache Nos Scar	Consumer	Accutane Ortho Tri-Cyclen (Ethinyl Estradiol/Norgestimate)	PS C C	Hlr Technology	ORAL

08/03/2000

FDA Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report

Date: 06/09/2000	ISR Number: 3514076-7	Report Type: Periodic	Company Report Number: 212324	Age: 20 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec Hypersensitivity Nos	Health Professional Other	Accutane Tri-Chlen (Ethinyl Estradiol/Norgestrel)	PS C C	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3514080-9	Report Type: Periodic	Company Report Number: 212429	Age: 21 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Acne Aggravated Depression Nec Dry Skin Hair Texture Abnormal Lip Dry Vocal Cord Disorder Nos	Other	Accutane	PS	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3514087-1	Report Type: Periodic	Company Report Number: 213085	Age:	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Dry Skin Hypoesthesia Loss Of Libido Malaise	Health Professional	Accutane	PS	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3514088-3	Report Type: Periodic	Company Report Number: 213089	Age: 21 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Condition Aggravated Dyslexia	Health Professional	Accutane	PS	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3514118-9	Report Type: Periodic	Company Report Number: 213808	Age: 17 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Abdominal Pain Nos Anorexia Blood Bilirubin Increased Blood Cholesterol Increased Blood Triglycerides Increased Depression Nec Dianhoea Nos Dry Mouth Dry Skin Dry Throat Gastritis Nos	Health Professional	Accutane	PS	Hlr Technology	ORAL		

FDA Adverse Event Reporting System (AERS)
Freedom of Information (FOI) Report

Date: 06/09/2000	ISR Number: 3514123-2	Report Type: Periodic	Company Report Number: 213966			Age: 34 YR	Gender: Female
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit Duration
Other	Bloodshot Eye Condition Aggravated Eye Discharge Panic Attack	Consumer	Accutane	PS	Hlr Technology	ORAL	
Date: 06/09/2000	ISR Number: 3514138-4	Report Type: Periodic	Company Report Number: 214249			Age: 23 YR	Gender: Female
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit Duration
Other	Aggression Anger Emotional Disturbance Nos	Consumer Health Professional Other	Accutane	PS	Hlr Technology	ORAL	
Date: 06/09/2000	ISR Number: 3514142-6	Report Type: Periodic	Company Report Number: 214338			Age: 22 YR	Gender: Male
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit Duration
Other	Depression Nec Diarrhoea Nos Dry Eye Nec Fatigue Headache Nos Mood Swings Nausea Palpitations Pyrexia Vertigo Nec Vomiting Nos	Other	Accutane	PS	Hlr Technology	ORAL	
Date: 06/09/2000	ISR Number: 3514161-X	Report Type: Periodic	Company Report Number: 214764			Age:	Gender: Female
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit Duration
Other	Abdominal Pain Upper Palpitations	Consumer	Accutane	PS	Hlr Technology	ORAL	
Date: 06/09/2000	ISR Number: 3514162-1	Report Type: Periodic	Company Report Number: 214815			Age: 17 YR	Gender: Female
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit Duration
Other	Burns Nos Depression Nec Dermatitis Nos Dry Skin Lip Dry	Consumer Other	Accutane	PS	Hlr Technology	ORAL	

FDA Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report

Date: 06/09/2000		ISR Number: 3514166-9		Report Type: Periodic		Company Report Number: 215174		Age: 35 YR		Gender: Female	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>			
Other	Anxiety Nec Depression Nec Feeling Abnormal Mood Swings Skin Disorder Nos Vulvovaginal Dryness	Consumer Other	Accutane	PS	HlrTechnology	ORAL					
Date: 06/09/2000		ISR Number: 3514181-5		Report Type: Periodic		Company Report Number: 215502		Age: 34 YR		Gender: Female	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>			
Other	Abdominal Pain Upper Appetite Decreased Back Pain Burning Sensation Nos Constipation Dehydration Depression Nec Dyspepsia Dysuria Eye Disorder Nos Fatigue Haematuria Present Lip Dry Localised Exfoliation Mouth Ulceration Muscle Cramps Oedema Upper Limb Pain Nos Pruritus Stomatitis Thirst Tongue Disorder Nos Urinary Frequency Urticaria Nos Vaginal Candidiasis Vaginal Infection Nos	Consumer	Accutane Birth Control Pill (Oral Contraceptive Nos) Vitamin E (Vitamin E)	PS C C	HlrTechnology	ORAL					
Date: 06/09/2000		ISR Number: 3515014-3		Report Type: Periodic		Company Report Number: 111410		Age: 30 YR		Gender: Female	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>			
Other	Arthralgia	Consumer	Accutane	PS	HlrTechnology	ORAL					

08/03/2000

FDA Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report

Date: 06/09/2000		ISR Number: 3515018-0		Report Type: Periodic		Company Report Number: 113029		Age: 21.YR		Gender: Male	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>			
Other	Depression Nec Erectile Disturbance	Health Professional	Accutane	PS	HlrTechnology	ORAL					
Date: 06/09/2000		ISR Number: 3515022-2		Report Type: Periodic		Company Report Number: 200554		Age: 27 YR		Gender: Female	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>			
Other	Aggression Alopecia Dry Eye Nec Dry Skin Epistaxis Fatigue Headache Nos Impaired Healing Mood Swings Myalgia Nasal Dryness Nausea Pruritus Skin Disorder Nos Vision Blurred Weakness	Consumer	Accutane Ortho Tri-Cyclen	PS C	HlrTechnology	ORAL					
Date: 06/09/2000		ISR Number: 3515024-6		Report Type: Periodic		Company Report Number: 200883		Age: 30 YR		Gender: Male	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>			
Other	Erectile Disturbance	Health Professional	Accutane	PS	HlrTechnology	ORAL					
Date: 06/09/2000		ISR Number: 3515027-1		Report Type: Periodic		Company Report Number: 201106		Age: 22 YR		Gender: Male	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>			
Other	Abdominal Pain Nos Alopecia Dyspnoea Nos Haemorrhage Nos Hypoesthesia Muscle Spasms Palpitations	Consumer	Accutane	PS	HlrTechnology	ORAL					

FDA Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report

Date: 06/14/2000 ISR Number: 3515210-5 Report Type: Expedited (15-Day) Company Report Number: 222459 Age: Gender: Female

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Life-Threatening	Airway Obstruction Nos	Consumer	Accutane	PS	Hlr Technology	ORAL		
Hospitalization - Initial or Prolonged Disability	Anemia Nos Anomaly Of External Ear Congenital Nos Apnoea	Health Professional Other						
Congenital Anomaly	Atelectasis							
Required Intervention To Prevent Permanent Impairment/Damage	Blindness Congenital Cardio-Respiratory Arrest Choking Complications Of Maternal Exposure To Therapeutic Drugs Congenital Abnormality Nos Congenital Central Nervous System Anomaly Nos Congenital Heart Disease Nos Congenital Spinal Cord Anomaly Nos Convulsions Nos Cyanosis Nos Deafness Conductive (Exc Otosclerosis) Decreased Activity Dermatitis Contact Developmental Delay Nos Ectropion Nec Eosinophilia (Exc Pulmonary) Erythema Nec Extracocular Muscle Paresis Eye Deformity Congenital Nos Eye Disorder Nos Facial Dysmorphism Failure To Thrive Feeding Disorder Nos Haemorrhage Nos Head Deformity Nos Hearing Impaired Hirsutism Hydrocephalus Nos Hyperreflexia Hypertonia Hypothalamo-Pituitary Disorders Nec							

FDA Adverse Event Reporting System (AERS)
Freedom of Information (FOI) Report

Date: 06/09/2000	ISR Number: 3516244-7	Report Type: Periodic	Company Report Number: 205605			Age: 14 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Anger Depression Nec Hypercholesterolaemia Injury Nos Mood Swings	Other	Accutane	PS	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3516247-2	Report Type: Periodic	Company Report Number: 205766			Age: 30 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Life-Threatening Hospitalization - Initial or Prolonged	Anxiety Nec Depression Nec Mental Impairment Nos Suicide Attempt	Consumer	Accutane	PS	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3516249-6	Report Type: Periodic	Company Report Number: 205788			Age: 34 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Anger Depression Nec Fatigue Irritability Mood Swings Rash Pustular Urticaria Nos	Consumer Health Professional	Accutane Entex (Orisafenesin/Phenylephrine Hydrochloride/Phenylpropanolamine Hydrochloride) Zytex (Cetirizine Hydrochloride) Minocyn(Minocycline) Desogca (Desogestrel/Ethinyl Estradiol)	PS C C C C	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3516253-8	Report Type: Periodic	Company Report Number: 206312			Age: 19 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Aggravated	Other	Accutane Birth Control Pills (Oral Contraceptive Nos)	PS C	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3516255-1	Report Type: Periodic	Company Report Number: 206535			Age: 27 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Acne Nos Chickenpox Convulsions Nos Depression Aggravated Nervousness Scar	Other	Accutane Marijuana (Cannabis)	PS C	Hlr Technology	ORAL		

FDA Adverse Event Reporting System (AERS)
 Freedom Of Information (FOI) Report

Date: 06/09/2000	ISR Number: 3516260-5	Report Type: Periodic	Company Report Number: 206779	Age: 18 YR	Gender: Female			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Depression Nec Hypertiglyceridaemia Photosensitivity Reaction Nos Social Avoidant Behaviour Tearfulness	Health Professional	Accutane Ortho Tri Cyclen (Bhinyl Estradiol/Norgestimate)	PS C	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3516263-0	Report Type: Periodic	Company Report Number: 206945	Age: 15 YR	Gender: Male			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Arthralgia Depression Nec Emotional Disturbance Nos Weight Decreased	Other	Accutane	PS	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3516264-2	Report Type: Periodic	Company Report Number: 206991	Age: 15 YR	Gender: Male			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Depression Nec	Health Professional	Accutane Prednisone (Prednisone)	PS SS	Hlr Technology	ORAL ORAL		
Date: 06/09/2000	ISR Number: 3516266-6	Report Type: Periodic	Company Report Number: 207012	Age: 18 YR	Gender: Male			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Depression Nec	Other	Accutane	PS	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3516269-1	Report Type: Periodic	Company Report Number: 207096	Age: 20 YR	Gender: Male			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Depression Nec		Accutane	PS	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3516271-X	Report Type: Periodic	Company Report Number: 207180	Age: 48 YR	Gender: Female			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Blood Triglycerides Increased Disturbance In Attention Nec Eye Irritation Headache Nos Peripheral Coldness Rigors Sinus Pain Tired Eyes Vision Blurred	Consumer	Accutane	PS	Hlr Technology	ORAL		

FDA Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report

Date:	ISR Number:	Report Type:	Company Report Number:	Age:	Gender:			
06/09/2000	3516277-0	Periodic	207513	18 YR	Male			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Anxiety Nec Depression Nec Emotional Disturbance Nos Fatigue Headache Nos Insomnia Nec Neck Pain Palpitations Temporomandibular Joint Syndrome Weight Decreased	Consumer Other	Accutane	PS	Hlr Technology	ORAL		
06/09/2000	3516278-2	Periodic	207538	19 YR	Male			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Death	Completed Suicide Dry Skin High Density Lipoprotein Decreased Lethargy Lip Dry Low Density Lipoprotein Increased Mood Swings Sedation Social Avoidant Behaviour	Other	Accutane	PS	Hlr Technology	ORAL		
06/09/2000	3516281-2	Periodic	207673	16 YR	Female			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Anxiety Nec Depressed Mood Depression Nec	Consumer Other	Accutane	PS	Hlr Technology	ORAL		
06/09/2000	3516283-6	Periodic	207778	22 YR	Male			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Hospitalization - Initial or Prolonged	Delusional Disorder, Paranoid Type Suicide Attempt		Accutane Adderall (Amphetamin Aspartate/Amphetaminesulfate/Dextroamphetamine Sacchrate/Dextroamphetamine Sulfa	PS C	Hlr Technology	ORAL		

FDA Adverse Event Reporting System (AERS)
 Region Of Information (ROI) Report

Date: 06/09/2000	ISR Number: 3516301-5	Report Type: Periodic	Company Report Number: 208136			Age: 17 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Death	Completed Suicide Dry Skin	Health Professional	Accutane	PS	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3516306-4	Report Type: Periodic	Company Report Number: 208264			Age: 18 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Acne Aggravated Depression Nec Mood Swings	Other	Accutane	PS	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3516312-X	Report Type: Periodic	Company Report Number: 208620			Age: 26 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Depression Nec Suicide Attempt	Health Professional	Accutane	PS	Hlr Technology	ORAL		
			Wellbutrin	C				
			Depakote	C				
			Cogentin	C				
			Lithium	C				
Date: 06/09/2000	ISR Number: 3516318-0	Report Type: Periodic	Company Report Number: 208764			Age:	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Burning Sensation Nos Depression Nec	Consumer	Accutane	PS	Hlr Technology	ORAL		
Date: 06/20/2000	ISR Number: 3516321-0	Report Type: Expedited (15-Day)	Company Report Number: 232323			Age: 20 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Anxiety Nec Attention Deficit/Hyperactivity Disorder Bipolar Disorder Nec Depression Nec Educational Problem Mood Swings	Consumer Other	Accutane Birth Control Pill (Oral Contraceptive Nos)	PS C	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3516329-5	Report Type: Periodic	Company Report Number: 209233			Age: 17 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Amnesia Nec Depression Nec Fatigue Mood Swings	Health Professional Other	Accutane Birth Control Pills	PS C	Hlr Technology	ORAL		

08/03/2000

FDA Adverse Event Reporting System (AERS)
 Freedom of Information (FOI) Report

Date	ISR Number	Report Type	Company Report Number	Age	Gender			
06/09/2000	3516332-5	Periodic	209395	41 YR	Female			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Anxiety Nec Condition Aggravated Depression Nec Hypercholesterolaemia Thinking Abnormal Nec Tinnitus Vertigo Nec	Consumer Health Professional	Accutane Allegra Oral Contraception Medrol	PS C C C	Hlr Technology	ORAL		
06/09/2000	3516341-6	Periodic	209717	16 YR	Female			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Depression Nec	Health Professional	Accutane	PS	Hlr Technology	ORAL		
06/09/2000	3516346-5	Periodic	209802	27 YR	Female			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Crying Depression Nec Mood Disorder Nos Suicidal Ideation	Consumer	Accutane Birth Control Pills Ginkgo Biloba	PS C C	Hlr Technology	ORAL		
06/09/2000	3516348-9	Periodic	209927	24 YR	Male			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Alopecia Condition Aggravated Confusion Depression Nec Dry Skin Headache Nos Lip Dry Nausea Neck Stiffness Schizophrenia Nos Suicidal Ideation Thinking Abnormal Nec Vomiting Nos Weight Decreased		Accutane Serzone (Nefazodone Hydrochloride) Wellbutrin (Bupropion Hydrochloride)	PS SS SS	Hlr Technology	ORAL ORAL ORAL		

FDA Adverse Event Reporting System (AERS)
 Product Of Information (POI) Report

Date: 06/09/2000	ISR Number: 3516719-0	Report Type: Periodic	Company Report Number: 215883		Age: 22 YR	Gender: Female
Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose/Unit Duration
Other	Mood Disorder Nos Weight Increased	Consumer	Accutane Birth Control Pill (Oral Contraceptive Nos)	PS C	Hlr Technology	ORAL
Date: 06/09/2000	ISR Number: 3516722-0	Report Type: Periodic	Company Report Number: 230799		Age:	Gender: Female
Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose/Unit Duration
Other	Amnesia Nec Headache Nos Vision Blurred	Consumer	Accutane	PS	Hlr Technology	ORAL
Date: 06/09/2000	ISR Number: 3516724-4	Report Type: Periodic	Company Report Number: 215996		Age: 14 YR	Gender: Female
Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose/Unit Duration
Other	Depression Nec Hormone Level Nos Abnormal Menstruation Irregular Mood Alteration Nos	Other	Accutane	PS	Hlr Technology	ORAL
Date: 06/09/2000	ISR Number: 3516725-6	Report Type: Periodic	Company Report Number: 230803		Age: 20 YR	Gender: Female
Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose/Unit Duration
Other	Dry Skin Insomnia Nec Joint Stiffness Lip Dry Tremor Nec	Health Professional	Accutane Ortho Tri Cyclen (Ethinyl Estradiol/Norgestimate)	PS C	Hlr Technology	ORAL
Date: 06/09/2000	ISR Number: 3516726-8	Report Type: Periodic	Company Report Number: 216208		Age: 42 YR	Gender: Female
Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose/Unit Duration
Other	Depression Nec Tinnitus	Health Professional Company Representative Other	Accutane	PS	Hlr Technology	ORAL
Date: 06/09/2000	ISR Number: 3516728-1	Report Type: Periodic	Company Report Number: 230828		Age:	Gender: Male
Outcome	PT	Report Source	Product	Role	Manufacturer	Route Dose/Unit Duration
Other	Abnormal Behaviour Nos Mood Swings	Consumer	Accutane	PS	Hlr Technology	ORAL

FDA Adverse Event Reporting System (AERS)
 Division of Information (DIDR)

Date: 06/09/2000	ISR Number: 3516730-X	Report Type: Periodic	Company Report Number: 230832	Age: 40 YR	Gender: Female			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Depression Nec Lip Dry Rectal Bleeding Vaginal Disorder Nos	Consumer Health Professional	Accutane	PS	Hlr Technology			
Date: 06/09/2000	ISR Number: 3516741-4	Report Type: Periodic	Company Report Number: 231006	Age:	Gender: Female			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Dry Skin Irritability Panic Attack	Consumer	Accutane Zoloft (Sertaline Hydrochloride)	PS SS	Hlr Technology	ORAL ORAL		
Date: 06/09/2000	ISR Number: 3516750-5	Report Type: Periodic	Company Report Number: 217704	Age: 20 YR	Gender: Female			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Anxiety Nec Depression Nec	Consumer Other	Accutane	PS	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3516753-0	Report Type: Periodic	Company Report Number: 217756	Age:	Gender: Male			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Crohn'S Disease Depression Nec	Other	Accutane	PS	Hlr Technology	ORAL		
Date: 06/20/2000	ISR Number: 3516754-2	Report Type: Expedited (15-Day)	Company Report Number: 222823	Age: 32 YR	Gender: Female			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Disability	Alopecia Depression Nec Dizziness (Exc Vertigo) Hair Colour Changes Hair Growth Abnormal Hair Texture Abnormal Headache Nos High Density Lipoprotein High Density Lipoprotein Increased Hypercholesterolaemia Hypertiglyceridaemia Major Depressive Disorder Nos Palpitations Panic Attack	Consumer	Accutane Ortho Tri-Cycle (Ethinyl Estradiol/Norgestimate)	PS C	Hlr Technology	ORAL		

FD-302 (Rev. 03-2002) (Continuation)
 National Center for Human Genome Research
 National Center for Human Genome Research

Date: 06/09/2000		ISR Number: 3516763-3		Report Type: Periodic		Company Report Number: 219277		Age: 28 YR		Gender: Female	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>			
Other	Aggression Anxiety Nec Depression Nec Headache Nos Nausea Suicidal Ideation Vision Blurred	Health Professional Other	Accutane Birth Control	PS C	Hlr Technology	ORAL					
Date: 06/09/2000		ISR Number: 3516768-2		Report Type: Periodic		Company Report Number: 216372		Age: 24 YR		Gender: Female	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>			
Other	Blood Bilirubin Increased Blood Cholesterol Increased Blood Sodium Decreased Blood Uric Acid Decreased Depression Nec Fatigue	Other	Accutane Zithromax (Azithromycin) Kenalog (Triamcinolone Acetonide)	PS C C	Hlr Technology	ORAL					
Date: 06/09/2000		ISR Number: 3516773-6		Report Type: Periodic		Company Report Number: 219718		Age: 19 YR		Gender: Female	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>			
Disability	Depression Nec	Consumer	Accutane Tri-Cyclen	PS C	Hlr Technology	ORAL					
Date: 06/09/2000		ISR Number: 3516777-3		Report Type: Periodic		Company Report Number: 220000		Age:		Gender: Female	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>			
Other	Acne Aggravated Anxiety Nec Depression Nec Dry Skin Lip Dry Scar Weight Decreased	Consumer	Accutane	PS	Hlr Technology	ORAL					
Date: 06/09/2000		ISR Number: 3516779-7		Report Type: Periodic		Company Report Number: 216390		Age:		Gender: Male	
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>			
Other	Aggression Anger Depressed Mood Mood Swings	Health Professional Other	Accutane	PS	Hlr Technology	ORAL					

08/03/2000

FDA Adverse Event Reporting System
Freedom of Information (FOI) Report

Date: 06/09/2000	ISR Number: 3516790-6	Report Type: Periodic	Company Report Number: 220639		Age: 17 YR	Gender: Female		
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec Muscle Cramps Suicidal Ideation	Health Professional	Accutane Birth Control Pills	PS C	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3516795-5	Report Type: Periodic	Company Report Number: 220914		Age: 19 YR	Gender: Male		
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Aggravated Emotional Disturbance Nos Suicidal Ideation	Consumer	Accutane	PS	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3516797-9	Report Type: Periodic	Company Report Number: 216571		Age: 26 YR	Gender: Female		
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Chest Pain Costochondritis Cystitis Nos Dry Eye Nec Dry Skin Ear Disorder Nos Fear, Focus Nec Galactorrhoea Glossitis Hyperventilation Infectious Mononucleosis Lip Dry Nasal Dryness Simsitis Nos Sore Throat Nos	Consumer	Accutane	PS	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3516799-2	Report Type: Periodic	Company Report Number: 221022		Age: 17 YR	Gender: Male		
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec	Health Professional	Accutane Zoloft	PS C	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3516803-1	Report Type: Periodic	Company Report Number: 221109		Age: 17 YR	Gender: Female		
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec	Other	Accutane	PS	Hlr Technology	ORAL		

FDA Adverse Event Reporting System (AERS)
 Freedom Of Information (FOI) Report

Date	ISR Number	Report Type	Company Report Number	Age	Gender			
06/09/2000	3516807-9	Periodic	221137	33 YR	Female			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Depression Nec Emotional Disturbance Nos Headache Nos Myalgia Sedation	Consumer Other	Accutane	PS	Hlr Technology	ORAL		
06/09/2000	3516810-9	Periodic	216767	17 YR	Male			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Abnormal Behaviour Nos Blood Triglycerides Increased Depression Nec Epistaxis Eye Irritation Headache Nos Lip Dry Red Eye	Consumer	Accutane Claritin (Loratadine)	PS C	Hlr Technology	ORAL		
06/09/2000	3516812-2	Periodic	221166	26 YR	Female			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Depression Nec Dry Skin Epistaxis Fatigue Headache Nos Hot Flashes Nos Lip Disorder Nos Lip Dry Mood Swings Vision Blurred Vulvovaginal Dryness	Health Professional Other	Accutane Demlen	PS C	Hlr Technology	ORAL		
06/09/2000	3516816-X	Periodic	221173	34 YR	Female			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Chest Pain Dermatitis Nos Dry Eye Nec Eye Irritation Fatigue Lip Disorder Nos	Health Professional Other	Accutane Accutane Capsules (Isotretinoin)	PS SS	Hlr Technology	ORAL		

FDA Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report

Date: 06/09/2000	ISR Number: 3516817-1	Report Type: Periodic	Company Report Number: 216791			Age: 17 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Abnormal Behaviour Nos Depression Aggravated	Health Professional	Accutane	PS	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3516820-1	Report Type: Periodic	Company Report Number: 221179			Age: 30 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Alopecia Blood In Stool Depression Nec Proctalgia	Consumer Other	Accutane Birth Control Fill	PS C	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3516836-5	Report Type: Periodic	Company Report Number: 210416			Age: 31 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Anxiety Nec Depression Nec Mood Alteration Nos	Consumer	Accutane Triphasil (Ethinyl Estradiol / Levonorgestrel)	PS C	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3516842-0	Report Type: Periodic	Company Report Number: 231486			Age:	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Panic Attack	Health Professional	Accutane	PS	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3516845-6	Report Type: Periodic	Company Report Number: 210546			Age: 20 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Appetite Decreased Depressed Mood Depression Nec Insomnia Nec Psychiatric Symptom Nos Suicidal Ideation	Other	Accutane Ortho Tri Cyclen (Ethinyl Estndiol / Norgestimate)	PS C	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3516847-X	Report Type: Periodic	Company Report Number: 210576			Age: 23 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Arthralgia Depression Nec Dry Skin Iritability Lip Dry Mood Swings	Other	Accutane Accutane Capsules (Isotretinoin) Accutane Capsules (Isotretinoin) Birth Control Pills (Oral Contraceptive Nos)	PS SS SS C	Hlr Technology	ORAL ORAL ORAL		

FDA Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report

Date: 06/09/2000	ISR Number: 3516817-1	Report Type: Periodic	Company Report Number: 216791			Age: 17 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Abnormal Behaviour Nos Depression Aggravated	Health Professional	Accutane	PS	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3516820-1	Report Type: Periodic	Company Report Number: 221179			Age: 30 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Alopecia Blood In Stool Depression Nec Proctalgia	Consumer Other	Accutane Birth Control Pill	PS C	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3516836-5	Report Type: Periodic	Company Report Number: 210416			Age: 31 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Anxiety Nec Depression Nec Mood Alteration Nos	Consumer	Accutane Triphasil (Ethinyl Estradiol / Levonorgestrel)	PS C	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3516842-0	Report Type: Periodic	Company Report Number: 231486			Age:	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Panic Attack	Health Professional	Accutane	PS	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3516845-6	Report Type: Periodic	Company Report Number: 210546			Age: 20 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Appetite Decreased Depressed Mood Depression Nec Insomnia Nec Psychiatric Symptom Nos Suicidal Ideation	Other	Accutane Ortho Tri Cyclen (Ethinyl Estradiol / Norgestimate)	PS C	Hlr Technology	ORAL		
Date: 06/09/2000	ISR Number: 3516847-X	Report Type: Periodic	Company Report Number: 210576			Age: 23 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Arthralgia Depression Nec Dry Skin Irritability Lip Dry Mood Swings	Other	Accutane Accutane Capsules (Isotretinoin) Accutane Capsules (Isotretinoin) Birth Control Pills (Oral Contraceptive Nos)	PS SS SS C	Hlr Technology	ORAL ORAL ORAL		

FDA Adverse Event Reporting System (AERS)
Freedom of Information (FOI) Report

Date	ISR Number	Report Type	Company Report Number	Age	Gender			
06/09/2000	3516851-1	Periodic	231738	17 YR	Female			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Alopecia Conjunctivitis Nec Depression Nec Dry Skin Ear Infection Nos Impetigo Nos Nasopharyngitis Pharyngitis Nos Pharyngitis Streptococcal	Consumer Health Professional	Accutane Amoxycillin (Amoxicillin)	PS C	Hlr Technology	ORAL		
06/09/2000	3516852-3	Periodic	210580	20 YR	Female			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Hospitalization - Initial or Prolonged	Anxiety Nec Depression Nec	Consumer Health Professional Other	Accutane	PS	Hlr Technology	ORAL		
06/09/2000	3516858-4	Periodic	217189		Male			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Other	Alopecia Localised Exfoliation Stress Symptoms	Consumer	Accutane	PS	Hlr Technology	UNKNOWN		
06/09/2000	3516864-X	Periodic	210590	20 YR	Female			
<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose/Unit</u>	<u>Duration</u>
Hospitalization - Initial or Prolonged	Aspartate Aminotransferase Increased Blood Cholesterol Blood Cholesterol Increased Blood Sodium Decreased Cheilitis Emotional Disturbance Nos Eosinophil Count Decreased Inflammation Nos Lip Dry Low Density Lipoprotein Increased Menstruation Irregular Pain In Limb	Consumer Health Professional Other	Accutane Ortho Tri-Cyclen (Ethinyl Estradiol / Norgestimate)	PS C	Hlr Technology	ORAL		