



Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

08/03/2000

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Disclaimer: The information contained in these reports has not been scientifically or otherwise verified as to a cause and effect relationship and cannot be used to estimate the incidence of adverse drug reactions.

Adverse Event Reporting System (AERS)
Office of Postmarketing Drug Risk Assessment
Brief Description with Caveats of System
October 18, 1999

IMPORTANT INFORMATION:

The Adverse Event Reporting System (AERS) in the Office of Postmarketing Drug Risk Assessment (OPDRA), was implemented to take advantage of up-to-date methods for data entry and database design. AERS contains all reports received since November 1, 1997.

BACKGROUND:

The AERS database is a computerized system for storing adverse events reported by health professionals and others. The system contains adverse events detected and reported after marketing of the drug.

AERS relies on health professional to detect new clinical events, to attribute the appearance of the clinical event to the administration of a drug, and to report that clinical event.

The health professional may choose to report the adverse reaction to the FDA or to a drug firm, who must, by law, report to the FDA. Ninety percent of the FDA's reports are received from drug manufacturers. OPDRA receives the remaining ten percent directly from other reporters. (i.e., Health Professionals and consumers).

Data from all reports are entered into AERS and the report images are scanned into an Electronic Filing System (EFS). All reports are retrieved by accessing the Individual Safety Report (ISR) number.

Copies of individual case safety reports, which are summarized in this printout, may be obtained by submitting a separate FOI request. When requests are submitted for copies of report images, the ISR number should be listed in tabular format in ascending order as shown in the following example:

ISR NUMBER

3000913-1
3000917-9
3001581-5

There is a \$29.00/Hour search time and a \$.50/page charge. Please note that there will be redactions made to all personal identifiers on the report.

Definitions of the FOI Report

Date	Date the report was received by the FDA.
ISR Number	Unique number for identifying an AERS report.
Report Type	The type of ISR received. Expedited (15-day) and periodic reports are from manufacturers; "direct" reports are voluntarily submitted to the FDA by non-manufacturers.

Report Type	Description
Expedited (15-day)	Mandatory reports received from the manufacturer informing the FDA of adverse events that are both serious and unexpected. By law, these reports must be delivered to the FDA, within 15 calendar days of the initial receipt by the manufacturer.
Periodic	These are mandatory reports that do not fall into the expedited category. These reports are delivered quarterly to the FDA.
Direct	These reports are from health professionals, private individuals or sources other than manufacturers.

Company Report Number	Manufacturer's unique report identifier.
Age	Numeric value of patient's age at event.
Gender	The gender of the patient (male, female, unknown, or Not specified).
Outcome	The results of the adverse event as. The following events are potential choices.

Outcome	DESCRIPTION
DE	Death
LT	Life-Threatening
HO	Hospitalization – Initial or Prolonged
DS	Disability
CA	Congenital Anomaly
RI	Required Intervention to prevent permanent impairment/damage
OT	Other

PT (Preferred Term)	The reported reaction, in medical terminology, describing the event. This is coded using the Medical Dictionary for Regulatory Activities (MedDRA).
Report Source	Identifies the initial source of the report. (i.e., Health Professional, Consumer, etc..)
Product	Name of drug.
Role	S = Suspect C = Concomitant PS = Primary Suspect SS = Secondary Suspect
*Suspect Drug	The drug that the initial reporter deemed most likely to be associated with the reactions.
Concomitant Drug	A list of any drugs taken at the same time as the suspect medication, but not suspected of causing the adverse event.
Manufacturer	The company that manufactures the drug.
Route	Route of administration of the drug.
Dose	Quantity of drug administered in a 24-hour period.
Units	Modifies the dose with units of measurements (e.g., mg, IU, ml, etc.).
Duration	Number of days the drug was used.

CAVEATS:

There are some important things to remember when reviewing or analyzing data from AERS.

1. Reports contain only those reactions voluntarily submitted either directly to the FDA or to the drug manufacturer by consumers and/or members of the health profession and which have been entered into the AERS computerized filing system since November 1, 1997.
2. The information contained in the reports has not been scientifically or otherwise verified.
3. For any given report, there is no certainty that the suspected drug caused the reaction. This is because physicians are encouraged to report suspected reactions. The event may have been related to the underlying disease for which the drug was given to concurrent drugs being taken or may have occurred by chance at the same time the suspected drug was taken.
4. Accumulated case reports cannot be used to calculate incidence or estimates of drug risk.
5. Numbers from these data must be carefully interpreted as reporting rates and not occurrence rates. True incidence rates cannot be determined from this database. Comparisons of drugs cannot be made from these data.

Form Approved by the Federal Bureau of Investigation
 Department of Justice
 4-750 (Rev. 10-6-79)

Date: 11/04/1983	ISR Number: 154121-2	Report Type: Expedited (15-Day)	Company Report Number: MS83661	Age: 15 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Depression Nec		Accutane	PS	Roche	ORAL		26
Date: 03/09/1983	ISR Number: 157641-X	Report Type: Expedited (15-Day)	Company Report Number: MS8398	Age: 25 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Palpitations		Accutane	PS	Roche	ORAL		
Date: 03/09/1983	ISR Number: 157646-9	Report Type: Expedited (15-Day)	Company Report Number: 00MS8384	Age: 19 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Annesia Nec Hepatic Function Abnormal Nos Jandice Nos Weight Decreased		Accutane	PS	Roche	ORAL		105
Date: 04/14/1983	ISR Number: 158987-1	Report Type: Expedited (15-Day)	Company Report Number: MS83-212	Age: 13 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Emotional Disturbance Nos Hyperkinetic Syndrome		Accutane Depakene Tegretol	PS C C	Roche	ORAL ORAL ORAL		153
Date: 05/13/1983	ISR Number: 161749-2	Report Type: Direct	Company Report Number:	Age: 42 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Coordination Abnormal Nos Nervousness Tachycardia Nos Tremor Nec		Accutane	PS	Roche	ORAL		
Date: 06/16/1983	ISR Number: 164688-6	Report Type: Expedited (15-Day)	Company Report Number: 00MS8335	Age: 17 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Emotional Disturbance Nos		Accutane	PS	Roche	ORAL		
Date: 06/16/1983	ISR Number: 164689-8	Report Type: Expedited (15-Day)	Company Report Number: 0MS83336	Age: 16 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Ansthenia Depression Nec Personality Disorder Nos		Accutane	PS	Roche	ORAL		

National Center for Human Genome Research
 Division of Population Sciences
 National Institutes of Health

Date: 06/16/1983		ISR Number: 164690-4		Report Type: Expedited (15-Day)		Company Report Number: OMS83291		Age: 21 YR		Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Other	Impotence		Accutane	PS	Roche	ORAL		120			
Date: 08/03/1983		ISR Number: 165237-9		Report Type: Periodic		Company Report Number: OMS83449		Age: 17 YR		Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Hospitalization - Initial or Prolonged	Amnesia Nec Benign Intracranial Hypertension Ecchymosis		Accutane	PS	Roche						
Date: 12/02/1983		ISR Number: 172586-7		Report Type: Expedited (15-Day)		Company Report Number: MS83678		Age: 38 YR		Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
	Asthma Nos Depression Nec Myalgia Oesophagitis		Accutane Anaprox	PS SS	Roche	ORAL		119			
Date: 12/14/1983		ISR Number: 172587-9		Report Type: Expedited (15-Day)		Company Report Number: MS83688		Age: 38 YR		Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Hospitalization - Initial or Prolonged	Depression Nec		Accutane	PS	Roche	ORAL		41			
Other			Lithium Restonil	C C	 Sandoz	ORAL ORAL					
Date: 12/13/1983		ISR Number: 172602-2		Report Type: Direct		Company Report Number:		Age: 20 YR		Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Other	Depression Nec	Health Professional	Accutane	PS	Roche	ORAL		95			
Date: 12/06/1983		ISR Number: 174700-6		Report Type: Periodic		Company Report Number: MS83537		Age: 32 YR		Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Other	Headache Nos Insomnia Nec Nervousness Palpitations		Accutane Erythromycin	PS C	Roche	ORAL ORAL		7 28			
Date: 02/01/1984		ISR Number: 176897-0		Report Type: Direct		Company Report Number: 00000000		Age: 30 YR		Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
	Amenorrhoea Nos Cheilitis	Consumer	Accutane	PS	Roche			68			

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

Date: 05/14/1984	ISR Number: 182736-4	Report Type: Periodic	Company Report Number: MS83745			Age: 30 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Alopecia Chelitis Confusion Nail Disorder Nos		Accutane Pamote	PS C	Roche	ORAL ORAL		101
Date: 03/08/1984	ISR Number: 183567-1	Report Type: Expedited (15-Day)	Company Report Number: MS8476			Age: 63 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec Sedation		Accutane	PS	Roche	ORAL		54
Date: 05/18/1984	ISR Number: 184682-9	Report Type: Direct	Company Report Number: 00000000			Age:	Gender: Unknown	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Impotence	Health Professional	Accutane	PS	Roche	ORAL		
Date: 05/14/1984	ISR Number: 184683-0	Report Type: Expedited (15-Day)	Company Report Number: MS8456			Age: 27 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Impotence		Accutane	PS	Roche	ORAL		118
Date: 06/21/1984	ISR Number: 184955-X	Report Type: Periodic	Company Report Number: 84192			Age: 37 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Depression Nec		Accutane	PS	Roche	ORAL		120
Date: 07/10/1984	ISR Number: 186192-1	Report Type: Periodic	Company Report Number: 84260			Age: 29 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Dysphonia		Accutane	PS	Roche	ORAL		64
Date: 07/18/1984	ISR Number: 186519-0	Report Type: Periodic	Company Report Number: MS84289			Age: 34 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Palpitations Syncope		Accutane Prednisone	PS C	Roche	ORAL ORAL		26 14
Date: 03/08/1984	ISR Number: 186549-9	Report Type: Expedited (15-Day)	Company Report Number: MS8496			Age: 18 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec Weight Decreased		Accutane	PS	Roche	ORAL		104

U.S. Department of Health and Human Services
 Division of Information (D-10) Report

Date: 10/11/1984	ISR Number: 301087-8	Report Type: Periodic	Company Report Number: MS84529			Age: 40 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Depression Nec		Accutane	PS	Roche	ORAL		78
Date: 10/11/1984	ISR Number: 301091-X	Report Type: Periodic	Company Report Number: MS84529			Age: 40 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Depression Nec		Accutane	PS	Roche	ORAL		78
Date: 10/26/1984	ISR Number: 301575-4	Report Type: Periodic	Company Report Number: MS84572			Age: 32 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Arthralgia Depression Nec		Accutane	PS	Roche	ORAL		126
Date: 10/17/1984	ISR Number: 301997-1	Report Type: Periodic	Company Report Number: MS84535			Age: 30 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Chest Pain Palpitations Tachycardia Nos		Accutane Naprosyn	PS C	Roche Syntex	ORAL ORAL		
Date: 10/17/1984	ISR Number: 301998-3	Report Type: Periodic	Company Report Number: MS84533			Age: 31 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec Libido Decreased		Accutane	PS	Roche	ORAL		140
Date: 10/23/1984	ISR Number: 302664-0	Report Type: Periodic	Company Report Number: MS84572			Age: 32 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Arthralgia Depression Nec		Accutane	PS	Roche	ORAL		126
Date: 10/18/1984	ISR Number: 303215-7	Report Type: Periodic	Company Report Number: MS84533			Age: 31 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec Libido Decreased		Accutane	PS	Roche	ORAL		140
Date: 10/29/1984	ISR Number: 303612-X	Report Type: Periodic	Company Report Number: MS84580			Age: 42 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Anaemia Nos Dyspnoea Nos Palpitations		Accutane	PS	Roche	ORAL		63

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
 Division of Information Systems

Date: 11/01/1984	ISR Number: 303920-2	Report Type: Periodic	Company Report Number: 84580			Age: 42 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Anemia Nos Dyspnoea Nos Palpitations		Accutane	PS	Roche	ORAL		63
Date: 11/13/1984	ISR Number: 305553-0	Report Type: Periodic	Company Report Number: MS84607			Age: 30 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Ear Disorder Nos Headache Nos Psychotic Disorder Nos		Accutane	PS	Roche	ORAL		
Date: 08/14/1984	ISR Number: 309598-6	Report Type: Expedited (15-Day)	Company Report Number: MS84354			Age: 70 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Confusion Eczema Nos		Accutane	PS	Roche	ORAL		60
Date: 08/24/1984	ISR Number: 309599-8	Report Type: Expedited (15-Day)	Company Report Number: MS84388			Age: 24 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Balanitis Nos Dry Skin Impotence Pain Nos		Accutane	PS	Roche	ORAL		150
Date: 08/14/1984	ISR Number: 309606-2	Report Type: Periodic	Company Report Number: MS84351			Age: 20 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Depression Nec		Accutane	PS	Roche	ORAL		150
Date: 09/03/1984	ISR Number: 309607-4	Report Type: Expedited (15-Day)	Company Report Number: MS84425			Age: 39 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Libido Decreased		Accutane	PS	Roche	ORAL		95
Date: 09/03/1984	ISR Number: 309610-4	Report Type: Expedited (15-Day)	Company Report Number: MS8426			Age: 45 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Depression Nec Rash Maculo-Papular Seborrhoea		Accutane	PS	Roche	ORAL		120

Adverse Drug Reaction System (ADRS)
Division of Biologics (D-10) Unit 5

Date: 08/24/1984	ISR Number: 309617-7	Report Type: Expedited (15-Day)	Company Report Number: MS84281			Age: 18 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Amnesia Nec		Accutane	PS	Roche	ORAL		2
Date: 09/06/1984	ISR Number: 311077-7	Report Type: Expedited (15-Day)	Company Report Number: 840200491001			Age: 5 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Disability	Congenital Abnormality Nos Hydrocephalus Nos Hypotonia Mental Retardation Severity Unspecified	Health Professional	Accutane Tylenol	PS C	Roche	ORAL ORAL		58
Date: 11/06/1984	ISR Number: 311571-9	Report Type: Periodic	Company Report Number: MS84-599			Age: 38 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Dysphonia		Accutane	PS	Roche	ORAL		90
Date: 12/18/1984	ISR Number: 311915-8	Report Type: Periodic	Company Report Number: MS84680			Age: 30 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Impotence Libido Decreased		Accutane	PS	Roche	ORAL		27
Date: 12/18/1984	ISR Number: 311921-3	Report Type: Periodic	Company Report Number: MS84678			Age: 44 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Anxiety Nec Ataxia Nec Multiple Sclerosis Sedation		Accutane Lithium Ativan Seconal Unspecified	PS C C C C	Roche	ORAL ORAL ORAL ORAL ORAL	G	
Date: 12/18/1984	ISR Number: 311948-1	Report Type: Expedited (15-Day)	Company Report Number: MS84676			Age: 35 MON	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged Other	Confusion Dermatitis Exfoliative Nos Epistaxis Hyperlipidaemia Nos		Accutane	PS	Roche	ORAL		111

Division of Health Planning, Statistics and Information Systems
 Bureau of Health Statistics
 Division of Information Systems

Date: 12/18/1984	ISR Number: 311950-X	Report Type: Expedited (15-Day)	Company Report Number: MS84686	Age: 32 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Death	Hypersensitivity Nos		Accutane	PS	Roche	ORAL		119
	Major Depressive Disorder Nos		Tofranil	C		ORAL		
Date: 11/23/1984	ISR Number: 312222-X	Report Type: Periodic	Company Report Number: MS84607	Age: 30 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Ear Disorder Nos		Accutane	PS	Roche	ORAL		126
	Headache Nos							
	Psychotic Disorder Nos							
Date: 11/08/1984	ISR Number: 312873-2	Report Type: Periodic	Company Report Number: MS84425	Age: 39 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Libido Decreased		Accutane	PS	Roche	ORAL		90
Date: 01/10/1985	ISR Number: 313432-8	Report Type: Periodic	Company Report Number: MS84710	Age: 70 YR	Gender: Unknown			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Amnesia Nec		Accutane	PS	Roche	ORAL		
Date: 01/10/1985	ISR Number: 313445-6	Report Type: Periodic	Company Report Number: MS84709	Age: 19 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Abnormal Dreams		Accutane	PS	Roche	ORAL		138
	Depression Nec		Septa Ds	C		ORAL		
	Sweating Increased		Ampicillin	C		ORAL	G	
			Keflex	C		ORAL	G	9
			Cleocin Hel	C		ORAL		
Date: 12/28/1984	ISR Number: 313485-7	Report Type: Expedited (15-Day)	Company Report Number: MS84696	Age: 23 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Depression Nec		Accutane	PS	Roche	ORAL		120
	Paranoia		Tofranil	C		ORAL		
Date: 12/28/1984	ISR Number: 313517-6	Report Type: Expedited (15-Day)	Company Report Number: MS84695	Age:	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Personality Disorder Nos		Accutane	PS	Roche	ORAL		

FDA Adverse Event Reporting System (AERS)
 Division of Information (D-01) Report

Date: 12/28/1984		ISR Number: 313607-8		Report Type: Expedited (15-Day)		Company Report Number: MS84708		Age: 52 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	Confusion	Health Professional	Accutane	PS	Roche	ORAL		35			
Other	Convulsions Nos		Hytone	C							
	Headache Nos		Decadron	C							
	Pyrexia										
Date: 12/28/1984		ISR Number: 313608-X		Report Type: Expedited (15-Day)		Company Report Number: MS84706		Age: 43 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	Health Professional	Accutane	PS	Roche	ORAL					
	Dermatitis Nos		Keflex	C							
	Emotional Disturbance Nos		Mycostatin	C							
	Nervousness										
Date: 12/28/1984		ISR Number: 313610-8		Report Type: Expedited (15-Day)		Company Report Number: MS84714		Age: 13 YR		Gender: Unknown	
<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>			
	Depression Nec		Accutane	PS	Roche	ORAL					
Date: 12/28/1984		ISR Number: 313636-4		Report Type: Expedited (15-Day)		Company Report Number: MS84709		Age: 19 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>			
	Abnormal Dreams		Accutane	PS	Roche	ORAL		138			
	Depression Nec		Erythronycin	C		ORAL	G				
	Sweating Increased		Ampicillin	C		ORAL	G				
			Septa Ds	C		ORAL		10			
			Keflex	C		ORAL		1			
Date: 12/28/1984		ISR Number: 313641-8		Report Type: Expedited (15-Day)		Company Report Number: MS84710		Age: 70 YR		Gender: Unknown	
<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	Amnesia Nec		Accutane	PS	Roche	ORAL					
Date: 12/28/1984		ISR Number: 313643-1		Report Type: Expedited (15-Day)		Company Report Number: MS84711		Age:		Gender: Unknown	
<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	Amnesia Nec		Accutane	PS	Roche	ORAL					

USA Adverse Drug Reporting System (ADRS)
 System Of Information (SOI) Report

Date: 01/04/1985		ISR Number: 313711-4	Report Type: Periodic	Company Report Number: MS84260		Age: 29 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Dysphonia Neoplasm Nos		Accutane	PS	Roche	ORAL		120
Date: 12/19/1984		ISR Number: 314914-5	Report Type: Periodic	Company Report Number: MS84661		Age: 17 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec		Accutane	PS	Roche	ORAL		47
Date: 12/19/1984		ISR Number: 314930-3	Report Type: Expedited (15-Day)	Company Report Number: MS84664		Age: 21 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Convulsions Nos Schizophrenia Nos		Accutane Tetracycline	PS C	Roche	ORAL ORAL		88
Date: 01/04/1985		ISR Number: 315186-8	Report Type: Periodic	Company Report Number: MS84714		Age: 13 YR	Gender: Unknown	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Depression Nec		Accutane	PS		ORAL		
Date: 01/04/1985		ISR Number: 315189-3	Report Type: Periodic	Company Report Number: MS84708		Age: 52 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Confusion		Accutane	PS	Roche	ORAL		
Date: 01/17/1985		ISR Number: 315194-7	Report Type: Periodic	Company Report Number: MS856		Age: 18 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Amnesia Nec		Accutane	PS	Roche	ORAL		
Date: 12/21/1984		ISR Number: 315346-6	Report Type: Periodic	Company Report Number: MS84676		Age: 35 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Confusion Dermatitis Exfoliative Nos Epistaxis Hyperlipidaemia Nos		Accutane	PS	Roche	ORAL		111
Date: 12/21/1984		ISR Number: 315352-1	Report Type: Periodic	Company Report Number: MS84680		Age: 30 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Impotence Libido Decreased		Accutane	PS	Roche	ORAL		27

Federal Bureau of Investigation
 Department of Justice
 Division of Information Systems

Date: 12/21/1984	ISR Number: 315364-8	Report Type: Periodic	Company Report Number: MS84686			Age: 32 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Death	Death		Accutane	PS	Roche	ORAL		119
	Depression Nec		Tofranil	C		ORAL		
	Non-Accidental Overdose							
Date: 01/17/1985	ISR Number: 316137-2	Report Type: Periodic	Company Report Number: MS855			Age: 36 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Thinking Abnormal Nec		Accutane	PS	Roche	ORAL		
Date: 01/04/1985	ISR Number: 316307-3	Report Type: Periodic	Company Report Number: MS84695			Age:	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Personality Disorder Nos		Accutane	PS	Roche	ORAL		
Date: 01/04/1985	ISR Number: 316308-5	Report Type: Periodic	Company Report Number: MS84696			Age: 23 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Agitation		Accutane	PS	Roche	ORAL		120
	Depression Nec		Tofranil	C		ORAL		
	Paranoia							
Date: 09/12/1984	ISR Number: 316444-3	Report Type: Expedited (15-Day)	Company Report Number: MS84434			Age: 30 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec		Accutane	PS	Roche	ORAL		60
Date: 09/11/1984	ISR Number: 316445-5	Report Type: Expedited (15-Day)	Company Report Number: MS84425			Age: 39 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Death	Libido Decreased		Accutane	PS	Roche	ORAL		
Date: 09/12/1984	ISR Number: 316454-6	Report Type: Expedited (15-Day)	Company Report Number: MS84433			Age: 35 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec		Accutane	PS	Roche	ORAL		73
Date: 09/12/1984	ISR Number: 316527-8	Report Type: Expedited (15-Day)	Company Report Number: MS84436			Age:	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Cleft Palate		Accutane	PS	Roche	ORAL		180
	Deafness Nos							

Federal Reporting System (FRS)
 National Reporting System (NRS)

Date: 01/04/1985	ISR Number: 316580-1	Report Type: Periodic	Company Report Number: MS84711			Age:	Gender: Unknown		
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration	
Other	Amnesia Nec		Accutane	PS	Roche				
Date: 01/14/1985	ISR Number: 317661-9	Report Type: Periodic	Company Report Number: MS856			Age:	Gender: Unknown		
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration	
Other	Amnesia Nec		Accutane	PS	Roche	ORAL			
Date: 01/14/1985	ISR Number: 317662-0	Report Type: Periodic	Company Report Number: MS855			Age:	Gender: Unknown		
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration	
Other	Amnesia Nec		Accutane	PS	Roche	ORAL			
Date: 01/29/1985	ISR Number: 319553-8	Report Type: Expedited (15-Day)	Company Report Number: 00044001			Age: 25 YR	Gender: Male		
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration	
Hospitalization - Initial or Prolonged	Psychotic Disorder Nos		Accutane Lithium	PS C	Roche	ORAL		730	
Date: 02/04/1985	ISR Number: 319614-3	Report Type: Periodic	Company Report Number: 85020006			Age: 26 YR	Gender: Male		
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration	
	Back Pain Cyst Nos Depression Nec		Accutane	PS	Roche	ORAL		214	
Date: 02/04/1985	ISR Number: 319620-9	Report Type: Periodic	Company Report Number: 85020004			Age: 25 YR	Gender: Male		
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration	
Hospitalization - Initial or Prolonged	Psychotic Disorder Nos		Accutane Lithium	PS C	Roche	ORAL		232 730	
Date: 09/21/1984	ISR Number: 322240-3	Report Type: Periodic	Company Report Number: MS84472			Age: 20 YR	Gender: Female		
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration	
Other	Depression Nec		Accutane Atarax	PS C	Roche	ORAL ORAL		32	
Date: 02/05/1985	ISR Number: 322402-5	Report Type: Expedited (15-Day)	Company Report Number: 85020009			Age: 26 YR	Gender: Male		
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration	
Other	Headache Nos		Accutane	PS	Roche	ORAL			

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 DEPARTMENT OF JUSTICE

Date: 01/28/1985	ISR Number: 325954-4	Report Type: Periodic	Company Report Number: 85020011			Age: 24 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Dysphonia		Accutane	PS	Roche	ORAL		600
Date: 01/30/1985	ISR Number: 326430-5	Report Type: Periodic	Company Report Number: 85020006			Age: 26 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Depression Nec Pain Nos Thinking Abnormal Nec		Accutane	PS	Roche	ORAL		
Date: 02/11/1985	ISR Number: 330947-7	Report Type: Periodic	Company Report Number: 85020009			Age: 26 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Headache Nos Hypertension Nos Insomnia Nec Nausea		Accutane Inderal Multivitamins Captopril	PS C C C	Roche	ORAL ORAL ORAL ORAL		
Date: 04/04/1985	ISR Number: 337875-1	Report Type: Periodic	Company Report Number: 85020037			Age: 16 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Hypotension Personality Disorder Nos		Accutane Florinal Midrin	PS C C	Roche	ORAL		125
Date: 03/29/1985	ISR Number: 339601-9	Report Type: Expedited (15-Day)	Company Report Number: 85020028			Age: 16 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Depression Nec		Accutane	PS	Roche	ORAL		141
Date: 04/01/1985	ISR Number: 339610-X	Report Type: Expedited (15-Day)	Company Report Number: 85020037			Age: 16 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Arthritis Nos Personality Disorder Nos Postural Hypotension		Accutane Florinal Midrin	PS C C	Roche	ORAL		141
Date: 03/14/1985	ISR Number: 342031-7	Report Type: Periodic	Company Report Number: 00281001			Age: 16 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Depression Nec		Accutane	PS	Roche	ORAL		141

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

Date: 05/12/1985		ISR Number: 342555-2		Report Type: Expedited (15-Day)		Company Report Number: 85020024		Age: 21 YR		Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Other	Confusion		Accutane	PS	Roche	ORAL		153			
	Hair Disorder Nos		Erythromycin	C		ORAL					
	Sedation		Motrin	C		ORAL	G				
	Weight Decreased										
Date: 05/07/1985		ISR Number: 342863-5		Report Type: Expedited (15-Day)		Company Report Number: 00532001		Age: 16 YR		Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Other	Depression Nec		Accutane	PS	Roche	ORAL		158			
	Personality Disorder Nos										
Date: 03/15/1985		ISR Number: 343680-2		Report Type: Periodic		Company Report Number: 00185001		Age: 17 YR		Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
	Impotence		Accutane	PS	Roche	ORAL		121			
Date: 03/15/1985		ISR Number: 343683-8		Report Type: Periodic		Company Report Number: 00254001		Age: 25 YR		Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
	Amnesia Nec		Accutane	PS	Roche	ORAL					
	Headache Nos										
	Vision Abnormal Nec										
Date: 05/09/1985		ISR Number: 344137-5		Report Type: Periodic		Company Report Number: 00386001		Age: 13 YR		Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Hospitalization - Initial or Prolonged	Depression Nec		Accutane	PS	Roche	ORAL		140			
	Hypertlipidaemia Nos		Tetracycline	C							
	Menometrorrhagia										
Date: 05/10/1985		ISR Number: 344273-3		Report Type: Periodic		Company Report Number: MS84294		Age: 16 YR		Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Other	Impotence		Accutane	PS	Roche	ORAL		67			
Date: 05/09/1985		ISR Number: 344498-7		Report Type: Periodic		Company Report Number: 00230001		Age: 20 YR		Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration			
Hospitalization - Initial or Prolonged	Psychotic Disorder Nos		Accutane	PS	Roche	ORAL					
Other											

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

Date: 05/10/1985	ISR Number: 345135-8	Report Type: Periodic	Company Report Number: MS84402			Age: 17 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Blood Alkaline Phosphatase Nos Increased Schizophrenia Nos		Accutane	PS	Roche	ORAL		142
Date: 05/10/1985	ISR Number: 345136-X	Report Type: Periodic	Company Report Number: 00285001			Age: 39 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Arthralgia Myalgia Tenosynovitis Thinking Abnormal Nec		Accutane Thyroid	PS C	Roche	ORAL ORAL		72 MG
Date: 05/10/1985	ISR Number: 345192-9	Report Type: Periodic	Company Report Number: 00010001			Age: 33 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Arthralgia Back Pain Insomnia Nec		Accutane	PS	Roche	ORAL		112
Date: 04/17/1985	ISR Number: 345326-6	Report Type: Expedited (15-Day)	Company Report Number: 85020042			Age: 43 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Depression Nec Emotional Disturbance Nos		Accutane	PS	Roche	ORAL		
Date: 05/10/1985	ISR Number: 345385-0	Report Type: Periodic	Company Report Number: MS84295			Age: 30 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Anxiety Nec		Accutane Sumycin Hcl	PS C	Roche	ORAL ORAL		
Date: 05/10/1985	ISR Number: 345405-3	Report Type: Periodic	Company Report Number: 00103001			Age: 16 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Alopecia Nail Disorder Nos Personality Disorder Nos		Accutane	PS	Roche	ORAL		100
Date: 04/29/1985	ISR Number: 345740-9	Report Type: Expedited (15-Day)	Company Report Number: 00524001			Age: 46 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Libido Decreased		Accutane	PS	Roche	ORAL		228

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES
 NATIONAL CENTER FOR HUMAN GENETICS

Date: 05/10/1985		ISR Number: 345888-9	Report Type: Periodic	Company Report Number: 00392001			Age: 17 YR	Gender: Male
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Alopecia Palpitations		Accutane	PS	Roche	ORAL		112
Date: 05/01/1985		ISR Number: 349045-1	Report Type: Periodic	Company Report Number: 00524001			Age: 46 YR	Gender: Male
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Libido Decreased		Accutane	PS	Roche	ORAL		228
Date: 05/09/1985		ISR Number: 349792-1	Report Type: Periodic	Company Report Number: MS84368			Age: 18 YR	Gender: Male
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec Thinking Abnormal Nec		Accutane	PS	Roche	ORAL		29
Date: 05/10/1985		ISR Number: 350264-9	Report Type: Periodic	Company Report Number: 00205001			Age: 19 YR	Gender: Female
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Acne Nos Depression Nec Drug Ineffective		Accutane	PS	Roche	ORAL		120
Date: 05/10/1985		ISR Number: 350278-9	Report Type: Periodic	Company Report Number: 00017001			Age: 32 YR	Gender: Female
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Palpitations		Accutane	PS	Roche	ORAL		44
Date: 05/10/1985		ISR Number: 350281-9	Report Type: Periodic	Company Report Number: 00015001			Age: 20 YR	Gender: Female
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Alopecia Anxiety Nec Asthenia Dizziness (Exc Vertigo)		Accutane	PS	Roche	ORAL		126
Date: 05/10/1985		ISR Number: 350295-9	Report Type: Periodic	Company Report Number: MS84214			Age: 20 YR	Gender: Female
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Insomnia Nec		Accutane	PS	Roche	ORAL		

U.S. Access to Personal Data (APDS)
Freedom of Information Act Report

Date: 05/10/1985	ISR Number: 350330-8	Report Type: Periodic	Company Report Number: 00078001			Age: 30 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Impotence		Accutane	PS	Roche	ORAL		69
Date: 05/10/1985	ISR Number: 350576-9	Report Type: Periodic	Company Report Number: MS84719			Age: 26 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec Myalgia Rectal Bleeding		Accutane	PS	Roche	ORAL		43
Date: 06/27/1985	ISR Number: 354278-4	Report Type: Expedited (15-Day)	Company Report Number: 00726001			Age: 24 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Myalgia Palpitations Tachycardia Nos		Accutane Modicon	PS C	Roche	ORAL		47
Date: 06/25/1985	ISR Number: 354283-8	Report Type: Expedited (15-Day)	Company Report Number: 00652001			Age: 17 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Aphasia Carotid Artery Stenosis Hemiplegia		Accutane	PS	Roche	ORAL		
Date: 10/07/1985	ISR Number: 366392-8	Report Type: Periodic	Company Report Number: 01147001			Age: 49 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Amnesia Nec Dry Skin Myopathy Vision Abnormal Nec		Accutane	PS	Roche	ORAL		128
Date: 10/16/1985	ISR Number: 367370-5	Report Type: Periodic	Company Report Number: 01217001			Age: 15 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Death	Depression Nec		Accutane	PS	Roche	ORAL		29
Date: 10/17/1985	ISR Number: 368132-5	Report Type: Expedited (15-Day)	Company Report Number: 01217001			Age: 15 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Death	Depression Nec		Accutane	PS	Roche	ORAL		29

U.S. Agency for International Development (AID)
 DIVISION OF INFORMATION COLLECTION

Date: 10/24/1985	ISR Number: 372390-0	Report Type: Periodic	Company Report Number: MS84426	Age: 45 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Condition Aggravated Depression Nec Seborrhoea Skin Disorder Nos		Accutane	PS	Roche	ORAL		120
Date: 12/01/1985	ISR Number: 373016-2	Report Type: Expedited (15-Day)	Company Report Number: 01548001	Age: 22 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Cerebrovascular Disorder Nos Hirsutism Hyporeflexia Psychotic Disorder Nos	Foreign	Accutane	PS	Roche	ORAL		17
Date: 10/23/1985	ISR Number: 373113-1	Report Type: Periodic	Company Report Number: MS84426	Age: 45 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Condition Aggravated Depression Nec Heat Rash Seborrhoea		Accutane	PS	Roche	ORAL		
Date: 12/10/1985	ISR Number: 376051-3	Report Type: Periodic	Company Report Number: 01147001	Age: 49 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Amnesia Nec Dry Skin Myopathy Vision Abnormal Nec		Accutane	PS	Roche	ORAL		90
Date: 01/07/1986	ISR Number: 378385-5	Report Type: Periodic	Company Report Number: 00747001	Age: 35 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Confusion Epistaxis Headache Nos Hyperlipidemia Nos		Accutane	PS	Roche	ORAL		111
Date: 02/10/1986	ISR Number: 384028-7	Report Type: Periodic	Company Report Number: 00112001	Age: 38 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Palpitations		Accutane	PS	Roche	ORAL		111

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

Date: 02/11/1986	ISR Number: 384033-0	Report Type: Expedited (15-Day)	Company Report Number: 00188001	Age: 43 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Alopecia Cheilitis Corneal Ulcer Nec Depression Nec	Literature	Accutane	PS	Roche	ORAL		244
Date: 02/25/1986	ISR Number: 384455-8	Report Type: Expedited (15-Day)	Company Report Number: 860200057001	Age: 15 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Arthralgia Depression Nec Personality Disorder Nos Syncope	Health Professional	Accutane	PS	Roche	ORAL		28
Date: 03/05/1986	ISR Number: 385499-2	Report Type: Expedited (15-Day)	Company Report Number: 860101669001	Age: 22 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Personality Disorder Nos Speech Disorder Nec Thinking Abnormal Nec	Foreign	Accutane	PS	Roche	ORAL		138
Date: 05/14/1986	ISR Number: 394615-8	Report Type: Expedited (15-Day)	Company Report Number: 860200518001	Age: 19 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Amnesia Nec	Foreign Health Professional	Accutane Alcohol	PS C	Roche	ORAL		42
Date: 06/30/1986	ISR Number: 401306-3	Report Type: Expedited (15-Day)	Company Report Number: 860200760001	Age: 16 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Amnesia Nec Conversion Disorder Lymphocytosis	Health Professional	Accutane Prednisone	PS C	Roche	ORAL		159
Date: 07/16/1986	ISR Number: 403506-5	Report Type: Expedited (15-Day)	Company Report Number: 860200823001	Age: 18 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged Other	Acne Nos Epistaxis Pharyngitis Nos Psychotic Disorder Nos	Health Professional	Accutane	PS	Roche	ORAL		417

U.S. Food and Drug Administration (FDA)
Division of Databases (DDB)
Division of Information (DOI) Report

Date: 08/07/1986	ISR Number: 406042-5	Report Type: Periodic	Company Report Number: 840200909001			Age: 20 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec Headache Nos Hirsutism Weight Decreased	Health Professional	Accutane	PS	Roche	ORAL		492
Date: 08/07/1986	ISR Number: 406043-7	Report Type: Periodic	Company Report Number: 840200943001			Age: 19 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Adrenal Insufficiency Nos Anxiety Nec Benign Intracranial Hypertension Hypotension	Consumer	Accutane	PS	Roche	ORAL		89
Date: 08/07/1986	ISR Number: 406548-9	Report Type: Periodic	Company Report Number: 850201251001			Age: 45 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec Emotional Disturbance Nos	Health Professional	Accutane Minocin	PS C	Roche	ORAL		7
Date: 08/01/1986	ISR Number: 406560-X	Report Type: Periodic	Company Report Number: 850201248001			Age: 16 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Anaemia Nos Condition Aggravated Depression Nec	Health Professional	Accutane	PS	Roche	ORAL		120
Date: 08/07/1986	ISR Number: 406570-2	Report Type: Periodic	Company Report Number: 860200213001			Age: 24 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec	Health Professional	Accutane	PS	Roche	ORAL		146
Date: 08/07/1986	ISR Number: 406581-7	Report Type: Periodic	Company Report Number: 850201180001			Age: 17 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Disability	Syncope Thinking Abnormal Nec	Health Professional	Accutane	PS	Roche	ORAL		133
Date: 08/07/1986	ISR Number: 406588-X	Report Type: Periodic	Company Report Number: 840200875001			Age: 23 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Infection Nos Nail Disorder Nos Personality Disorder Nos	Health Professional	Accutane	PS	Roche	ORAL		112

FDA Adverse Event Reporting System (AERS)
 Product Identification (PID) Report

Date: 08/07/1986	ISR Number: 406590-8	Report Type: Periodic	Company Report Number: 860200262001			Age: 57 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Nervousness	Health Professional	Accutane	PS	Roche	ORAL		
Date: 08/07/1986	ISR Number: 407261-4	Report Type: Periodic	Company Report Number: 850201462001			Age: 30 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Agitation Headache Nos Tachycardia Nos	Consumer	Accutane	PS	Roche	ORAL		173
Date: 08/07/1986	ISR Number: 407266-3	Report Type: Periodic	Company Report Number: 850201315001			Age: 31 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Impotence	Health Professional	Accutane	PS	Roche	ORAL		51
Date: 08/07/1986	ISR Number: 407270-5	Report Type: Periodic	Company Report Number: 850200849001			Age: 17 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Alopecia Depression Nec Granuloma Nos Nail Disorder Nos	Health Professional	Accutane	PS	Roche	ORAL		130
Date: 08/07/1986	ISR Number: 407291-2	Report Type: Periodic	Company Report Number: 860200187001			Age: 29 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Depression Nec	Health Professional	Accutane	PS	Roche	ORAL		
			Lithium	C				
			Thorazine	C				
			Xanax	C				
			Aventyl	C				
Date: 08/07/1986	ISR Number: 407299-7	Report Type: Periodic	Company Report Number: 850200613001			Age: 19 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Impotence	Health Professional	Accutane	PS	Roche	ORAL		145
			Theo-Dur	C				
			Ventolin	C				
			Intal	C				
			Dimetapp	C				

FDA Adverse Event Reporting System (FAERS)
 Program of Information on Reports

Date: 08/07/1986	ISR Number: 408677-2	Report Type: Periodic	Company Report Number: 850200610001			Age: 28 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Dizziness (Exc Vertigo) Personality Disorder Nos Syncope	Health Professional	Accutane	PS	Roche	ORAL		99
Date: 07/21/1986	ISR Number: 409013-8	Report Type: Expedited (15-Day)	Company Report Number: 860200853001			Age: 17 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Death	Emotional Disturbance Nos Major Depressive Disorder Nos	Consumer	Accutane	PS	Roche	ORAL		
Date: 08/07/1986	ISR Number: 409359-3	Report Type: Periodic	Company Report Number: 850201352001			Age: 17 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Disability	Depression Nec Personality Disorder Nos	Health Professional	Accutane	PS	Roche	ORAL		4
Date: 08/07/1986	ISR Number: 409394-5	Report Type: Periodic	Company Report Number: 850200920001			Age:	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Abnormal Dreams	Health Professional	Accutane	PS	Roche	ORAL		140
Date: 08/07/1986	ISR Number: 410567-6	Report Type: Periodic	Company Report Number: 850200594001			Age: 21 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec Dermatitis Contact Impotence Refractive Errors Nos	Consumer	Accutane Minoxin	PS C	Roche	ORAL		231
Date: 08/07/1986	ISR Number: 410569-X	Report Type: Periodic	Company Report Number: 850200585001			Age: 42 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Abdominal Pain Nos Dyspepsia Insomnia Nec Sweating Increased	Health Professional	Accutane Prednisone Keflex	PS C C	Roche	ORAL		4
Date: 08/07/1986	ISR Number: 410666-9	Report Type: Periodic	Company Report Number: 860200020001			Age: 28 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Anorexia Condition Aggravated Depression Nec Nausea	Health Professional	Accutane	PS	Roche	ORAL		76

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Adverse Event Reporting System (AERS)
 System of Information (SOI) Report

Date: 08/07/1986	ISR Number: 410727-4	Report Type: Periodic	Company Report Number: 850201040001			Age:	Gender: Male		
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration	
Other	Major Depressive Disorder Nos	Health Professional	Accutane	PS	Roche	ORAL			
Date: 08/07/1986	ISR Number: 411141-8	Report Type: Periodic	Company Report Number: 850201058001			Age: 20 YR	Gender: Male		
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration	
Other	Apathy Mydriasis	Health Professional	Accutane	PS	Roche	ORAL			
Date: 08/07/1986	ISR Number: 411260-6	Report Type: Periodic	Company Report Number: 850200477001			Age: 35 YR	Gender: Female		
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration	
Disability	Condition Aggravated Depression Nec Skin Discolouration	Health Professional	Accutane	PS	Roche	ORAL		42	
Date: 08/07/1986	ISR Number: 411361-2	Report Type: Periodic	Company Report Number: 850200655001			Age: 17 YR	Gender: Male		
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration	
Disability	Depression Nec	Health Professional	Accutane	PS	Roche	ORAL		135	
Date: 08/07/1986	ISR Number: 411909-8	Report Type: Periodic	Company Report Number: 850201406001			Age: 19 YR	Gender: Female		
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration	
Other	Conjunctivitis Nec Dysphonia Menstrual Disorder Nos	Health Professional	Accutane	PS	Roche	ORAL		102	
Date: 08/07/1986	ISR Number: 413358-5	Report Type: Periodic	Company Report Number: 860200306001			Age: 17 YR	Gender: Male		
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration	
Hospitalization - Initial or Prolonged	Blindness Night Condition Aggravated Hyperlipidaemia Nos Mania	Health Professional	Accutane Lithium Minocin Tagamet	PS C C C	Roche	ORAL		285	
Date: 08/07/1986	ISR Number: 413372-X	Report Type: Periodic	Company Report Number: 850201557001			Age: 20 YR	Gender: Female		
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration	
Other	Condition Aggravated Dysphonia Laryngitis Nos	Health Professional	Accutane	PS	Roche	ORAL		115	

FD-302a (Rev. 12-1-83) Reporting System (ADDS)
 System of Information (PH) Report

Date: 08/07/1986	ISR Number: 413406-2	Report Type: Periodic	Company Report Number: 840200961001			Age: 19 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Arthralgia Depression Nec Headache Nos Nausca	Health Professional	Accutane Alcohol	PS C	Roche	ORAL		168
Date: 08/07/1986	ISR Number: 413453-0	Report Type: Periodic	Company Report Number: 850200707001			Age: 35 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Antinuclear Factor Positive Asthenia Depression Nec Myalgia	Health Professional	Accutane	PS	Roche	ORAL		
Date: 08/07/1986	ISR Number: 413603-6	Report Type: Periodic	Company Report Number: 86020049001			Age: 18 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Major Depressive Disorder Nos	Health Professional	Accutane	PS	Roche	ORAL		46
Date: 08/07/1986	ISR Number: 413606-1	Report Type: Periodic	Company Report Number: 860200031001			Age: 28 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec	Health Professional	Accutane	PS	Roche	ORAL		83
Date: 08/07/1986	ISR Number: 413616-4	Report Type: Periodic	Company Report Number: 850201580001			Age: 22 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Abdominal Pain Nos Depression Nec Emotional Disturbance Nos Headache Nos	Health Professional	Accutane	PS	Roche	ORAL		4
Date: 08/07/1986	ISR Number: 413625-5	Report Type: Periodic	Company Report Number: 850201478001			Age: 34 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec	Health Professional	Accutane Marax	PS C	Roche	ORAL		168
Date: 07/23/1986	ISR Number: 414343-X	Report Type: Direct	Company Report Number:			Age: 25 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Anxiety Nec Depression Nec	Health Professional	Accutane	PS	Roche	ORAL		48

Adverse Event Reporting System (AERS)
 Division of Information Systems

Date: 08/17/1986	ISR Number: 414344-1	Report Type: Periodic	Company Report Number: 850200925001			Age: 39 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Dysphonia	Health Professional	Accutane	PS	Roche	ORAL		120
Date: 08/07/1986	ISR Number: 415015-8	Report Type: Periodic	Company Report Number: 850200985001			Age: 46 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Impotence	Health Professional	Accutane	PS	Roche	ORAL		732
Date: 08/07/1986	ISR Number: 415022-5	Report Type: Periodic	Company Report Number: 860200129001			Age:	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Amnesia Nec Coordination Abnormal Nos Urinary Tract Infection Nos Varicose Veins Nos	Consumer	Accutane	PS	Roche	ORAL		778
Date: 08/07/1986	ISR Number: 415249-2	Report Type: Periodic	Company Report Number: 860200115001			Age: 29 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Aspartate Aminotransferase Increased Blood Creatine Phosphokinase Increased Blood Lactate Dhydrogenase Increased Depression Nec	Health Professional	Accutane Hydrodiuril	PS C	Roche	ORAL		16
Date: 07/28/1986	ISR Number: 425361-X	Report Type: Periodic	Company Report Number: 840201005003			Age:	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Delirium	Health Professional	Accutane	PS	Roche	ORAL		
Date: 11/13/1986	ISR Number: 430401-8	Report Type: Expedited (15-Day)	Company Report Number: 860201286001			Age: 19 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Acne Nos Hostility	Consumer	Accutane	PS	Roche	ORAL		196
Other	Major Depressive Disorder Nos Weight Decreased		Lithium Meclan Tetracycline Celestone	C C C C				

FDA Adverse Event Reporting System (AERS)
 System of Organization (SO) Report

Date: 02/11/1987	ISR Number: 447708-0	Report Type: Expedited (15-Day)	Company Report Number: 860200086001	Age: 21 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Death	Alanine Aminotransferase Increased Back Pain Major Depressive Disorder Nos Personality Disorder Nos	Health Professional	Accutane	PS	Roche	ORAL		104
Date: 02/17/1987	ISR Number: 447722-5	Report Type: Direct	Company Report Number:	Age: 22 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec Emotional Disturbance Nos	Health Professional	Accutane	PS	Roche	ORAL		90
Date: 02/05/1987	ISR Number: 448059-0	Report Type: Expedited (15-Day)	Company Report Number: 8602000952001	Age: 22 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Cardiovascular Disorder Nos Depression Nec Hypotension Tachycardia Nos	Health Professional	Accutane	PS	Roche	ORAL		20
Date: 02/05/1987	ISR Number: 448066-8	Report Type: Expedited (15-Day)	Company Report Number: 870200061001	Age: 17 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Death	Major Depressive Disorder Nos	Health Professional	Accutane	PS	Roche	ORAL		94
Date: 02/17/1987	ISR Number: 448219-9	Report Type: Direct	Company Report Number:	Age: 24 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Ashenia Depression Nec	Health Professional	Accutane	PS	Roche	ORAL		49
Date: 02/06/1987	ISR Number: 448450-2	Report Type: Expedited (15-Day)	Company Report Number: 840200020001	Age: 20 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Calcium Metabolism Disorder Major Depressive Disorder Nos Non-Accidental Overdose Tenosynovitis	Health Professional	Accutane	PS	Roche	ORAL		1188
Date: 03/18/1987	ISR Number: 453579-9	Report Type: Expedited (15-Day)	Company Report Number: 870200261001	Age: 17 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Death	Cardiac Arrest Chest Pain	Health Professional	Accutane Tetracycline	PS C	Roche	ORAL		4

FDA Adverse Event Reporting System (AERS)
 System Of Information (SOI) Report

Date: 04/13/1987		ISR Number: 458010-5	Report Type: Expedited (15-Day)	Company Report Number: 870200228001	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	Conjunctivitis Nec Depression Nec Vasodilatation	Health Professional	Accutane Minocin	PS C	Roche	ORAL		86	
Date: 04/16/1987		ISR Number: 461294-0	Report Type: Expedited (15-Day)	Company Report Number: 870200134001	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>	
Hospitalization - Initial or Prolonged Other	Anxiety Nec Epistaxis Headache Nos Major Depressive Disorder Nos	Health Professional	Accutane	PS	Roche	ORAL		349	
Date: 05/12/1987		ISR Number: 462882-8	Report Type: Expedited (15-Day)	Company Report Number: 860200851001	Age: 1 MON	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 Other	Congenital Abnormality Nos Mental Retardation Severity Unspecified	Health Professional	Accutane	PS	Roche	ORAL		144	
Date: 05/12/1987		ISR Number: 463495-4	Report Type: Expedited (15-Day)	Company Report Number: 870200501001	Age: 29 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 Hyperlipidaemia Nos Paresthesia Nec	Health Professional	Accutane	PS	Roche	ORAL		208	
Date: 05/22/1987		ISR Number: 464073-3	Report Type: Periodic	Company Report Number: 850201217001	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>	
Death	Major Depressive Disorder Nos	Health Professional	Accutane	PS	Roche	ORAL		30	
Date: 05/08/1987		ISR Number: 465397-6	Report Type: Expedited (15-Day)	Company Report Number: 870200283001	Age: 42 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 Disability Other	Amnesia Nec Coma Nec Dermatitis Nos Infection Nos	Consumer	Accutane Valium Nitracort Hytone Kwell	PS C C C C	Roche	ORAL			

FDA Adverse Event Reporting System (AERS)
 Division of Information (D-01) Report

Date: 06/02/1987	ISR Number: 467421-3	Report Type: Expedited (15-Day)	Company Report Number: 870200301001	Age: 23 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Hyperlipidaemia Nos	Health Professional	Accutane	PS	Roche	ORAL		40
Disability	Joint Disorder Nos		Minocin	C				
Other	Neurosis Nos							
	Oedema Nos							
Date: 07/30/1987	ISR Number: 477054-0	Report Type: Periodic	Company Report Number: 870200376001	Age: 18 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Dry Skin	Health Professional	Accutane	PS	Roche	ORAL		6
	Emotional Disturbance Nos							
	Epistaxis							
	Face Oedema							
Date: 07/30/1987	ISR Number: 477073-4	Report Type: Periodic	Company Report Number: 870200322001	Age: 30 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Alopecia	Health Professional	Accutane	PS	Roche	ORAL		117
	Condition Aggravated							
	Headache Nos							
	Neurosis Nos							
Date: 07/30/1987	ISR Number: 477424-0	Report Type: Periodic	Company Report Number: 860200451001	Age: 24 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Amnesia Nec	Health Professional	Accutane	PS	Roche	ORAL		87
	Confusion							
	Headache Nos		Benzoyl Peroxide	C				
	Insomnia Nec		Cleocin-T	C				
Date: 07/30/1987	ISR Number: 477426-4	Report Type: Periodic	Company Report Number: 860200563001	Age: 42 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Anxiety Nec	Consumer	Accutane	PS	Roche	ORAL		
	Hypercholesterolaemia		Valium	C				
	Hypertension Nos							
	Nervousness							
Date: 07/30/1987	ISR Number: 477452-5	Report Type: Periodic	Company Report Number: 860201212001	Age: 34 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Alopecia	Health Professional	Accutane	PS	Roche	ORAL		96
	Depression Nec							
	Headache Nos							

FDA Adverse Event Reporting System (AERS)
 System of Information (SOI) Report

Date: 07/30/1987	ISR Number: 477703-7	Report Type: Periodic	Company Report Number: 860201124001			Age: 22 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Disability	Depression Nec Keratoconjunctivitis	Health Professional	Accutane	PS	Roche	ORAL		60
Date: 07/30/1987	ISR Number: 477880-8	Report Type: Periodic	Company Report Number: 860201417001			Age: 24 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Abnormal Dreams Dry Skin Hepatic Function Abnormal Nos Keratoconjunctivitis	Consumer	Accutane	PS	Roche	ORAL		51
Date: 07/30/1987	ISR Number: 477888-2	Report Type: Periodic	Company Report Number: 860201215001			Age: 25 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Personality Disorder Nos	Health Professional	Accutane	PS	Roche	ORAL		60
Date: 07/30/1987	ISR Number: 477889-4	Report Type: Periodic	Company Report Number: 860201253001			Age: 23 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec Hypertonia Infection Nos Weight Decreased	Consumer	Accutane Augmentin Ampicillin Prednisone Unipen	PS C C C C	Roche	ORAL		90
Date: 07/30/1987	ISR Number: 478027-4	Report Type: Periodic	Company Report Number: 860201489001			Age: 24 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec Hypercholesterolaemia Keratoconjunctivitis Urticaria Nos	Health Professional	Accutane	PS	Roche	ORAL		242
Date: 07/30/1987	ISR Number: 478209-1	Report Type: Periodic	Company Report Number: 860201244001			Age: 19 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Abdominal Pain Nos Hyperlipidaemia Nos Palpitations Tachycardia Nos	Health Professional	Accutane	PS	Roche	ORAL		127

FDA Adverse Event Reporting System (AERS)
 Program of International Drug Reporting

Date: 07/30/1987	ISR Number: 478215-7	Report Type: Periodic	Company Report Number: 860200568001			Age: 17 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Personality Disorder Nos	Health Professional	Accutane	PS	Roche	ORAL		320
Date: 07/30/1987	ISR Number: 478233-9	Report Type: Periodic	Company Report Number: 860200841003			Age:	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Personality Disorder Nos	Health Professional	Accutane	PS	Roche	ORAL		
Date: 07/30/1987	ISR Number: 478255-8	Report Type: Periodic	Company Report Number: 860200611001			Age: 31 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Alopecia Depression Nec Dry Skin Photosensitivity Reaction Nos	Health Professional	Accutane	PS	Roche	ORAL		91
Date: 07/30/1987	ISR Number: 478260-1	Report Type: Periodic	Company Report Number: 860200714001			Age: 21 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec	Health Professional	Accutane	PS	Roche	ORAL		2
Date: 07/30/1987	ISR Number: 478272-8	Report Type: Periodic	Company Report Number: 870200196001			Age: 48 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Agitation Conjunctivitis Nec Headache Nos Vision Abnormal Nec	Health Professional	Accutane Premarin Thyroid	PS C C	Roche	ORAL		5
Date: 07/30/1987	ISR Number: 478296-0	Report Type: Periodic	Company Report Number: 870200113001			Age:	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Depression Nec Personality Disorder Nos	Health Professional	Accutane	PS	Roche			
Date: 07/30/1987	ISR Number: 478847-6	Report Type: Periodic	Company Report Number: 860200999001			Age: 30 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Emotional Disturbance Nos Insomnia Nec Unintended Pregnancy	Health Professional	Accutane	PS	Roche	ORAL		50

Adverse Event Reporting System (AERS)
 National Drug Information Program

Date: 07/30/1987	ISR Number: 478852-X	Report Type: Periodic	Company Report Number: 860200906001			Age: 29 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	Convulsions Nos Depression Nec Headache Nos Vomiting Nos	Health Professional	Accutane Vicodin Elavil Sansert	PS C C C	Roche	ORAL		31
Date: 07/30/1987	ISR Number: 479438-3	Report Type: Periodic	Company Report Number: 860201102001			Age: 25 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	Personality Disorder Nos Weight Decreased	Health Professional	Accutane	PS	Roche	ORAL		88
Date: 07/30/1987	ISR Number: 479450-4	Report Type: Periodic	Company Report Number: 860200993001			Age: 19 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	Impotence	Health Professional	Accutane	PS	Roche	ORAL		112
Date: 07/30/1987	ISR Number: 479452-8	Report Type: Periodic	Company Report Number: 860200986001			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	Hostility Personality Disorder Nos	Health Professional	Accutane	PS	Roche	ORAL		
Date: 07/30/1987	ISR Number: 479458-9	Report Type: Periodic	Company Report Number: 860200958001			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	Anxiety Nec Arthralgia Pruritus Vaginal Discharge	Health Professional	Accutane Hydrocortisone Teldrin	PS C C	Roche	ORAL		181
Date: 07/30/1987	ISR Number: 479466-8	Report Type: Periodic	Company Report Number: 860200411001			Age: 39 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 Asthenia Dry Skin Nervousness	Consumer	Accutane	PS	Roche	ORAL		23
Date: 07/30/1987	ISR Number: 479480-2	Report Type: Periodic	Company Report Number: 860200301001			Age: 28 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	Impotence	Health Professional	Accutane	PS	Roche	ORAL		96

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FD-302a (Rev. 12-13-83) Reporting System (SERS)
 Division of Investigation (DOJ) Report

Date: 08/05/1987	ISR Number: 479575-3	Report Type: Periodic	Company Report Number: 860200865001			Age: 16 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Acne Nos Blood Alkaline Phosphatase Nos Increased Depression Nec Headache Nos	Health Professional	Accutane	PS	Roche	ORAL		44
Date: 07/30/1987	ISR Number: 479590-X	Report Type: Periodic	Company Report Number: 860200841001			Age:	Gender: Unknown	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Personality Disorder Nos	Health Professional	Accutane	PS	Roche	ORAL		
Date: 07/30/1987	ISR Number: 479591-1	Report Type: Periodic	Company Report Number: 860200841002			Age:	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Personality Disorder Nos	Health Professional	Accutane	PS	Roche	ORAL		
Date: 07/30/1987	ISR Number: 479724-7	Report Type: Periodic	Company Report Number: 860201189001			Age: 18 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec	Health Professional	Accutane	PS	Roche	ORAL		42
Date: 07/30/1987	ISR Number: 479762-4	Report Type: Periodic	Company Report Number: 860200472001			Age: 37 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Amnesia Nec	Health Professional	Accutane	PS	Roche	ORAL		
Date: 07/30/1987	ISR Number: 479763-6	Report Type: Periodic	Company Report Number: 860200473001			Age: 16 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Agitation Hostility Personality Disorder Nos	Health Professional	Accutane	PS	Roche	ORAL		
Date: 07/30/1987	ISR Number: 479764-8	Report Type: Periodic	Company Report Number: 860200474001			Age: 36 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec Emotional Disturbance Nos Insomnia Nec Nervousness	Health Professional	Accutane	PS	Roche	ORAL		11

Pharmaceutical Reporting System (PERS)
 Division of Information Control

Date: 07/30/1987 ISR Number: 479788-0 Report Type: Periodic Company Report Number: 870200038001 Age: 26 YR Gender: Male									
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration	
Other	Asthenia Depression Nec Thinking Abnormal Nec	Health Professional	Accutane	PS	Roche	ORAL		152	
Date: 07/30/1987 ISR Number: 479791-0 Report Type: Periodic Company Report Number: 870200049001 Age: 26 YR Gender: Female									
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration	
Other	Depression Nec Keratoconjunctivitis	Health Professional	Accutane	PS	Roche	ORAL		103	
Date: 07/27/1987 ISR Number: 481107-0 Report Type: Expedited (15-Day) Company Report Number: 860201428001 Age: 42 YR Gender: Female									
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration	
Hospitalization - Initial or Prolonged	Coma Nec Dementia Nos	Health Professional	Accutane	PS	Roche	ORAL			
Disability	Dermatitis Nos		Valium	C					
Other	Sepsis Nos		Nutracor Kenalog Topicort	C C C					
Date: 08/18/1987 ISR Number: 481252-X Report Type: Expedited (15-Day) Company Report Number: 870200889001 Age: 34 YR Gender: Male									
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration	
Hospitalization - Initial or Prolonged	Condition Aggravated Major Depressive Disorder Nos	Health Professional	Accutane	PS	Roche	ORAL		327	
Other	Pain Nos Rhinitis Nos		Lithium Capoten Navane	C C C					
Date: 07/30/1987 ISR Number: 481323-8 Report Type: Periodic Company Report Number: 860200445001 Age: 19 YR Gender: Male									
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration	
Disability	Delusion Nos Paranoia	Health Professional	Accutane	PS	Roche	ORAL			
Date: 07/30/1987 ISR Number: 481329-9 Report Type: Periodic Company Report Number: 860200413001 Age: 40 YR Gender: Female									
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration	
Other	Cheilitis Condition Aggravated Depression Nec Dry Skin	Health Professional	Accutane	PS	Roche	ORAL		140	

FDA Adverse Event Reporting System (AERS)
 National Drug Information (NUI) Report

Date: 07/30/1987 ISR Number: 481334-2 Report Type: Periodic Company Report Number: 860200494001 Age: 39 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	Blood Creatine Phosphokinase Increased Influenza Like Illness Insomnia Nec Neuritis Nos	Consumer	Accutane Tetracycline	PS C	Roche	ORAL		13
Date: 07/30/1987 ISR Number: 481339-1 Report Type: Periodic Company Report Number: 860201028001 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>
	Depression Nec Dry Mouth Dry Skin Insomnia Nec	Consumer	Accutane	PS	Roche	ORAL		120
Date: 07/30/1987 ISR Number: 481388-3 Report Type: Periodic Company Report Number: 860200821001 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	Dry Skin Major Depressive Disorder Nos Nausea Non-Accidental Overdose	Health Professional	Accutane	PS	Roche	ORAL		112
Date: 07/30/1987 ISR Number: 481442-6 Report Type: Periodic Company Report Number: 870200779001 Age: 14 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 Hyperlipidaemia Nos Impaired Healing Skin Discolouration	Health Professional	Accutane Prednisone	PS C	Roche	ORAL		155
Date: 07/30/1987 ISR Number: 481472-4 Report Type: Periodic Company Report Number: 860201497001 Age: 23 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 Other	Condition Aggravated Depression Nec Emotional Disturbance Nos Insomnia Nec	Health Professional	Accutane	PS	Roche	ORAL		57
Date: 07/30/1987 ISR Number: 481595-X Report Type: Periodic Company Report Number: 860201462001 Age: 24 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	Impotence	Health Professional	Accutane	PS	Roche	ORAL		291

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

Date: 07/30/1987	ISR Number: 481669-3	Report Type: Periodic	Company Report Number: 870200393001			Age: 19 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Dermatitis Nos Dry Skin Palpitations	Health Professional	Accutane	PS	Roche	ORAL		85
Date: 07/30/1987	ISR Number: 481684-X	Report Type: Periodic	Company Report Number: 860200539001			Age: 33 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Dysphonia Laryngitis Nos Rhinitis Nos Sinusitis Nos	Health Professional	Accutane	PS	Roche	ORAL		124
Date: 07/30/1987	ISR Number: 481690-5	Report Type: Periodic	Company Report Number: 860200582001			Age: 16 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged Other	Back Pain Depression Nec Headache Nos Hypercholesterolemia	Health Professional	Accutane Prednisone	PS C	Roche	ORAL		149
Date: 09/21/1987	ISR Number: 488002-1	Report Type: Expedited (15-Day)	Company Report Number: 870200186001			Age: 44 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Anxiety Nec Pruritus Skin Discolouration	Health Professional	Accutane Tylenol	PS C	Roche	ORAL		9
Date: 11/12/1987	ISR Number: 498538-5	Report Type: Expedited (15-Day)	Company Report Number: 870201184001			Age: 36 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Condition Aggravated Palpitations	Health Professional	Accutane Motrin	PS C	Roche	ORAL		45
Date: 11/20/1987	ISR Number: 504235-X	Report Type: Expedited (15-Day)	Company Report Number: 870201294001			Age: 25 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Palpitations Supraventricular Tachycardia	Health Professional	Accutane	PS	Roche	ORAL		20
Date: 12/08/1987	ISR Number: 504245-2	Report Type: Expedited (15-Day)	Company Report Number: 870201373001			Age: 21 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Acne Nos Dermatitis Nos	Health Professional	Accutane	PS	Roche	ORAL		488

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

Date: 12/28/1987 ISR Number: 504981-8 Report Type: Expedited (15-Day) Company Report Number: 870201450001 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	Major Depressive Disorder Nos	Health Professional	Accutane	PS	Roche	ORAL		153
Date: 02/04/1988 ISR Number: 510057-6 Report Type: Expedited (15-Day) Company Report Number: 880200028001 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>
Death	Major Depressive Disorder Nos Non-Accidental Overdose	Health Professional	Accutane	PS	Roche	ORAL		5
			Enovid	C				
			Darvocet-N	C				
Date: 02/05/1988 ISR Number: 510881-X Report Type: Expedited (15-Day) Company Report Number: 880200030001 Age: 23 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	Delusion Nos Psychotic Disorder Nos	Health Professional	Accutane	PS	Roche	ORAL		3
			Lithobid	C				
Date: 04/11/1988 ISR Number: 516354-2 Report Type: Expedited (15-Day) Company Report Number: 880200382001 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>
Hospitalization - Initial or Prolonged	Apathy Hostility	Health Professional	Accutane	PS	Roche	ORAL		72
Other	Paranoia							
Date: 04/06/1988 ISR Number: 517122-8 Report Type: Expedited (15-Day) Company Report Number: 870200281001 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>
Hospitalization - Initial or Prolonged	Epistaxis Headache Nos Major Depressive Disorder Nos	Health Professional	Accutane	PS	Roche	ORAL		350
Date: 07/06/1988 ISR Number: 530830-8 Report Type: Expedited (15-Day) Company Report Number: 880200786001 Age: 16 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>
Death	Major Depressive Disorder Nos	Health Professional	Accutane	PS	Roche	ORAL		100
Date: 07/06/1988 ISR Number: 531912-7 Report Type: Expedited (15-Day) Company Report Number: 880100584001 Age: 16 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 Dreams	Foreign Health Professional	Accutane	PS	Roche	ORAL		14

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

Date: 07/30/1987	ISR Number: 532010-9	Report Type: Periodic	Company Report Number: 8502000985001	Age: 46 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Abscess Nos Impotence	Health Professional	Accutane	PS	Roche	ORAL		1095
Date: 08/03/1988	ISR Number: 535046-7	Report Type: Expedited (15-Day)	Company Report Number: 850101548001	Age: 22 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Dry Mouth Hirsutism Hyperpituitarism Nos Psychotic Disorder Nos	Foreign Health Professional	Accutane	PS	Roche	ORAL		17
Date: 08/17/1988	ISR Number: 537031-8	Report Type: Expedited (15-Day)	Company Report Number: 880200890001	Age: 39 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged Other	Depression Nec Hypoglycaemia Nos Hypothyroidism Joint Disorder Nos	Health Professional	Accutane	PS	Roche	ORAL		462
Date: 08/19/1988	ISR Number: 537742-4	Report Type: Periodic	Company Report Number: 870201546001	Age: 16 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Amnesia Nec Apathy Depression Nec Dry Skin	Health Professional	Accutane	PS	Roche	ORAL		134
Date: 08/19/1988	ISR Number: 537746-1	Report Type: Periodic	Company Report Number: 870201531001	Age: 18 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Abnormal Dreams Back Pain Condition Aggravated Convulsions Nos	Health Professional	Accutane	PS	Roche	ORAL		163
Date: 08/19/1988	ISR Number: 537750-3	Report Type: Periodic	Company Report Number: 870201517001	Age: 39 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec Emotional Disturbance Nos	Health Professional	Accutane	PS	Roche	ORAL		15

FDA Adverse Event Reporting System (AERS)
 Product Identification (PID) Report

Date: 08/19/1988	ISR Number: 537756-4	Report Type: Periodic	Company Report Number: 870201484001			Age: 19 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Palpitations	Health Professional	Accutane	PS	Roche	ORAL		33
Date: 08/19/1988	ISR Number: 538134-4	Report Type: Periodic	Company Report Number: 870201198001			Age: 40 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Asthenia Influenza Like Illness Thinking Abnormal Nec	Health Professional	Accutane	PS	Roche	ORAL		7
Date: 08/19/1988	ISR Number: 538137-X	Report Type: Periodic	Company Report Number: 870201207001			Age: 20 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Abnormal Dreams	Health Professional	Accutane	PS	Roche	ORAL		120
Date: 08/19/1988	ISR Number: 538138-1	Report Type: Periodic	Company Report Number: 870201206001			Age: 32 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Abnormal Dreams Depression Nec Emotional Disturbance Nos	Health Professional	Accutane	PS	Roche	ORAL		127
Date: 08/19/1988	ISR Number: 538140-X	Report Type: Periodic	Company Report Number: 870201420001			Age: 18 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Alopecia Amenorrhoea Nos Depression Nec Skin Discoloration	Consumer	Accutane	PS	Roche	ORAL		144
Date: 08/19/1988	ISR Number: 538142-3	Report Type: Periodic	Company Report Number: 870201455001			Age: 21 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Blood Alkaline Phosphatase Nos Increased Condition Aggravated Hostility Personality Disorder Nos	Health Professional	Accutane	PS	Roche	ORAL		71
Date: 08/19/1988	ISR Number: 538950-9	Report Type: Periodic	Company Report Number: 870200485001			Age: 18 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec Emotional Disturbance Nos	Consumer	Accutane	PS	Roche	ORAL		103

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

Date: 08/19/1988	ISR Number: 538951-0	Report Type: Periodic	Company Report Number: 870200482001			Age: 17 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Emotional Disturbance Nos Major Depressive Disorder Nos	Health Professional	Accutane	PS	Roche	ORAL		50
Date: 08/19/1988	ISR Number: 538953-4	Report Type: Periodic	Company Report Number: 870200529001			Age: 39 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Cataract Nec Nervousness Vasodilatation	Health Professional	Accutane	PS	Roche	ORAL		156
Date: 08/19/1988	ISR Number: 538959-5	Report Type: Periodic	Company Report Number: 870200510001			Age: 16 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Breast Neoplasm Nos Personality Disorder Nos	Health Professional	Accutane	PS	Roche	ORAL		518
Date: 08/19/1988	ISR Number: 538962-5	Report Type: Periodic	Company Report Number: 870200895001			Age: 27 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Acne Nos Depression Nec Dysmenorrhoea Keratoconjunctivitis	Health Professional	Accutane	PS	Roche	ORAL		102
Date: 08/19/1988	ISR Number: 539000-0	Report Type: Periodic	Company Report Number: 870200639001			Age: 25 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Disability	Ashtenia Depression Nec	Health Professional	Accutane	PS	Roche	ORAL		135
Date: 08/19/1988	ISR Number: 539130-3	Report Type: Periodic	Company Report Number: 880200107001			Age: 17 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec Influenza Like Illness Weight Decreased	Health Professional	Accutane	PS	Roche	ORAL		
Date: 08/19/1988	ISR Number: 539170-4	Report Type: Periodic	Company Report Number: 870200801001			Age: 35 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Palpitations	Health Professional	Accutane Retin-A	PS C	Roche	ORAL		29

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

Date: 08/19/1988	ISR Number: 539181-9	Report Type: Periodic	Company Report Number: 870200652001			Age: 43 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Condition Aggravated Emotional Disturbance Nos Hypercholesterolaemia Leucopenia Nos	Health Professional	Accutane Seldane	PS C	Roche	ORAL		157
Date: 08/19/1988	ISR Number: 539201-1	Report Type: Periodic	Company Report Number: 880200266001			Age: 16 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Anaemia Nos Blood Lactate Dehydrogenase Increased Insomnia Nec	Health Professional	Accutane Erythromycin	PS C	Roche	ORAL		50
Date: 08/19/1988	ISR Number: 539239-4	Report Type: Periodic	Company Report Number: 880200041001			Age: 34 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Emotional Disturbance Nos Headache Nos Paresthesia Nec	Health Professional	Accutane	PS	Roche	ORAL		67
Date: 08/19/1988	ISR Number: 539417-4	Report Type: Periodic	Company Report Number: 870200947001			Age: 28 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Abnormal Dreams Amnesia Nec Benign Intracranial Hypertension Vertigo Nec	Health Professional	Accutane Aspirin	PS C	Roche	ORAL		121
Date: 08/19/1988	ISR Number: 539442-3	Report Type: Periodic	Company Report Number: 870201356001			Age: 24 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Condition Aggravated Depression Nec	Health Professional	Accutane	PS	Roche	ORAL		
Date: 08/19/1988	ISR Number: 539447-2	Report Type: Periodic	Company Report Number: 870201115001			Age: 37 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Cough Dysphonia Menorrhagia	Health Professional	Accutane	PS	Roche	ORAL		126

FDA Adverse Event Reporting System (AERS)
 Product Information (PID) Report

Date: 08/19/1988	ISR Number: 539456-3	Report Type: Periodic	Company Report Number: 870201159001			Age: 15 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Acne Nos Depression Nec Insomnia Nec	Health Professional	Accutane	PS	Roche	ORAL		153
Date: 08/19/1988	ISR Number: 539713-0	Report Type: Periodic	Company Report Number: 870201075001			Age: 35 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec Libido Decreased	Health Professional	Accutane	PS	Roche	ORAL		145
Date: 08/19/1988	ISR Number: 539812-3	Report Type: Periodic	Company Report Number: 870200617001			Age: 17 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Bronchitis Nos Dry Skin Personality Disorder Nos Urinary Tract Infection Nos	Health Professional	Accutane	PS	Roche	ORAL		154
Date: 08/19/1988	ISR Number: 539821-4	Report Type: Periodic	Company Report Number: 870200643001			Age: 15 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged Other	Depression Nec Hepatic Function Abnormal Nos Hostility Hypericaemia	Health Professional	Accutane Mellaril Sinequan	PS C C	Roche	ORAL		29
Date: 08/19/1988	ISR Number: 540162-X	Report Type: Periodic	Company Report Number: 870200608001			Age: 17 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Personality Disorder Nos	Health Professional	Accutane	PS	Roche	ORAL		56
Date: 08/19/1988	ISR Number: 541346-7	Report Type: Periodic	Company Report Number: 880200139001			Age: 20 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Amnesia Nec Condition Aggravated	Health Professional	Accutane	PS	Roche	ORAL		135
Date: 08/19/1988	ISR Number: 541353-4	Report Type: Periodic	Company Report Number: 880200167001			Age:	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Alopecia Condition Aggravated Depression Nec	Consumer	Accutane Parnate	PS C	Roche	ORAL		119

FDA Adverse Event Reporting System (AERS)
Randomized Information (RI) Report

Date: 08/19/1988	ISR Number: 541355-8	Report Type: Periodic	Company Report Number: 880200171001	Age: 28 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Cardiovascular Disorder Nos Hyperventilation	Health Professional	Accutane	PS	Roche	ORAL		57
Date: 08/19/1988	ISR Number: 542456-0	Report Type: Periodic	Company Report Number: 870201297001	Age: 35 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Palpitations	Health Professional	Accutane	PS	Roche	ORAL		9
Date: 08/19/1988	ISR Number: 542469-9	Report Type: Periodic	Company Report Number: 870201369001	Age: 23 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Epistaxis Hypercholesterolaemia Hyperlipidaemia Nos Personality Disorder Nos	Health Professional	Accutane	PS	Roche	ORAL		111
Date: 08/19/1988	ISR Number: 542481-X	Report Type: Periodic	Company Report Number: 870200738001	Age: 19 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Aspartate Aminotransferase Increased Depression Nec	Health Professional	Accutane	PS	Roche	ORAL		181
Date: 08/19/1988	ISR Number: 542579-6	Report Type: Periodic	Company Report Number: 870201316001	Age: 28 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Abnormal Dreams Impotence Libido Decreased	Health Professional	Accutane	PS	Roche	ORAL		110
Date: 08/19/1988	ISR Number: 542580-2	Report Type: Periodic	Company Report Number: 870201327001	Age: 27 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Emotional Disturbance Nos Hostility Personality Disorder Nos	Health Professional	Accutane Intal	PS C	Roche	ORAL		
Date: 09/09/1988	ISR Number: 542716-3	Report Type: Direct	Company Report Number:	Age: 27 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Disability	Alopecia Depression Nec Photosensitivity Reaction Nos Skin Disorder Nos	Consumer	Accutane	PS	Roche	ORAL		97

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

Date: 08/19/1988	ISR Number: 544032-2	Report Type: Periodic	Company Report Number: 870201223001			Age: 20 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Amnesia Nec Arthralgia Hyperlipidaemia Nos	Health Professional	Accutane	PS	Roche	ORAL		67
Date: 08/19/1988	ISR Number: 544040-1	Report Type: Periodic	Company Report Number: 870200933001			Age: 17 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Amnesia Nec Arrhythmia Nos Chest Pain Dermatitis Exfoliative Nos	Health Professional	Accutane	PS	Roche	ORAL		120
Date: 08/19/1988	ISR Number: 544044-9	Report Type: Periodic	Company Report Number: 870200534001			Age: 19 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Ashenia Blood Bilimbin Increased Depression Nec Hepatitis Nos	Health Professional	Accutane	PS	Roche	ORAL		31
Date: 08/19/1988	ISR Number: 544088-7	Report Type: Periodic	Company Report Number: 880200046001			Age: 54 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Personality Disorder Nos	Health Professional	Accutane	PS	Roche	ORAL		
Date: 08/19/1988	ISR Number: 544093-0	Report Type: Periodic	Company Report Number: 880200042001			Age: 22 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Chest Pain Palpitations	Health Professional	Accutane	PS	Roche	ORAL		8
Date: 08/19/1988	ISR Number: 544096-6	Report Type: Periodic	Company Report Number: 870201562001			Age: 14 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Dry Mouth Personality Disorder Nos	Health Professional	Accutane Tetracycline	PS C	Roche	ORAL		21
Date: 08/19/1988	ISR Number: 544121-2	Report Type: Periodic	Company Report Number: 880200394001			Age:	Gender: Unknown	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Other	Hostility	Health Professional	Accutane	PS	Roche	ORAL		

Drug Event Reporting System (DERS)
 System of Information (SIR) Report

Date: 11/02/1988	ISR Number: 553830-0	Report Type: Direct	Company Report Number:			Age: 16 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Hostility Mania Psychotic Disorder Nos	Health Professional	Accutane Tetracycline Retin-A	PS C C	Roche	ORAL		14
Date: 10/28/1988	ISR Number: 554169-X	Report Type: Expedited (15-Day)	Company Report Number: 880201176001			Age: 16 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged Other	Bipolar I Disorder Condition Aggravated Hostility Psychotic Disorder Nos	Health Professional	Accutane	PS	Roche	ORAL		22
Date: 12/02/1988	ISR Number: 558399-2	Report Type: Expedited (15-Day)	Company Report Number: 870103027001			Age: 18 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Major Depressive Disorder Nos Non-Accidental Overdose Paresthesia Nec Speech Disorder Nec	Foreign Health Professional	Accutane Oxazepam Doxepin Hydrochloride Methylprednisolone Erythromycin	PS C C C C	Roche	ORAL		1
Date: 12/19/1988	ISR Number: 559371-9	Report Type: Expedited (15-Day)	Company Report Number: 880201083001			Age: 18 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged Other	Arthralgia Major Depressive Disorder Nos Psychotic Disorder Nos	Health Professional	Accutane Retin-A	PS SS	Roche Ortho	ORAL		14
Date: 01/19/1989	ISR Number: 565743-9	Report Type: Direct	Company Report Number:			Age: 17 YR	Gender: Female	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Disability	Confusion Dry Mouth Dry Skin Thinking Abnormal Nec	Health Professional	Accutane	PS	Roche			65
Date: 02/22/1989	ISR Number: 569194-2	Report Type: Expedited (15-Day)	Company Report Number: 890200109001			Age: 43 YR	Gender: Male	
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Death Hospitalization - Initial or Prolonged	Delirium	Health Professional	Accutane	PS	Roche	ORAL		32

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

Date: 02/22/1989 ISR Number: 569194-2 Report Type: Expedited (15-Day) Company Report Number: 890200109804 Manufacturer: Roche									
Outcome	PT	Product	Accutane	Role	PS	Route	ORAL	Dose/Unit	Duration
Other	Delirium								32
Date: 03/30/1989 ISR Number: 579176-2 Report Type: Expedited (15-Day) Company Report Number: 890200199001 Age: 33 YR Gender: Male									
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration	
Disability	Dysarthria	Health Professional	Accutane	PS	Roche	ORAL		731	
	Hepatic Function Abnormal Nos								
	Multiple Sclerosis								
	Vision Abnormal Nec								
Date: 03/30/1989 ISR Number: 579177-4 Report Type: Expedited (15-Day) Company Report Number: 880400212001 Age: 36 YR Gender: Female									
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration	
Other	Anislyopia Nos	Foreign	Roaccutane	PS	Roche	ORAL		55	
	Ataxia Nec	Health Professional	Ethinyl Estadiol	C					
	Dysarthria		Cyproterone Acetate	C					
Date: 03/30/1989 ISR Number: 579183-X Report Type: Expedited (15-Day) Company Report Number: 89U200209001 Age: 19 YR Gender: Male									
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration	
Hospitalization - Initial or Prolonged	Delusion Nos	Health Professional	Accutane	PS	Roche	ORAL		132	
Disability	Hallucination Nos								
Other	Major Depressive Disorder Nos								
	Psychotic Disorder Nos								
Date: 05/12/1989 ISR Number: 583883-5 Report Type: Expedited (15-Day) Company Report Number: 890200393001 Age: 24 YR Gender: Male									
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration	
Hospitalization - Initial or Prolonged	Convulsions Nos	Health Professional	Accutane	PS	Roche	ORAL			
Disability	Delirium								
	Encephalitis Nos								
	Paralysis Nos								
Date: 06/28/1989 ISR Number: 596087-7 Report Type: Expedited (15-Day) Company Report Number: 890200522002 Age: Gender: Unknown									
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration	
Hospitalization - Initial or Prolonged	Schizophrenia Nos	Health Professional	Accutane	PS	Roche	ORAL			

FDA Adverse Event Reporting System (AERS)
 Product Information (PI) Report

Date: 06/28/1989	ISR Number: 599182-1	Report Type: Expedited (15-Day)	Company Report Number: 890200522001	Age: 17 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged Other	Hypercholesterolaemia Hyperlipidaemia Nos Schizophrenia Nos	Health Professional	Accutane	PS	Roche	ORAL		121
Date: 08/08/1989	ISR Number: 601690-1	Report Type: Expedited (15-Day)	Company Report Number: 890200654001	Age: 18 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged Other	Amnesia Nec Blood Magnesium Decreased Hypocalcaemia Renal Tubular Disorder Nos	Health Professional	Accutane	PS	Roche	ORAL		140
Date: 08/25/1989	ISR Number: 608203-9	Report Type: Expedited (15-Day)	Company Report Number: 8900200658001	Age: 18 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Disability	Amblyopia Nos Depression Nec Skin Disorder Nos Weight Decreased	Health Professional	Accutane	PS	Roche	ORAL		154
Date: 09/01/1989	ISR Number: 609517-9	Report Type: Expedited (15-Day)	Company Report Number: 890200754001	Age: 20 YR	Gender: Male			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Alopecia Condition Aggravated Psychotic Disorder Nos	Health Professional	Accutane Navane	PS C	Roche	ORAL		29
Date: 10/05/1989	ISR Number: 618712-4	Report Type: Direct	Company Report Number:	Age: 34 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Agitation Confusion Hallucination Nos	Health Professional	Accutane	PS	Roche	ORAL		14
Date: 10/12/1989	ISR Number: 623566-6	Report Type: Expedited (15-Day)	Company Report Number: 890200886001	Age: 22 YR	Gender: Female			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Bipolar I Disorder Condition Aggravated	Health Professional	Accutane Navane Tegretol Klonopin Asendin	PS C C C C	Roche	ORAL		21