



02-APR-1998-0115

Page 1 of 2



A. Patient information			
1. Patient identifier [Redacted] In confidence	2. Age at time of event; or 15 Date of birth: [Redacted]	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight 200 lbs kgs
B. Adverse event or product problem			
1. <input checked="" type="checkbox"/> Adverse event and/or <input type="checkbox"/> Product problem (e.g., defects/malfunctions)			
2. Outcome attributed to adverse event (check all that apply)			
<input checked="" type="checkbox"/> death 10/27/94 (mortality)		<input type="checkbox"/> disability	
<input checked="" type="checkbox"/> life-threatening		<input checked="" type="checkbox"/> congenital anomaly required intervention to prevent permanent impairment/damage	
<input checked="" type="checkbox"/> hospitalization-initial or prolonged		<input type="checkbox"/> other:	
3. Date of event (m/d/y)	10/94	4. Date of this report (m/d/y)	03/23/98
5. Describe event or problem			
THERAFLU Caplets - Unknown: 3/28/98 - Report received from lawyer of a 15 year old boy who ingested Tylenol and Theraflu, became jaundiced and was admitted to the hospital. During hospitalization he was administered four doses of Tylenol. Patient went into coma and died from liver failure 10/27/94. Additional information requested.			
6. Relevant tests/laboratory data, including dates			
liver function tests grossly abnormal, Hepatitis A and B negative, Hepatitis C unknown			
7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)			
blind lt eye from pellet gun accident, ear infections, pneumonia age 3 requiring hospitalization, jaundice as an infant, burned at age 3 by car catalytic converter			

C. Suspect medication(s)			
1. Name (give labeled strength & manufacturer, if known)			
#1 THERAFLU-UNKNOWN-NVCH			
#2 TYLENOL-ACETAMINOPHEN-MCNEIL CONSUMER PROD.			
2. Dose, frequency & route used		3. Therapy dated (if unknown, give duration from/to (or best estimate))	
#1 Unknown/Unk/PO		#1 Unknown	
#2 Unknown/Unk/PO		#2 Unknown	
4. Diagnosis for use (indication)		5. Event abated after use stopped or dose reduced	
#1 Unknown		#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply	
#2 Unknown		#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply	
6. Lot # (if known)	7. Exp. date (if known)		
#1 Unknown	#1 Unknown		
#2 Unknown	#2 Unknown		
9. NDC # — for product only (if known)		8. Event reappeared after reintroduction	
N/A		#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply	
		#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply	
10. Concomitant medical products and therapy dates (exclude treatment of event)			
Unknown			
G. All manufacturers			
1. Contact office — name/address (& mailing site for devices)		2. Phone number	
Novartis Consumer Health, Inc. 560 Morris Ave. Summit, NJ 07901-1312		908-598-7730	
4. Date received by manufacturer (m/d/y)		5. Report source (check all that apply)	
11/16/95		<input type="checkbox"/> foreign <input type="checkbox"/> study <input type="checkbox"/> literature <input type="checkbox"/> consumer health professional <input type="checkbox"/> user facility <input type="checkbox"/> company representative <input type="checkbox"/> distributor <input checked="" type="checkbox"/> other: lawyer	
6. If IND, protocol #		(A) NDA # NO NDA	
N/A		IND # _____ PLA # _____	
7. Type of report (check all that apply)		pre-1938 <input type="checkbox"/> yes OTC <input checked="" type="checkbox"/> yes product	
<input type="checkbox"/> 5-day <input checked="" type="checkbox"/> 15-day <input type="checkbox"/> 10-day <input type="checkbox"/> periodic <input checked="" type="checkbox"/> Initial <input type="checkbox"/> follow-up # _____		8. Adverse event term(s) HEPATIC FAILURE	
9. Mfr. report number			
0180787A			
E. Initial reporter			
1. Name, address & phone #			
Mr. [Redacted] Esq. [Redacted] [Redacted] Ave. [Redacted]			
2. Health professional?	3. Occupation	4. Initial reporter also sent report to FDA	
<input type="checkbox"/> yes <input checked="" type="checkbox"/> no	N/A	<input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> unk	

CONTINUED



Facsimile of FDA Form 3500A

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

RECEIVED AT DRUG SAFETY SURVEILLANCE



02-APR-1998-0116

Individual Safety Report



3058231-1-00

Page 2 of
Form 3500A Cont

Novartis Consumer Health, Inc.

MFR Report # 0180787A

Patient Initials: [REDACTED]

CONTINUATION OF B7: and spent 3 weeks in burn unit, cut hand 7/93 requiring stitches after playing in creek that contained raw sewage and human waste, virus 5/94, drank alcohol about once/year, has twin brother.