



A. Patient information

1. Patient Identifier NI in confidence	2. Age at time of event: 50 yrs or Date of birth: NI	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight NI lbs or NI kgs
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B. Adverse event or product problem

1. Adverse event and/or Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

<input checked="" type="checkbox"/> death Unknown (notify)	<input type="checkbox"/> disability
<input type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input checked="" type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
	<input type="checkbox"/> other: _____

3. Date of event (month/year): UNK

4. Date of this report (month/year): 12/16/98

5. Describe event or problem

Initial Notification (7-Dec-98)

A 50-year-old male patient DIED of ACUTE LIVER FAILURE SECONDARY TO ACETAMINOPHEN INTOXICATION.

He had a history of chronic ethanol abuse. On an unspecified date, he suffered fractured ribs during an occupational injury. He was treated and released with a prescription for Percocet. In addition to Percocet he had been taking acetaminophen 500 mg 3-4 tablets every 2 hours for pain for at least 4 days. Several days after his injury, he went to the emergency department with CHEST PAIN and vomiting. On physical examination he was PALE and jaundiced. His liver function *

6. Relevant tests/laboratory data, including dates

Aspartate Aminotransferase (AST) >3000 IU/L

Alanine Aminotransferase (ALT) >3000 IU/L

Alkaline Phosphatase - ALK-P 355 IU/L

Bilirubin, Total 11.7 mg/dL *

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

Broken ribs suffered during an occupational injury; treated with Percocet for pain and had been taking acetaminophen 500 mg 3-4 tablets Q2H for at least 4 days for pain Chronic ethanol abuse *

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)

#1 PERCO CET

#2 ACETAMINOPHEN

2. Dose, frequency & route used

#1 *

#2 UNK UNK PO

3. Therapy dates (if unknown, give duration) (month or best estimate)

#1 NI to NI

#2 NI to NI Duration: 4 days

4. Diagnosis for use (indication)

#1 GENERAL SYMPTOMS NEC

#2 GENERAL SYMPTOMS NEC

5. Event abated after use stopped or dose reduced

#1 yes no doesn't apply

#2 yes no doesn't apply

6. Lot # (if known)

#1 NI

#2 NI

7. Exp. date (if known)

#1 NI

#2 NI

8. Event reappeared after reintroduction

#1 yes no doesn't apply

#2 yes no doesn't apply

9. NDC # - for product problems only (if known)

#1 NI

#2 NI

10. Concomitant medical products and therapy dates (exclude treatment of event)

NI

G. All manufacturers

1. Contact office - name/address (& mailing site for devices)

DuPont Pharmaceuticals Company
Chestnut Run Plaza, BR1132
P.O. Box 80723
Wilmington DE 19880-0723 USA

2. Phone number
(302) 892-1873

3. Report source (check all that apply)

foreign
 study
 literature
 consumer
 health professional
 user facility
 company representative
 distributor
 other:

4. Date received by manufacturer (month/year)
12/07/98

5. (A)NDA # 85-106

IND # _____

PLA # _____

pre-1938 yes

OTC product yes

6. If IND, protocol #

7. Type of report (check all that apply)

5-day 15-day

10-day periodic

Initial follow-up # _____

8. Adverse event term(s)

HEPATIC FAILURE, BRADYCARDIA, CHEST PAIN, PALLOR, PROTHROMBIN DECREASED, APTT ABNORMAL (DPC), DRUG LEVEL INCREASED

E. Initial reporter

Name, address & phone #

Dr. [REDACTED]

Occupation
Physician

2. Health professional?
 yes no

3. Occupation
Physician

4. Report to FDA
 yes no unk

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CDR



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

Individual Safety Report

t Pharmaceuticals Company

Domain Facsimile	Approved by FDA on 3/22/94
Mfr report #	1998PER0100
JF/Out report #	
FDA Use Only	

3172348-2-00-12

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

A. Patient information			
1. Patient identifier NI in confidence	2. Age at time of event: or _____ Date of birth: _____	3. Sex <input type="checkbox"/> female <input type="checkbox"/> male	4. Weight ____ lbs or ____ kgs
B. Adverse event or product problem			
1. <input type="checkbox"/> Adverse event and/or <input type="checkbox"/> Product problem (e.g., defects/malfunctions)			
2. Outcomes attributed to adverse event (check all that apply)			
<input type="checkbox"/> death (month/yr)		<input type="checkbox"/> disability	
<input type="checkbox"/> life-threatening		<input type="checkbox"/> congenital anomaly	
<input type="checkbox"/> hospitalization - initial or prolonged		<input type="checkbox"/> required intervention to prevent permanent impairment/damage	
		<input type="checkbox"/> other: _____	
3. Date of event (month/yr)	4. Date of this report (month/yr)		
5. Describe event or problem			
6. Relevant tests/laboratory data, including dates			
7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)			

C. Suspect medication(s)			
1. Name (give labeled strength & mfr/labeler, if known)			
#3 ETHANOL			
#4			
2. Dose, frequency & route used		3. Therapy dates (if unknown, give duration) <small>From (or best estimate)</small>	
#3 UNK UNK PO		#3 NI to NI	
#4		#4	
4. Diagnosis for use (indication)		5. Event abated after use stopped or dose reduced	
#3 UNKN CAUSE MORB/MORT NEC		#3 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply	
#4		#4 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
6. Lot # (if known)	7. Exp. date (if known)		8. Event reappeared after reintroduction
#3 NI	#3 NI		#3 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply
#4	#4		#4 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply
9. NDC # - for product problems only (if known)			
#3 NI		#4	
10. Concomitant medical products and therapy dates (exclude treatment of event)			

G. All manufacturers	
1. Contact office - name/address (& mailing site for devices)	2. Phone number
	3. Report source (check all that apply)
	<input type="checkbox"/> foreign
	<input type="checkbox"/> study
	<input type="checkbox"/> literature
	<input type="checkbox"/> consumer
	<input type="checkbox"/> health professional
	<input type="checkbox"/> user facility
	<input type="checkbox"/> company representative
	<input type="checkbox"/> distributor
	<input type="checkbox"/> other:
4. Date received by manufacturer (month/yr)	5. (A)NDA # _____
	IND # _____
	PLA # _____
6. If IND, protocol #	pre-1938 <input type="checkbox"/> yes
	OTC product <input type="checkbox"/> yes
7. Type of report (check all that apply)	8. Adverse event term(s)
<input type="checkbox"/> 5-day <input type="checkbox"/> 15-day	
<input type="checkbox"/> 10-day <input type="checkbox"/> periodic	
<input type="checkbox"/> Initial <input type="checkbox"/> follow-up # _____	
9. Mfr. report number	

E. Initial reporter			
1. Name, title & address			
DEC 21 1998			
2. Health professional?		3. Occupation	
<input type="checkbox"/> yes <input type="checkbox"/> no			
4. Initial reporter also sent report to FDA			
<input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> unk			



Domain Facsimile of
FDA Form 3500A

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Item completed on continuation pages.

INDIVIDUAL SAFETY REPORT



Pfizer Pharmaceuticals Company

3172348-2-00-03

MED WATCH	A.1. Patient Identifier	G.2. Mfr. report number	Page 3 of 3
	NI	1998PER0100	

B.6. Describe event or problem

[continuation:] tests were: AST > 3000 IU/L, ALT > 3000 IU/L, ALKALINE PHOSPHATASE 355 IU/L, AMMONIA 74 uMOL/L, and TOTAL BILIRUBIN 11.7 MG/DL. His PT WAS 37.8 SECONDS and his PTT WAS 49. A urine drug screen was negative for amphetamines, barbiturates, benzodiazepines, cannabinoids, cocaine, opiates, and phencyclidine. Serum toxicology revealed no ethanol. His ACETAMINOPHEN LEVEL WAS 2 MG/L and his SALICYLATE LEVEL WAS 15.12 MG/L. He was treated with N-acetylcysteine and appeared to be stable. Approximately 16 hours after entering the hospital he developed INTRACTABLE BRADYCARDIA and died. An autopsy revealed MASSIVE HEPATIC NECROSIS consistent with acetaminophen intoxication and chronic alcoholism. The medical examiner ruled the cause of death as acute liver failure secondary to acetaminophen intoxication.

This information was provided in a form 3500A by R. W. Johnson Pharmaceutical Research Institute (manufacturer report number 981007-107013868) based on clarification of the American Journal of Emergency Medicine 16(5); 1998: 443-497 (case 231).

B.8. Relevant tests/laboratory data, including dates

[continuation:] Prothrombin Time 37.8 sec.
 Partial Thromboplastin Time 49
 74 uMol/L AMMONIA

URINE DRUG SCREEN: NEGATIVE FOR AMPHETAMINES, BARBITURATES, BENZODIAZEPINES, CANNABINOIDS, COCAINE, OPIATES AND PHENCYCLIDINE

SERUM TOXICOLOGY: NO ETHANOL, ACETAMINOPHEN 2 MG/L, SALICYLATES 15.12 MG/L
 POSITIVE VIRAL HEPATITIS STRAINS A AND B

B.7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

[continuation:] Viral hepatitis A and B

C.2. Dose, frequency & route used (Suspect #1)

1500 - 2000 MG Q2H QD PO

E.1. Name, address & phone #

[continuation:] Phone: [REDACTED]

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