



27-FEB-1998-0451



McNEIL CONSUMER I  
FORT WASHIN

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Individual Safety Report



\*3037699-0-00\*

**A. Patient information**

1. Patient identifier [redacted] In confidence	2. Age at time of event: 45 yrs or Date of birth: [redacted]	3. Sex (X) female ( ) male	4. Weight Unk lbs or kgs
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**B. Adverse event or product problem**

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

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

(X) death (mo/day/yr) 4/13/94	( ) disability
( ) life-threatening	( ) congenital anomaly
(X) hospitalization - initial or prolonged	( ) required intervention to prevent permanent impairment/damage
	( ) other:

3. Date of event (mo/day/yr) 4/13/94

4. Date of this report (mo/day/yr) 02/17/98

**C. Suspect medication(s)**

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

#1 Unknown TYLENOL® acetaminophen product

#2

2. Dose, frequency & route used

#1 unknown dose, orally

#2

3. Therapy dates (if unknown, give duration) from/to (or best estimate)

#1 begin 3/13/94; unk. duration

#2

4. Diagnosis for use (indication)

#1 ill with flu-like symptoms

#2

5. Event abated after use stopped or dose reduced

#1 ( ) Yes ( ) No (X) N/A

#2 ( ) Yes ( ) No ( ) N/A

6. Lot # (if known)

#1 Unknown

#2

7. Exp. date (if known)

#1 Unknown

#2

8. Event reappeared after reintroduction

#1 ( ) Yes ( ) No (X) N/A

#2 ( ) Yes ( ) No ( ) N/A

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

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

none

Cont' Sect.B.7. Autopsy report: Diffuse hepatocellular necrosis w/ microvesicular fat & bile plugging - acetaminophen/alcohol associated hepatic injury

**G. All manufacturers**

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

McNeil Consumer Products Company  
Medical Affairs  
7050 Camp Hill Road  
Ft. Washington, PA 19034

2. Phone number  
215-233-7820

3. Report source (check all that apply)

( ) foreign  
( ) study  
( ) literature  
( ) consumer  
( ) health professional  
( ) user facility  
( ) company represent:  
( ) distributor  
(X) other:  
attorney

4. Date received by manufacturer (mo/day/yr) 12/31/97

5. (A) NDA # 17-552  
IND #  
PLA #  
pre-1938 ( ) Yes  
OTC product (X) Yes

6. If IND, protocol #

7. Type of report (check all that apply)

( ) 5-day (X) 15-day  
( ) 10-day ( ) periodic  
( ) Initial (X) follow-up # 1

8. Adverse event term(s)

DEATH LIVER FAILURE  
PANCREATITIS COAGULATION DIS  
KIDNEY FAIL ACU ACIDOSIS  
RESPIRATORY DIS SHOCK

5. Describe event or problem

Notification via attorney letter & COMPLAINT of DEATH in 45 yo F. Addl info rec'd from FDA on 12/31/97, upon request to Docket No.77N-094W, Ref.94, Vol.6 of 7: Case doc.#9 is f/u to previously reported Mfr#0505223A. Med records indicate pt was feeling sick 1 wk PTA. Vomited for 5 days PTA, temp up to 101 w/chills. On night PTA, became delirious & was brought to ER. Pt was hypotensive & hypothermic. Pt gave hx of taking Tylenol along w/ alcohol. Required intubation for respiratory arrest & ADM to ICU. Dx at this time was septic SHOCK, organ system failure including hemorrhagic, PANCREATITIS, ACUTE RENAL FAILURE, LIVER FAILURE, severe METABOLIC ACIDOSIS, DIC(COAGULATION DISORDER) & severe ARDS (RESPIRATORY DISORDER). Developed pneumothorax(3/22/94). Prognosis was grave & went into complete renal failure. Pt died 4/13/94.

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8. Relevant tests/laboratory data, including dates

3/18/94 Temp=92, P=96, R=24, B/P was not obtainable; ABG="725", CO2=14, PO2=208, 99% sat on 100% F1O2, WBC=25, HGB=9.5, HCT=29.3, PLT=310, MCV=80.7, HCO3=9, BUN=14 MG/DL, Creat=5.2 MG/DL, AMY=1306 U/L, lipase=5830 I/U (See Sect.B.7)

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

before this illness, pt had a hx of regular alcohol consumption on a daily or almost daily basis; pt did not eat any substantial amt of food during that time

Cont'Sect.B.6. BILI=3.8 MG/DL, ALB=3.6 GM/DL, ALK PHOS=163, PT=43.8, PTT=57.3, LDH=38441, SGOT=15205 U/L, SGPT=4051 U/L, Tylenol level=12 (time unknown) (See Sect.C.10)

**E. Initial reporter**

1. Name, address & phone #

[redacted]

2. Health professional? ( ) Yes (X) No

3. Occupation  
attorney

4. Initial reporter also sent report to FDA (X) Yes ( ) No ( ) Unk



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