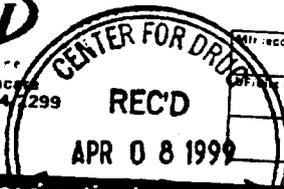




McNeil Consumer Healthcare  
McNeil Consumer Healthcare  
Fort Washington, PA 19034-7299



Approved by FDA on 11/15/93

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FDA use only

**A. Patient information**

1. Patient identifier 01706580 In confidence	2. Age at time of event: or 27 yrs 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)

( ) death (mc/dav/yr) 10/27/94	( ) disability
( ) life-threatening	( ) congenital anomaly
(X) hospitalization - initial or prolonged	( ) required intervention to prevent permanent impairment/damage
	( ) other:

3. Date of event (mo/dav/yr) 10/10/94

4. Date of this report (mo/dav/yr) 03/30/99

**C. Suspect medication(s)**

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

#1 TYLENOL Analgesic

#2

2. Dose, frequency & route used

#1 "6g", 1g q4h x 2-3 d

#2

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

#1 2-3 days PTA

#2

4. Diagnosis for use (indication)

#1 abdominal pain APR 09 1999

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

#1 Unknown

#2

8. Event reappeared after reintroduction

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

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

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

vitamins; Sec B.7 cont: AP=112, tbili=18.2, TP=4.5, ALB=2.2, PT=26.7, NH3=4.33, H/H=9/25.3, PLT=129, glu=99, pH=7.17, PCO2=60, PO2=73, HCO3=22, O2SAT=89; Sec B.5 cont: tis B virus infection & underlying cause of death as hepatorenal failure

DSS

ADVERSE EVENT REPORTING SYSTEM

**G. All manufacturers**

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

McNeil Consumer Healthcare  
Medical Affairs  
7050 Camp Hill Road  
Ft. Washington, PA 19054

2. Phone number  
215-273-7820

3. Report source (check all that apply)

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

4. Date received by manufacturer (mo/day/yr) 03/29/99

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

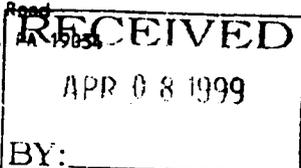
6. # IND, protocol #

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)

OVERDOSE OVERDOSE  
ABORTION COAGULATION DIS  
HEPATORENAL SYN EDEMA LUNG  
CONVULSION DEATH



5. Describe event or problem

Notification via litigation of case summaries provided by MD/co-author of lit report (N Engl J Med 1997; 337: 1112-7). Info provided based on extracted data from med rec of pts hosp for acetaminophen ingestion b/t 1/1/92&4/30/95. According to data, 27yo took 6g/d(OVERDOSE)of an unk TYLENOL® product. Addl info rec'd 3/29/99: Med rec indicate pt presented at 25-26 wk gestation to ER on 10/13/94 w/3 d h/o N/V, RUQ pain spreading to entire abd, w/fever, malaise, myalgias, epistaxis, general bleeding, scant hematemesis & occ vag spotting. Pt took 1g of Tylenol q4hx2-3d PTA. Adm to hosp(10/13/94) w/dx fulm hepatitis w/known h/o hepatitis B. Pt moved to MICU (10/23/94), since mental status deteriorated. No FHT by US; pt spontaneously aborted 10/24/94(ABORTION). Pt had coagulopathy (COAGULATION DISORDER), HEPATORENAL SYNDROME w/increasing NH4 level & ARF w/pulm edema(LUNG EDEMA). Bld glucose levels maintained by D50W & airway by intubation. 10/26/94: pt having seizures(CONVULSION). On 10/27/94, pt died. DEATH report list immediate cause of death as hepatic-(See sec C10)

6. Relevant tests/laboratory data, including dates

10/13/94: AST=5140, ALT=3980, AP=156, tbili=4.5, TP=5.9, ALB=3.1, PT=29.5, PTT=59.4, PLT=140, glu=148, (2000)APAP=5 w/last APAP dose @1650; 10/13-14/94: US GB:1.6cm simple cyst in the superior rt lobe of the liver. GB partially (See Sec B.7)

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

H/O cocaine abuse, denies IVDA, occ ETOH, 9/23/94: HBsAg(+); Sec B6 cont: contracted; thick GB wall; 10/14/94: SCR=0.9, AP=173, tbili=5.1, TP=4.9, ALB=2.5, PT=39.3, PTT=63.2 WBC=7.9 H/H=9.7/27.7, PLT=118, glu=69, Fe=66, ferritin=3159 TIBC=278; HBsAg(+), a-HBc(+), a-HCV(-), a-HBcIgM(+), a-HAV-IgM(-), 10/26/94: SCR=5.3, AST=72, ALT=91, (See Sec C.10)

**E. Initial reporter**

1. Name, address & phone #

[redacted] MD  
[redacted] Medical Ctr  
[redacted]

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

3. Occupation  
physician

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



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