

Individual Safety Report



\*3166471-6-00-01\*

**McNEIL**

CONSUMER PRODUCTS COMPANY  
RT WASHINGTON, PA 19034

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Approved by FDA on 11/15/93

Mfr report # \_\_\_\_\_

UF/Dist report # \_\_\_\_\_

FDA use only

**A. Patient information**

1. Patient identifier [redacted] In confidence	2. Age at time of event: 40 yrs Date of birth: [redacted]	3. Sex (X) female ( ) male	4. Weight lbs or 44 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) 6/26/96  
( ) life-threatening  
( ) hospitalization - initial or prolonged

( ) disability  
( ) congenital anomaly  
( ) required intervention to prevent permanent impairment/damage  
( ) other:

3. Date of event (mo/day/yr) 6/22/96

4. Date of this report (mo/day/yr) 11/23/98

**C. Suspect medication(s)**

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

#1 **TYLENOL** analgesic unknown  
#2 **BAYER®** Nighttime product (cont. Sec. C10)

2. Dose, frequency & route used

#1 "at least 2 q4h", po  
#2 unknown dose qhs, po

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

#1 6/96; "several days PTA"  
#2 6/96; "several days PTA"

4. Diagnosis for use (indication)

#1 headache  
#2 unknown

5. Event abated after use stopped or dose reduced

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

6. Lot # (if known)

#1 Unknown  
#2 unknown

7. Exp. date (if known)

#1 Unknown  
#2 unknown

8. Event reappeared after reintroduction

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

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

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

aspirin [Sect C1 cont]:VICODIN®;unk dose;6/96:"several days PTA" [Sect B5 cont]: dated 7/3/96 also lists: immediate cause of death: alcoholic cardiomyopathy; other significant conditions contributing to death: acetaminophen toxicity

5. Describe event or problem

Notif via Summons & Complaint of DEATH allegedly assoc w/TYLENOL® in adult female. Addl info rec'd 2/20/98: Records indicate a 40yof presented to ER 6/22/96 w/3D hx of epigastric/flank PAIN, N/V & weakness. Pt w/hx of heavy EtOH consumption which she stopped 3D PTA, took TYLENOL at least 2 q4h (OVERDOSE), a BAYER® Nighttime prod qhs, & VICODIN® prn x several days PTA. Pt admitted to hosp due to markedly abnormal labs initial dx: acute HEPATITIS & ACUTE KIDNEY(renal) FAILURE. Up course per disch summary: MUCOMYST tx for acetaminophen toxicity+alcoholic hepatitis. On 6/25/96 pt had HEART(cardiopulmonary)ARREST & became comatose after resuscitated. Anoxic ENCEPHALOPATHY, adult RESPIRATORY DISTRESS syndrome noted w/poor overall prognosis. On 6/27/96, life support removed. Pt pronounced dead @1700. Addl info rec'd 11/18/98: Death certificate dated 7/2/96 lists immediate cause of death: anoxic encephalopathy due to cardiopulmonary arrest, due to arrythmia; other significant conditions contributing to death: alcoholic hepatitis, cirrhosis of liver. Death cert (See Sect C10)

**G. All manufacturers**

1. Contact office - name/address (& mfg 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 representative  
( ) distributor  
(X) other: attorney

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6. Relevant tests/laboratory data, including dates

6/22/96: WBC=2.2, Hgb=14.7, Hct=40.8, bands=38, PT=18.8, INR=2.6, BUN=32, Cr=5.1, bili=2.3, SGOT=5900, SGPT=5100, hepatitis panel= negative, acetaminophen=57; 6/23/96: acetaminophen=10; 6/24/96: acetaminophen=7; 6/25/96: PO2=448, PCO2=38 [See Sect B7]

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

Hx of heavy EtOH use (binge drinking)x15 yrs; Hx of smoking 2 packs or more cigarettes/day for unspecified time period; Hx of breast biopsy in 4/95 (fibroadenoma; no malignancy); NKDA [Sect. B6 cont.]: pH=6.82 (98% sat on 100% O2), SGOT=102, SGPT=102, chest X-ray=pulmonary edema; 6/27/96: PO2=68, PCO2=33, pH=7.38 (92% sat on 30% O2)

4. Date received by manufacturer (mo/day/yr) 11/18/98

5. (A) NDA # 17-552

6. If IND, protocol #

IND # \_\_\_\_\_  
PLA # \_\_\_\_\_  
pre-1938 ( ) Yes  
OTC product (X) Yes

7. Type of report (check all that apply)

( ) 5-day (X) 15-day  
( ) 10-day ( ) periodic  
( ) Initial (X) follow-up # 2

8. Adverse event term(s)

DEATH  
OVERDOSE  
KIDNEY FAIL ACU  
ENCEPHALOPATHY

PAIN  
HEPATITIS  
HEART ARREST  
RESPIRATORY DIS

9. Mfr. report number  
0913381A

**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 ( ) Yes ( ) No (X) 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.