



3203039-7-00-01

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

McNEIL

McNEIL CONSUMER PRODUCTS COMPANY
FORT WASHINGTON, PA 19034

Page ____ of ____

Approved by FDA on 11/15/93

Mfr report # _____

UF/Dist report # _____

FDA use only

A Patient information

1. Patient identifier [REDACTED]	2. Age at time of event: 31 yrs or Date of birth: _____	3. Sex (X) female () male	4. Weight 117 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) 1/13/99

() life-threatening

(X) hospitalization - initial or prolonged

() disability

() congenital anomaly

() required intervention to prevent permanent impairment/damage

() other:

3. Date of event (mo/day/yr) 1/13/99

4. Date of this report (mo/day/yr) 02/11/99

5. Describe event or problem

Consumer report rec'd via Internet of DEATH allegedly associated with the use of a **TYLENOL** acetaminophen product in her sister. Consumer reports that sister ingested an unknown amount of **TYLENOL** for sinus headaches. Sister experienced **VOMITING** an unspecified time later & went to a 24 hr clinic believing she had the flu. She was hydrated & sent home. The next day, sister continued to feel sick and was taken to ER where she reportedly experienced **CONVULSIONS** & went into a **COMA**. She was transferred to another hospital. According to consumer, sister was diagnosed with **HEPATIC FAILURE** (liver failure) & **BRAIN EDEMA** (brain was swollen). Consumer reported that sister may have needed a liver transplant. Sister survived for 4-5 days. Consumer reports that sister's liver function began to return but sister died an unspecified amount of time later. Consumer reported that sister was a social drinker & may have taken product after drinking. Sister's doctor reportedly attributed event to **APAP** but believed alcohol may have also contributed.

6. Relevant tests/laboratory data, including dates

reports blood levels of acetaminophen elevated, liver enzymes elevated, and unspecified test revealed swelling of the brain

RECEIVED
FEB 18 1999
BY: _____

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

broken nose - summer of 1998, unspecified back injury; NKDA

DSS

FEB 22 1999

C. Suspect medication(s)

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

#1 **TYLENOL Analgesic Unknown**

#2 _____

2. Dose, frequency & route used

#1 unknown dose, po

#2 _____

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

#1 unknown dates or duration

#2 _____

4. Diagnosis for use (indication)

#1 sinus headaches due to broken nose

#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)

unknown

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

215-273-7820

3. Report source (check all that apply)

() foreign

() study

() literature

(X) consumer

() health professional

() user facility

() company representative

() distributor

() other:

4. Date received by manufacturer (mo/day/yr) 02/10/99

5. (A) NDA # 19-872

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

(X) Initial () follow-up # _____

8. Adverse event term(s)

DEATH VOMITING

CONVULSION COMA

LIVER FAILURE EDEMA BRAIN

9. Mfr. report number

1120516A

E. Initial reporter

1. Name, address & phone # _____

2. Health professional? () Yes () No

3. Occupation _____

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