



Mfr report #
UF/Olat report #
FDA use only

A. Patient information **C. Suspect medication(s)**

1. Patient identifier
2. Age at time of event: 46 yrs
3. Sex (X)female
4. Weight unk lbs or kgs

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 () disability
() life-threatening () congenital anomaly
() hospitalization - initial or prolonged (X) required intervention to prevent permanent impairment/damage
() other:

3. Date of event 1/99
4. Date of this report 02/22/00

5. Describe event or problem
Consumer alleges that the use of Extra Strength TYLENOL[®] acetaminophen Tablets was associated with LIVER DAMAGE (degenerative liver disease). Consumer reports taking 500 mg of Extra Strength TYLENOL as needed from 6/84 to 5/99. In 1/99, consumer reports visiting her physician for an unspecified reason. Physician reportedly suggested consumer had hepatitis in the past based on unspecified lab tests. Rejecting this diagnosis, in 5/99, consumer went to a specialist who reportedly diagnosed her with degenerative, liver disease. Consumer reports that she believes it was due to TYLENOL poisoning her liver. Addl info rec'd 2/22/00: Medical Data Follow-Up Form completed by consumer indicates that she took 2 Extra Strength TYLENOL[®] Tablets 4 to 6 times daily for a varied period of time for pain from a back operation. About a year ago, she reportedly developed degenerative liver disease caused by TYLENOL. Consumer was seen by a physician. She reports that she discontinued use of the product and still has a "deceased liver".

6. Relevant tests/laboratory data, including dates
unspecified date: blood tests reportedly revealed degenerative liver disease

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)
ruptured disc and 4 pinched nerves, back fusion (1998), diabetes, arthritis; allergic to sulfa drugs, codeine, KEFLEX[®], DARVON[®], TORADOL[®]

1. Name (give labeled strength & mfr/labeler, if known)
#1 Extra Strength TYLENOL Tablets
#2

2. Dose, frequency & route used
#1 1000 mg, 4-6 times a day
#2

3. Therapy dates (if unknown, give duration from/to (or best estimate))
#1 6/84-5/99; 15 yrs
#2

4. Diagnosis for use (indication)
#1 pain from back operation
#2

5. Event abated after use stopped or dose reduced
#1 () Yes (X) No () 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)
ELAVIL[®], unspecified diabetic medication

G. All manufacturers

1. Contact office - name/address (& mfring site for devices)
McNeil Consumer Healthcare
Medical Affairs
7050 Camp Hill Road
Ft. Washington, PA 19034
2. Phone number 215-273-7303
3. Report source (check all that apply)
() foreign
() study
() literature
(X) consumer
health professional
() professional
() user facility
() com. representative
() distributor
() other:

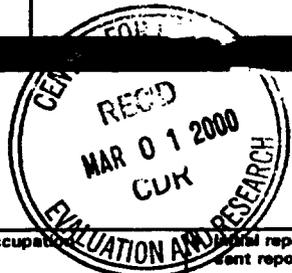
4. Date received by manufacturer (mo/day/yr) 02/22/00
5. (A) NDA # 19-872
IND #
PLA #
pre-1938 () Yes
OTC product (X) Yes

6. If IND, protocol #
7. Type of report (check all that apply)
() 5-day (X) 15-day
() 10-day () periodic
() Initial (X) follow-up # 1

8. Adverse event term(s)
LIVER DAMAGE
9. Mfr. report number 1293834A

E. Initial reporter

1. Name, address & phone #
2. Health professional? () Yes () No
3. Occupational reporter also sent report to FDA () Yes () No () Unk





Mfr report #
UF/Dist report #
FDA use only

A. Patient information

1. Patient identifier unknown in confidence	2. Age at time of event: or 20 yrs Date of birth: 02/18/1979	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) 02/12/00	() disability
() life-threatening	() congenital anomaly
() hospitalization - initial or prolonged	() required intervention to prevent permanent impairment/damage
() other:	
3. Date of event (mo/day/yr) 2/11/00	4. Date of this report (mo/day/yr) 03/06/00

5. Describe event or problem

Consumer report received via Internet of DEATH (she passed away) allegedly associated with the use of an unspecified TYLENOL® acetaminophen product in her 20 year old daughter. According to report, on an unspecified date, her daughter took an OVERDOSE of TYLENOL. On 2/11/00, "her liver died" (LIVER FAILURE) and on 2/12/00, "she was gone." No further information was provided.



6. Relevant tests/laboratory data, including dates
unknown

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

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)	
#1 unspecified TYLENOL product	
#2	
2. Dose, frequency & route used	3. Therapy dates (if unknown, give duration) from/to (or best estimate)
#1 "overdose", po	#1 unknown dates or duration
#2	#2
4. Diagnosis for use (indication)	5. Event abated after use stopped or dose reduced
#1 unknown	#1 () Yes () No (X) N/A
#2	#2 () Yes () No () N/A
6. Lot # (if known)	7. Exp. date (if known)
#1 unknown	#1 unknown
#2	#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)	
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10. Concomitant medical products and therapy dates (exclude treatment of event) unknown	

G. All manufacturers

1. Contact office - name/address (& mfring site for devices)	2. Phone number
McNeil Consumer Healthcare Medical Affairs 7050 Camp Hill Road Ft. Washington, PA 19034	215-273-7303
4. Date received by manufacturer (mo/day/yr) 03/04/00	3. Report source (check all that apply)
6. If IND, protocol #	() foreign () study () literature (x) consumer () health professional () user facility () company representative () distributor (x) other: Internet
7. Type of report (check all that apply)	5. (A) NDA # 19-872 IND # PLA # pre-1938 () Yes OTC product (X) Yes
() 5-day (X) 15-day () 10-day () periodic (X) Initial () follow-up #	8. Adverse event term(s) DEATH OVERDOSE LIVER FAILURE
9. Mfr. report number 1325474A	

E. Initial reporter

1. Name, address & phone #		
DSS MAR - 9 2000 MAR X 8 2000		
2. Health professional?	3. Occupation	4. Initial reporter also sent report to FDA
() Yes () No		() Yes () No () Unk