



McNeil
Consumer Healthcare
McNeil Consumer Healthcare
Ft. Washington, PA 19334-2299

Approved by FDA on 11/15/93

Mfr report # _____

UP/Dist report # _____

FDA use only

Page _____ of _____

A. Patient information

1. Patient identifier In confidence	2. Age at time of event: 40 yrs Date of birth: _____	3. Sex (X) female () male	4. Weight unk lbs or kgs
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C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)	
#1 unknown TYLENOL product	#2 _____
2. Dose, frequency & route used	3. Therapy dates (if unknown, give duration) from/to for best estimate
#1 unknown dose, po	#1 unknown dates; approx 14 days
#2 _____	#2 _____
4. Diagnosis for use (indication)	5. Event abated after use stopped or dose reduced
#1 abdominal pain	#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. MDC # - for product problems only (if known)	8. Event reappeared after reintroduction
- -	#1 () Yes () No (X) N/A
	#2 () Yes () No () N/A
10. Concomitant medical products and therapy dates (exclude treatment of event) none	

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)	() disability (X) death approx 3/96 (m/d/y) () life-threatening (X) hospitalization - initial or prolonged () other:
3. Date of event (m/d/y)	4. Date of this report (m/d/y)
approx 3/96	03/23/00

5. Describe event or problem

Consumer's written report of DEATH allegedly associated with the use of one of our TYLENOL® acetaminophen products in her sister-in-law. According to report, sister-in-law died of hepatitis after taking product. Addl info rec'd 3/23/00: Phone call to consumer revealed that sister-in-law was approximately 40 years old at time of death. About 4 years ago, she was reportedly diagnosed with "hepatitis B or C". Physician reportedly prescribed TYLENOL for abdominal pain associated with the hepatitis. Sister-in-law took an unknown amount of an unknown TYLENOL product for approximately 14 days. Sister-in-law reportedly was "doubled-over" in pain (ABDOMINAL PAIN) and was yellow (JAUNDICE). Consumer reports that her sister-in-law was subsequently admitted to the hospital and was in a COMA. She reportedly died approximately 1 week after admission to hospital. According to consumer, physician attributed her sister-in-law's death to the use of TYLENOL with her hepatitis. 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.)

hepatitis "B or C"; NKDA

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 (m/d/y)	5. (A) NDA #
03/22/00	19-872
6. If IND, protocol #	IND #
	PLA #
	pre-1938 () Yes
7. Type of report (check all that apply)	OTC product (X) Yes
() 5-day (X) 15-day () 10-day () periodic (X) initial () follow-up #	8. Adverse event term(s)
	DEATH PAIN ABDOMINAL JAUNDICE COMA
9. Mfr. report number	
1336023A	

E. Initial reporter

1. Name, address & phone #		
DSS APR 04 2000 APR 3 X 2000		
2. Health professional?	3. Occupation	4. Initial reporter also sent report to FDA
() Yes () No		() Yes () No () No