



McNeil
Consumer Healthcare
McNeil Consumer Healthcare
Washington, PA 19034-2299

Approved by FDA on 11/15/93
Mfr report # _____
UF/Dist report # _____
FDA use only

THE FDA M...

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A. Patient information

1. Patient identifier In confidence	2. Age at time of event: or 11 mo Date of birth:	3. Sex () female (X) male	4. Weight lbs or 10 kgs
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C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known) #1 unknown TYLENOL® product #2		3. Therapy dates (if unknown, give duration) from/to (or best estimate) #1 4/28/99-4/30/99; 3 days #2	
2. Dose, frequency & route used #1 "nl dose by weight", po #2		4. Diagnosis for use (indication) #1 unknown #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) 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)	
(X) death (unknown mo/day/yr)	() disability
() life-threatening	() congenital anomaly
(X) hospitalization - initial or prolonged	() required intervention to prevent permanent impairment/damage
() other:	
3. Date of event (mo/day/yr) 5/3/99	4. Date of this report (mo/day/yr) 06/29/99

5. Describe event or problem
Pharmacist report of LIVER FAILURE (acute hepatic failure) allegedly associated w/use of an unknown TYLENOL® product in an 11 mo old male pt. According to pharmacist, pt's physician stated pt received a "normal dose for his weight" for 3 days beginning on 4/28/99. Pharmacist did not know indication for use. On 5/3/99, pt adm to hosp w/lethargy (SOMNOLENCE) & JAUNDICE. Blood analysis reportedly revealed LIVER FUNCTION TESTS ABNORMAL & increased PT & PTT (COAGULATION DISORDER). Pt was treated with vitamin K, lactulose, & empiric antibiotics. Addl info rec'd 6/24/99: Pharmacist reports pt expired (DEATH) while awaiting liver transplant. On approx 5/5/99, pt was transferred to second hospital for liver transplant. Within 1 week of transfer, pt reportedly expired before transplant was available. Course of liver failure was reportedly unknown. According to pharmacist, primary physician at first hospital did not attribute death to TYLENOL®. No further information was provided.

6. Relevant tests/laboratory data, including dates
5/3/99 TBili=20.5, DBili=15.7, SGOT=3169, SGPT=2188, PT=29.9, PTT=89.8, INR=5.71, APAP level=undetectable

7. Other relevant history, including preexisting medical conditions, allergies, race, pregnancy, smoking and alcohol use, hepatic dysfunction, etc.
no known conditions; NKDA

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 215-273-7820
4. Date received by manufacturer (mo/day/yr) 06/24/99		3. Report source (check all that apply) () foreign () study () literature () consumer (X) health professional () user facility () company representative () distributor () other:
6. If IND, protocol #		
5. (A) NDA # 19-872 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 # 1		
8. Adverse event term(s) DEATH LIVER FAILURE SOMNOLENCE JAUNDICE LIVER FUNC ABNO COAGULATION DIS		
9. Mfr. report number 1170493A		

E. Initial reporter

1. Name, address & phone # RPh Hospital Drive JUL 07 1999			
2. Health professional? (X) Yes () No	3. Occupation pharmacist	4. Initial reporter also sent report to FDA () Yes () No (X) Unk	

RECEIVED
JUL 02 1999

REC'D
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EVALUATION