

**Individual Safety Report**



\*3306179-7-00-01\*

**MCNEIL**  
Consumer Healthcare  
McNeil Consumer Healthcare  
Fort Washington, PA 19034-2299

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Mfr report #
UP/Dist report #
FDA use only

**Patient information**

**C. Suspect medication(s)**

1. Patient identifier  In confidence	2. Age at time of event: 35 yrs or Date of birth:	3. Sex (X) female  ( ) male	4. Weight unk lbs or kgs
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1. Name (give labeled strength & mfr/labeler, if known) #1 Extra Strength <b>TYLENOL</b> Tablets #2		3. Therapy dates (if unknown, give duration) from/to (or best estimate) #1 unknown dates or duration #2	
2. Dose, frequency & route used #1 "taken as directed" #2		5. Event abated after use stopped or dose reduced #1 ( ) Yes ( ) No (X) N/A #2 ( ) Yes ( ) No ( ) N/A	
4. Diagnosis for use (indication) #1 unknown #2		8. Event reappeared after reintroduction #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	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)	
( ) death (mo/day/yr) 07/31/98	( ) disability
( ) life-threatening	( ) congenital anomaly
(X) hospitalization - initial or prolonged	( ) required intervention to prevent permanent impairment/damage
( ) other:	

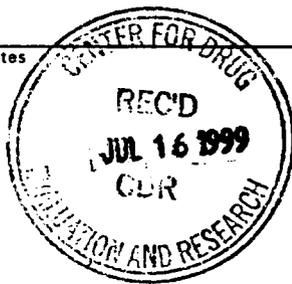
3. Date of event (mo/day/yr) 7/26/98	4. Date of this report (mo/day/yr) 07/07/99
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5. Describe event or problem

Written report received via FDA (MSB File Number:99-00345) from consumer of DEATH & PAIN allegedly associated with the use of Extra Strength **TYLENOL**® acetaminophen Tablets in her daughter. According to report, consumer's daughter had taken an unspecified amount of Extra Strength **TYLENOL** on an empty stomach. Daughter's pain was intense. Consumer did not specify details regarding daughter's death. Additional information received 7/6/99: Mother's written note indicates daughter was taking product as directed on package label. Duration of therapy was not specified. Mother reported that daughter had taken product on an empty stomach. According to mother, on 7/26/98, daughter began experiencing continuing pain. Daughter was taken to ER on 7/27/98 & subsequently admitted to hospital. Mother described illness as LIVER DAMAGE due to Tylenol & reported that daughter died on 7/31/98. Death certificate reportedly reads "death due to Tylenol toxicity".

6. Relevant tests/laboratory data, including dates unknown
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7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)  
no known conditions; NKDA



**DSS**

JUL 19 1999

ADVERSE EVENT REPORTING SYSTEM

**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) 07/06/99		3. Report source (check all that apply) ( ) foreign ( ) study ( ) literature (X) consumer  ( ) health professional ( ) user facility  ( ) company representative ( ) distributor (X) other: FDA
5. (A) NDA # 19-872 IND # PLA # pre-1938 ( ) Yes OTC product (X) Yes		
6. If IND, protocol #		8. Adverse event term(s) DEATH PAIN LIVER DAMAGE
7. Type of report (check all that apply) ( ) 5-day (X) 15-day ( ) 10-day ( ) periodic ( ) Initial (X) follow-up # 1		
9. Mfr. report number 1104769A		

**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		