

Individual Safety Report



3504942-0-00-01

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM



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

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Approved by FDA on 11/15/93

Mfr report #
UF/Clot report #
FDA use only

A. Patient information				C. Suspect medication(s)			
1. Patient Identifier [Redacted]	2. Age at time of event: or 35 yrs Date of birth: 12/18/1964	3. Sex (X) female () male	4. Weight unk lbs or kgs	1. Name (give labeled strength & mfr/labeler, if known) #1 Extra Strength TYLENOL product #2 ethanol			
2. Outcomes attributed to adverse event (check all that apply) (X) death 05/12/00 () life-threatening (X) hospitalization - initial or prolonged () disability () congenital anomaly () required intervention to prevent permanent impairment/damage () other:				2. Dose, frequency & route used #1 1000 mg, qid, po #2 "6 beers", po		3. Therapy dates (if unknown, give duration) from/to (or best estimate) #1 5/7/00-5/8/00; 12 hours #2 5/7/00-5/8/00; 12 hours	
3. Date of event 5/8/00				4. Date of this report 05/15/00			
5. Describe event or problem Consumer report received via Internet alleges that the use of a TYLENOL acetaminophen product and ethanol was associated with LIVER DAMAGE and DEATH in his sister. According to consumer, his sister took product for a toothache and was drinking some beers. She reportedly died 5/12/2000 at 3:12. Addl info rec'd 5/18/00 via telephone: According to consumer, his sister experienced toothache pain on 5/7/00 in the evening and took 4 doses (1000 mg each) of TYLENOL over approximately a 12 hour period. She also drank approximately 6 beers that evening. On 5/8/00, she became queasy and sick (NAUSEA). On 5/9/00, she went to the hospital and was admitted. On 5/10/00, she was transferred to a second hospital to receive care from a liver specialist. According to consumer, the physician's diagnosis was toxic poisoning from the combination of high doses of TYLENOL and the beers. Her liver reportedly shut down and as a result of that, her kidneys shut down (KIDNEY FAILURE) and her heart stopped (HEART ARREST). She (See Sect B6)				4. Diagnosis for use (indication) #1 toothache pain #2 unknown		5. Event abated after use stopped or dose reduced #1 () Yes (X) No () N/A #2 () Yes (X) No () N/A	
6. Relevant tests/laboratory data, including dates unknown (Sect B5 cont): reportedly was too weak for a liver transplant.				6. Lot # (if known) #1 unknown #2 unknown		7. Exp. date (if known) #1 unknown #2 unknown	
7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) no known conditions; consumer reports his sister was not a chronic drinker, but occasionally did drink beer; NKDA				8. Adverse event term(s) LIVER DAMAGE DEATH NAUSEA KIDNEY FAILURE HEART ARREST			
8. All manufacturers				9. NDC # - for product problems only (if known) - -			
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			
4. Date received by manufacturer 05/15/00				3. Report source (check all that apply) () foreign () study () literature (X) consumer health professional () user facility company representative () distributor (X) other: Internet			
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 (X) initial () follow-up #				8. Initial reporter also sent report to FDA () Yes () No () Unk			
9. Mfr. report number 1362320A				E. Initial reporter			
1. Name, address & phone #				1. Name, address & phone #			
2. Health professional?				3. Occupation			
() Yes () No				() Yes () No () Unk			

