

Individual Safety Report



3617943-9-00-01*

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 #
UP/Dist report #
FDA use only

A. Patient information

1. Patient identifier [redacted] In confidence	2. Age at time of event: 38 yrs or Date of birth: 04/10/1961	3. Sex () female (X) male	4. Weight unk lbs or kgs
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C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)		3. Therapy dates (if unknown, give duration) from/to (or best estimate)	
#1 Extra Strength TYLENOL PM product		#1 3/17/00-3/18/00; 2 days	
2. Dose, frequency & route used		5. Event abated after use stopped or dose reduced	
#1 4 pills/day, po		#1 () Yes () No (X) N/A	
#2		#2 () Yes () No () N/A	
4. Diagnosis for use (indication)		8. Event reappeared after reintroduction	
#1 for sleep		#1 () Yes () No (X) N/A	
#2		#2 () Yes () No () N/A	
6. Lot # (if known)	7. Exp. date (if known)	9. NDC # - for product problems only (if known)	
#1 Unknown	#1 Unknown		
#2	#2		
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) 3/21/00	() disability
() life-threatening	() congenital anomaly
(X) hospitalization - initial or prolonged	(X) required intervention to prevent permanent impairment/damage
() other:	
3. Date of event (mo/day/yr) 3/19/00	4. Date of this report (mo/day/yr) 06/05/00

5. Describe event or problem

Consumer report of DEATH allegedly associated with the use of an Extra Strength TYLENOL[®] PM product in his 38 yo brother. According to consumer, his brother had a few beers (probably 4-5) on 3/17/00 & took 4 TYLENOL PM to help him sleep. On 3/18/00, he took another 4 TYLENOL PM because he was still having difficulty sleeping. By the next morning, on 3/19/00, his brother reportedly felt ill (REACTION UNEVALUABLE) & was throwing up (VOMITING) so he spent the entire day in bed. On Monday morning, 3/20/00, pt was allegedly taken to ER via ambulance. In ER, pt tx'd w/unspecified IV's, then transferred to ICU of a 2nd hospital where tx w/ MUCONYST[®] was initiated. Pt was reportedly in LIVER FAILURE & KIDNEY FAILURE & was placed on dialysis. He was also placed on a respirator because of brain swelling (BRAIN EDEMA). Twelve hrs later, on 3/21/00, pt's heart stopped (HEART ARREST) & he expired. According to consumer, MD reportedly attributed pt's death to his use of Tylenol PM, noting his alcohol use & Hepatitis C as (See Sect B6)

6. Relevant tests/laboratory data, including dates

in hospital: pH reportedly=7.1, acetaminophen level unknown by reporter. (Sect B5 Cont) contributing factors. Addl info rec'd 6/2/2000. Medical Records Authorization form completed by brother indicates that the (see Sect B7)

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

hepatitis C x 3 years caused by shellfish, reports brother drank beer (unknown amount) on most weekends; NKDA (Sect B5 Cont) description of illness is acetaminophen poisoning. Form also indicates date of admission was /20/00. No further information was provided.

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) 06/02/00		3. Report source (check all that apply)	
6. If IND, protocol #		() foreign () study () literature (X) consumer () health professional () user facility () company representative () distributor () other:	
7. Type of report (check all that apply)		5. (A) NDA # IND # PLA # pre-1938 () Yes OTC product (X) Yes	
() 5-day (X) 15-day () 10-day () periodic () Initial (X) follow-up # 1		8. Adverse event term(s)	
9. Mfr. report number 1350987A		DEATH REACTION UNEVAL VOMITING LIVER FAILURE KIDNEY FAILURE EDEMA BRAIN HEART ARREST	

E. Initial reporter

1. Name, address & phone # NOV 28 2000			
2. Health professional? () Yes () No	3. Occupation	4. Initial reporter also sent report to FDA () Yes () No () Unk	



Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.