



06-AUG-1998-0539

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

**McNEIL**

NEIL CONSUMER PRODUCTS COMPANY  
FORT WASHINGTON, PA 19034

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\*3114180-1-00\*

UP/Date report of \_\_\_\_\_  
FDA use only

<b>A. Patient information</b>				<b>C. Suspect medication(s)</b>			
1. Patient Identifier	2. Age at time of event: 26 yrs or Date of birth	3. Sex (X) female ( ) male	4. Weight unk (lbs) or kgs	1. Name (give labeled strength & mfr/labeler, if known) #1 An unspecified <b>TYLENOL</b> product #2		3. Therapy dates (if unknown, give duration from/to (or best estimate)) #1 since at least 1990 #2	
<b>B. Adverse event or product problem</b>				2. Dose, frequency & route used #1 unknown dose #2			
1. X Adverse event and/or Product problem (e.g., defects/malfunctions)				4. Diagnosis for use (indication) #1 severe headache #2		6. Event related after use stopped or dose reduced #1 (X) Yes ( ) No ( ) N/A #2 ( ) Yes ( ) No ( ) N/A	
2. Outcomes attributed to adverse event (check all that apply) ( ) death (mo/day/yr) ( ) life-threatening (X) hospitalization - initial or prolonged ( ) other: recovered				5. Lot # (if known) #1 Unknown #2		7. Exp. date (if known) #1 Unknown #2	
3. Date of event (mo/day/yr) 7/5/94		4. Date of this report (mo/day/yr) 07/27/98		8. Event reappeared after reintroduction #1 ( ) Yes ( ) No (X) N/A #2 ( ) Yes ( ) No ( ) N/A			
5. Describe event or problem Notification by litigation of acute liver failure (HEPATIC FAILURE) & COMA. Summons & Complaint indicates pt consumed TYLENOL since at least 1990. Addl info rec'd 7/24/98: Consultation report of 7/6/94 indicates pt drank some margaritas & got a little "tipsy" 2 days PTA. On 7/5/94, pt had vomiting & dry heaves & was seen in clinic. Pt diagnosed w/ pancreatitis & sent home. Later that day, pt did not improve went to ER hypotensive (HYPOTENSION) w/ABDOMINAL PAIN. Pt admitted. Laparotomy revealed ischemic liver. DC Summary of 7/8/94 indicates US of hepatic veins r/o Budd Chiari. Bacterial cultures (-). HBsAB titer=5.0. Remaining hepatitis profile (-). According to PMH, pt took Tylenol profusely & possibly a large dose on 7/3/94. On 7/8/94, pt transferred to 2nd hospital for liver transplant. Principal Dx: hepatic failure w/necrosis secondary to toxin possibly acetaminophen, acute renal failure (ACUTE KIDNEY FAILURE), pulmonary edema (LUNG EDEMA), comatose state, severe coagulopathy (COAGULATION DISORDER) & FEVER. LFT's improved. DC 8/24/94.				9. NDC # - for product problems only (if known)			
6. Relevant tests/laboratory data, including dates ER: BP=70/40 (doppler), P=120, pH=7.12, pCO2=15, pO2=130; WBC=32000 w/20 bands, neutrophils=72, Hgb=12.7, serum lipase=218, amylase=801, Pt & aPtt markedly high, LDH=30395, SGOT=6635, SGPT=13484, alk phos=high, tbili=4.1, Cr=3, BUN=9; (See Sect 87)				10. Concomitant medical products and therapy dates (exclude treatment of event) Complaint indicates consumption of two mixed fruit drinks which contained a normal amount of beverage alcohol prior to consumption of the Tylenol product on 7/3/94; TEGRETOLO, IMITREX®, STADOL®, amitriptyline; PHENERGAN® (dose on 7/5/94)			
7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) subdural hematoma & surgery at age 13, migraine headaches, seizure disorder, ? TYLENOL abuse in past for migraines, drinks on occasion; allergic to EMETROL® & DILANTIN®; (Sect 16 cont) 7/6/94 acetaminophen serum - none detected, liver bge biopsy: zonal necrosis, coagulative, predominantly centrilobular. Extensive microvascular steatosis.				<b>G. All manufacturers</b>			
				1. Contact office - name/address (& mfring site for devices) McNeil Consumer Products Company Medical Affairs 7050 Camp Hill Road Ft. Washington, PA 19034		2. Phone number 215-233-7820	
				4. Date received by manufacturer (mo/day/yr) 07/24/95		3. Report source (check all that apply) ( ) foreign ( ) study ( ) literature ( ) consumer ( ) health professional ( ) user facility ( ) company representative ( ) distributor (X) other: attorney	
				6. If IND, protocol #		(A) NDA # 17-552 IND # PLA # pre-1038 ( ) 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) LIVER FAILURE COMA HYPOTENSION PAIN ABDOMINAL KIDNEY FAIL ACU EDEMA LUNG COAGULATION DIS FEVER	
				8. Mfr. report number 0418408A			
				<b>E. Initial reporter</b>			
				1. Name, address & phone # _____ Esq Suite _____ _____ Street _____ _____		AUG 7 1998	
				2. Health professional? ( ) Yes (X) No		3. Occupation attorney	
				4. Initial reporter also sent report to FDA ( ) Yes ( ) No (X) 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.