



27-FEB-1998-0459



McNEIL CONSUMER PRODUCTS
FORT WORTH, TEXAS

Page

Individual Safety Report



3037717-X-00

11/15/93
Use only

A. Patient information				C. Suspect medication(s)			
1. Patient identifier Case # 6 In confidence	2. Age at time of event: 42 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 "TYLENOL DS" #2			
B. Adverse event or product problem				2. Dose, frequency & route used #1 at least 6-8 per day, po #2		3. Therapy dates (if unknown, give duration; from/to for best estimate) #1 unknown dates or duration #2	
1. X Adverse event and/or Product problem (e.g., defects/malfunctions)				4. Diagnosis for use (indication) #1 fatigue, achiness, malaise & URI #2		5. Event abated after use stopped or dose reduced #1 () Yes () No (X) N/A #2 () Yes () No () N/A	
2. Outcomes attributed to adverse event (check all that apply) (X) death (1/16/94) (mo/day/yr) () life-threatening (X) hospitalization - initial or prolonged () disability () congenital anomaly () required intervention to prevent permanent impairment/damage () other:				6. Lot # (if known) #1 Unknown #2		7. Exp. date (if known) #1 Unknown #2	
3. Date of event 12/27/93 (mo/day/yr)		4. Date of this report 02/12/98 (mo/day/yr)		8. Event reappeared after reintroduction #1 () Yes () No (X) N/A #2 () Yes () No () N/A			
5. Describe event or problem Reports of 19 cases compiled by attorney & sent to FDA; Agency forwarded these reports to McNeil upon request to Docket No. 77N-094W, Ref. 94, Vol. 6 of 7. Of the 19 cases, 11 were previously submitted to FDA by McNeil (Mfr. # 0158783A, 0171537A, 0284020A, 0325998A, 0374114A, 0495613A, 0505064A, 0505223A, 0505252A, 0599479A, 0673820A). Case document #6 of 42 YO F w/ long hx of alcoholic abuse (at least 2 drinks/ day) who was "taking Tylenol DS at least 6-8/day". Pt jaundiced, fatigued & admitted to hosp (12/28/93) w/elevated LFTs. On 12/29/93, pt transferred to 2nd hosp w/fulminant HEPATIC FAILURE for possible liver transplant. D/c dx: fulminant hepatic failure secondary to TYLENOL & hx of alcohol use, acute KIDNEY TUBULAR NECROSIS secondary to TYLENOL, SEPSIS, DIC (COAGULATION DISORDER), cerebral edema (BRAIN EDEMA) & ischemia, HYPOGLYCEMIA & brain injury due to hypoglycemia & fungal INFECTION & fungemia. At 2nd hosp, pt listed for transplantation. Pt's condition continued to deteriorate & pt was taken off transplant list on 1/2/94. Pt expired (DEATH) on 1/16/94.				9. NDC # - for product problems only (if known) -			
6. Relevant tests/laboratory data, including dates 12/27/93: D.bili=5.7mg/dL, T.bili=6.9mg/dL, GGT=189U/L, Alk Phos=254IU/L, AST=4019IU/L, ALT=1599IU/L, LDH=13847U/L, glucose=51mg/dL, BUN=6mg/dL, Cr=0.8, BUN/Scr=7.2; 12/29/93: acetaminophen level=51 (at least 48hrs post-ingestion) (See Sect C10)				10. Concomitant medical products and therapy dates (exclude treatment of event) unspecified decongestant, amoxicillin, SELDANE® & ampicillin (Cont'Sect.B.6) Initial labs of SGOT=18395, bili=8.1, AlkPhos=469, PT=36.7, SCR=2.7, glucose=67; 12/29/93: blood culture(+) for Torulopsis; 1/2/94 acetaminophen level=4.3, ANA=positive			
7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) hx of smoking 1 pack/day, HTN, long hx of alcoholic abuse (at least 2 drinks per day), positive family hx for liver disease, PUD in 1980's, gravida 2, para 3, tonsillectomy in distant past, tubal ligation 1985, fibrocystic breast disease, Hyst. secondary to enlarged uterus w/leiomyoma, uterine fibroids in 1993; allergic to erythromycin				G. All manufacturers			
				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) 12/31/97		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-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. Adverse event term(s) LIVER FAILURE NECRO KIDNEY TU SEPSIS COAGULATION DIS EDEMA BRAIN HYPOGLYCEMIA INFECTION DEATH	
				9. Mfr. report number 0932414A			
				E. Initial reporter			
				1. Name, address & phone # [Redacted] [Redacted] Avenue [Redacted] [Redacted]			
2. Health professional? () Yes (X) No		3. Occupation attorney		4. Initial reporter also sent report to FDA (X) 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.