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27-FEB-1998-0460

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Individual Safety Report
#3037719-3-00*

FDA on 11/16/93
FDA use only

A. Patient information			
1. Patient identifier Case # 10 In confidence	2. Age at time of event: 51 yrs or Date of birth:	3. Sex (X) female () male	4. Weight 114 lbs or kgs
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)			
<input type="checkbox"/> disability <input type="checkbox"/> death (mo/day/yr) <input type="checkbox"/> life-threatening <input checked="" type="checkbox"/> hospitalization - initial or prolonged <input type="checkbox"/> congenital anomaly <input type="checkbox"/> required intervention to prevent permanent impairment/damage <input type="checkbox"/> other:			
3. Date of event 4/5/94 (mo/day/yr)	4. Date of this report 02/12/98 (mo/day/yr)		
5. Describe event or problem			
<p>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#10 indicates 51yo F w/long term H/O EtOH use,who apparently took large doses (OVERDOSE) of Tylenol for last several weeks. Began taking more & more Tylenol.Takes on a pretty regular basis. Noted to take up to 7 at a time.Admits taking 4 at a time. On 4/5/94,2 days after last reported dose, pt to ER w/NAUSEA & VOMITING. Adm to hosp for acute HEPATIC FAILURE.Rec'd MUCOMYST® & cimetidine. Developed pneumonia. D/C 4/15/95 in stable condition w/dx of COPD,acetaminophen toxicity,alcoholic liver disease,probable cirrhosis & HYPOKALEMIA. Readmitted(4/16/98)for progressive SOB(DYSPNEA).Condition worsened & transfer'd to 2nd hosp for tx of liver failure,renal failure(KIDNEY FAILURE) & pulmonary insufficiency(LUNG DISORDER). No further info provided.</p>			
8. Relevant tests/laboratory data, including dates			
<p>On 4/5/94, bicarb=15,creat=1.8,alb=3.3,SGOT=19383,SGPT=8701, LDH=23452, alk phos=257, bili=4.4,anion gap=15,acetaminophen level=14,PT=40,PTT=46; HBsAg,HBCAb,HCVAb,& HepA Ab-IgM non reactive, HBsAB pending, B/P=98/50 (See Sect.B.7)</p>			
7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)			
<p>chronic obstructive pulmonary disease (emphysema), multiple pulmonary emboli, deep vein thrombosis; avg of 3 6-packs beer/month; smokes approx 1 pack per day or more. (Cont'Sect.B.6.) 4/16/94: SGOT=143, SGPT=205, LDH=313, alk phos=427, T Bili=15, amylase=66, WBC=21000 w/minimal shift to left, NA=126</p>			

1. Name (give labeled strength & mfr/labeler, if known)	
#1 TYLENOL Analgesic Unknown	
#2	
2. Dose, frequency & route used	3. Therapy dates (if unknown, give duration from/to (or best estimate)
#1 unknown dose, po	#1 until 4/3/94; several weeks
#2	#2
4. Diagnosis for use (indication)	5. Event abated after use stopped or dose reduced
#1 unknown	#1 () Yes () No (X) N/A
#2	#2 () Yes () No () N/A
6. Lot # (if known)	7. Exp. date (if known)
#1 Unknown	#1 Unknown
#2	#2
8. Event reappeared after reintroduction	
#1 () Yes () No (X) N/A	
#2 () Yes () No () N/A	
9. NDC # - for product problems only (if known)	
10. Concomitant medical products and therapy dates (exclude treatment of event)	
none	

G. All manufacturers	
1. Contact office - name/address (& mailing tag for devices)	2. Phone number
McNeil Consumer Products Company Medical Affairs 7050 Camp Hill Road Ft. Washington, PA 19034	215-233-7820
4. Date received by manufacturer (mo/day/yr)	5. (A) NDA #
12/31/97	17-552
6. If IND, protocol #	IND #
	PLA #
	pre-1938 () Yes
7. Type of report (check all that apply)	OTC product (X) Yes
() 5-day (X) 15-day	
() 10-day () periodic	
(X) initial () follow-up #	
9. Mfr. report number	8. Adverse event term(s)
0932526A	OVERDOSE NAUSEA VOMIT LIVER FAILURE DYSPNEA KIDNEY FAILURE LUNG DISORDER PNEUMONIA HYPOKALEMIA

E. Initial reporter		
1. Name, address & phone #		
[Redacted]		
2. Health professional?		
() Yes (X) No		
3. Occupation		4. Initial reporter also sent report to FDA
attorney		() 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