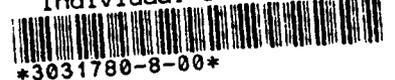




19-FEB-1998-0694



McNEIL CONSUME
FORT WASHI



3031780-8-00

Page

FDA use on

A. Patient information				C. Suspect medication(s)					
1. Patient identifier Case 182 In confidence	2. Age at time of event: or 17 yrs Date of birth:	3. Sex (X) female () male	4. Weight unk lbs or kgs	1. Name (give labeled strength & mfr. labeler, if known) #1 unknown acetaminophen product #2		2. Dose, frequency & route used #1 unknown dose, po #2			
B. Adverse event or product problem				3. Therapy dates (if unknown, give duration from/to for best estimate) #1 unknown #2		5. Event abated after use stopped or dose reduced #1 () Yes () No (X) N/A #2 () Yes () No () N/A			
				4. Diagnosis for use (indication) #1 unknown #2		8. Event reappeared after reintroduction #1 () Yes () No (X) N/A #2 () Yes () No () N/A			
1. X Adverse event and/or Product problem (e.g., defects/malfunctions)				6. Lot # (if known) #1 Unknown #2		7. Exp. date (if known) #1 Unknown #2			
2. Outcomes attributed to adverse event (check all that apply): (X) death unknown () disability () life-threatening () congenital anomaly (X) hospitalization - initial or prolonged () required intervention to prevent permanent impairment/damage () other:				9. NDC # - for product problems only (if known)				10. Concomitant medical products and therapy dates (exclude treatment of event): See attached case report form provided by	
3. Date of event unknown (mo/day/yr)		4. Date of this report 02/06/98 (mo/day/yr)		5. Describe event or problem Case # 182 received from 1996 case fatality data. See attached case report form provided by					
6. Relevant tests/laboratory data, including dates See attached case report form provided by				G. All manufacturers					
7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) See attached case report form provided by				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) 01/30/98		3. Report source (check all that apply): () foreign () study (X) literature () consumer (X) health professional () user facility () company representative () distributor () other:			
6. If IND, protocol #				5. (A) NDA # 17-552 IND # PLA # pre-1938 () Yes OTC product (X) Yes		8. Adverse event term(s) OVERDOSE CONFUSION TACHYCARDIA CREATININE INC ACIDOSIS LIVER FUNC ABNO EEG ABNORMAL DEATH			
7. Type of report (check all that apply) () 5-day (X) 15-day () 10-day () periodic (X) Initial () follow-up #				9. Mfr. report number 0929273A					
E. Initial reporter				1. Name, address & phone # Center Suite Avenue					
2. Health professional? (X) Yes () No		3. Occupation physician		4. Initial reporter also sent report to FDA () Yes () No (X) Unk					



Facsimile Form 3500A

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

[REDACTED] FATALITY: 1996 [REDACTED]

Case Number: 182
Age: 17 yrs
Substances: Acetaminophen
Chronicity: Unknown
Route: Ingestion
Reason: Unknown
Pre-Hospital Arrest? No

A 17-year-old female presented to the ED confused, combative, and agitated. Vital signs were 150/90, afebrile, tachycardia. Urine toxicology screen was positive for opiates. Serum creatinine 3.8 and the patient had an anion gap of 20. SGOT/SGPT were approximately 15,000. N-acetyl cysteine therapy was begun. The patient was intubated. ABG showed pH 7.43, pCO2 22, pO2 195. APAP level reported as 79 mcg/mL. LFTs continued to rise. EEG showed flat line, therefore the patient was not considered a candidate for transplantation. The patient expired two days after admission.