



19-FEB-1998-0638

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McNEIL CONSUMER PR
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Page of

Individual Safety Report



3032557-X-00

A. Patient information				C. Suspect medication(s)			
1. Patient Identifier Case 217 In confidence	2. Age at time of event: 44 yrs or Date of birth:	3. Sex () female (X) male	4. Weight unk lbs or kgs	1. Name (give labeled strength & mfr/labeler, if known) #1 unknown acetaminophen product #2 ibuprofen			
B. Adverse event or product problem				2. Dose, frequency & route used #1 "excessive amounts", po #2 "excessive amounts", po		3. Therapy dates (if unknown, give duration) from/to (or best estimate) #1 over previous 3-4 weeks #2 over previous 3-4 weeks	
1. X Adverse event and/or Product problem (e.g., defects/malfunctions)				4. Diagnosis for use (indication) #1 unidentified pain #2 unidentified pain		5. Event abated after use stopped or dose reduced #1 () Yes () No (X) N/A #2 () Yes () No (X) N/A	
2. Outcomes attributed to adverse event (check all that apply) (X) death : unknown (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 unknown		7. Exp. date (if known) #1 Unknown #2 unknown	
3. Date of event (mo/day/yr) unknown		4. Date of this report (mo/day/yr) 02/06/98		8. Event reappeared after reintroduction #1 () Yes () No (X) N/A #2 () Yes () No (X) N/A			
5. Describe event or problem Case # 217 received from the ██████████ 1996 fatality data. See attached case report form provided by ██████████				9. NDC # - for product problems only (if known) - -			
6. Relevant tests/laboratory data, including dates See attached case report form provided by ██████████				10. Concomitant medical products and therapy dates (exclude treatment of event) Sect. C1 cont'd #3. ethanol (unknown dose or duration) Sect. C10: See attached case report form provided by ██████████			
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 ██████████				G. All manufacturers			
				1. Contact office - name/address (& mailing 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. # IND, protocol #		5. (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) OVERDOSE STUPOR TACHYCARDIA NPN INCREASED LIVER FAILURE PANCREATITIS GASTRITIS DEATH	
				9. Mfr. report number 0929978A			
				E. Initial reporter			
				1. Name, address & phone # ██████████ ██████████ Centers Suite ██████████ Avenue ██████████			
				2. Health professional? (X) Yes () No		3. Occupation physician	
				4. Initial reporter also sent report to FDA () Yes () No (X) Unk			

RECEIVED
FEB 19 1998
EVALUATED



19-FEB-1998-0639



3032557-X-01

 FATALITY: 1996 

Case Number: 217

Age: 44 yrs

Substances: Acetaminophen
ethanol
ibuprofen

Chronicity: Chronic

Route: Ingestion

Reason: Ther error

Pre-Hospital Arrest? No

A 44-year-old male presented to the local Emergency Department (ED). On initial assessment he was unresponsive, normotensive, with a heart rate of 110 beats/min, a respiration rate of 30 breaths/min, and a temperature of 35C. His past medical history was significant for liver disease and alcohol abuse. He was apparently on a waiting list for liver transplantation. Reportedly, over the previous 3-4 weeks, he had been taking excessive amounts of acetaminophen and ibuprofen to control some unidentified pain. Initial laboratory studies were significant for ALT > 2000 U/L, alkaline phosphatase > 1000 U/L, total bilirubin 6 mg/dL, and serum ammonia 154 mcg/dL. A blood sample, drawn about 11.5 hours after arrival to the ED, showed an acetaminophen level of 42 mcg/mL. N-acetylcysteine was administered by nasal gastric tube. His condition progressively deteriorated. He died approximately 32 hours after arrival to hospital. Final diagnoses were acute on chronic hepatic failure associated with alcohol and acetaminophen toxicity, chronic pancreatitis, and gastritis.