



19-FEB-1998-0578



McNEIL CONSUMER PF
FORT WASHINGTON



3032402-2-00

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A. Patient information				C. Suspect medication(s)			
1. Patient identifier Case 15 In confidence	2. Age at time of event: or 49 yrs Date of birth:	3. Sex () female (X) male	4. Weight unk lbs or kgs	1. Name (give labeled strength & mfr/labeler, if known) #1 VICODIN® #2 ethanol			
B. Adverse event or product problem				2. Dose, frequency & route used #1 unknown dose, po #2 binge drinking, po		3. Therapy dates (if unknown, give duration) from/to (or best estimate) #1 unknown dates or duration #2 chronic	
1. X Adverse event and/or Product problem (e.g., defects/malfunctions)				4. Diagnose for use (indication) #1 dental pain #2 unknown		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) () congenital anomaly () life-threatening () required intervention to prevent permanent impairment/damage (X) hospitalization - initial or prolonged () other:				6. Let # (if known) #1 Unknown #2 unknown		7. Exp. date (if known) #1 Unknown #2 unknown	
3. Date of event 4/10/96 (mo/day/yr)		4. Date of this report 02/06/98 (mo/day/yr)		8. Event recurred after reintroduction #1 () Yes () No (X) N/A #2 () Yes () No (X) N/A		9. NDC # - for product problems only (if known)	
5. Describe event or problem Case # 15 received from the [redacted] 1996 case fatality data. See attached case report form provided by [redacted]				10. Concomitant medical products and therapy dates (exclude treatment of event) See attached case report form provided by [redacted]			
6. Relevant tests/laboratory data, including dates See attached case report form provided by [redacted]				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 [redacted]				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. If IND, protocol #		(A) NOA # 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 SEPSIS LIVER FAILURE KIDNEY FAILURE ENCEPHALOPATHY ACIDOSIS HEART ARREST DEATH	
				9. Mfr. report number 0929612A			
				E. Initial reporter			
				1. Name, address & phone # [redacted] MD [redacted] Centers Suite [redacted] Avenue [redacted]			
2. Health professional? (X) Yes () No		3. Occupation physician		4. Initial reporter also sent report to FDA () Yes () No (X) Unk			





19-FEB-1998-0579



3032402-2-01

[REDACTED] FATALITY: 1996 [REDACTED]

Case Number: 15

Age: 49 yrs

Substances: Ethanol
acetaminophen/hydrocodone

Chronicity: Chronic

Route: Ingestion

Reason: Int Unknown

Pre-Hospital Arrest? No

A 49 year old male with a history of alcoholism and hepatitis contributing to underlying liver damage presented to [REDACTED] in [REDACTED] at 1100 4/10/96. He had been prescribed Vicodin for dental pain within the 2 weeks prior to his arrival at the ER that day. The patient had been binge drinking. It is unknown whether he was taking the Vicodin in the manner prescribed. He presented with abdominal pain and hematemesis. Upon examination he was found to have esophagitis, duodenal ulcers, septicemia, liver and kidney failure. He quickly deteriorated and became hypotensive and encephalopathic. His acetaminophen level was 48mcg/ml and salicylate level was 7mcg/dl. His SGOT and SGPT were in the 10's of thousands IU/L, his PT was 33s and PTT was 63s, his pH was 7.25, he had an anionic gap of 40, creatinine of 6 mg/dl and WBC of 18,000 cmm. He was treated with fluids, bicarbonate, antibiotics and a loading dose of mucomyst. Treatment with alcohol for a possible ethylene glycol or methanol ingestion was considered but never initiated. Later labs indicated that ethylene glycol and methanol were not a factor. Dialysis was considered at another facility but the patient died of cardiac arrest at 2340 4/10/96. His death was consistent with end stage alcoholic liver disease complicated by the chronic ingestion of acetaminophen.