



19-FEB-1998-0654



McNEIL CONSUMER PR  
FORT WASHINGT

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\*3032575-1-00\*

A. Patient information				C. Suspect medication(s)			
1. Patient identifier Case 203 In confidence	2. Age at time of event: or Date of birth: 35 yrs	3. Sex ( ) female (X) male	4. Weight unk lbs or kgs	1. Name (give labeled strength & mfr/labeler, if known) #1 unknown TYLENOL acetaminophen product #2 TYLENOL #3			
B. Adverse event or product problem				2. Dose, frequency & route used		3. Therapy dates (if unknown, give duration) from/to (or best estimate)	
1. X Adverse event and/or Product problem (e.g., defects/malfunctions)				#1 unknown dose, po		#1 over a few days	
2. Outcomes attributed to adverse event (check all that apply)				#2 unknown dose, po		#2 over a few days	
(x) death (mo/day/yr) unknown				4. Diagnosis for use (indication)		5. Event abated after use stopped or dose reduced	
( ) life-threatening				#1 abdominal pain		#1 ( ) Yes ( ) No (X) N/A	
(x) hospitalization - initial or prolonged				#2 abdominal pain		#2 ( ) Yes ( ) No (X) N/A	
( ) other:				6. Lot # (if known)		7. Exp. date (if known)	
3. Date of event unknown (mo/day/yr)				#1 Unknown		#1 Unknown	
4. Date of this report 02/09/98 (mo/day/yr)				#2 unknown		#2 unknown	
5. Describe event or problem				9. NDC # - for product problems only (if known)			
Case # 203 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				G. All manufacturers			
See attached case report form provided by [redacted]				1. Contact office - name/address (& mfrng site for devices)		2. Phone number	
7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)				McNeil Consumer Products Company Medical Affairs 7050 Camp Hill Road Ft. Washington, PA 19034		215-233-7820	
See attached case report form provided by [redacted]				4. Date received by manufacturer (mo/day/yr) 01/30/98		3. Report source (check all that apply)	
8. Mfr. report #				5. (A) NDA # 17-552		( ) foreign	
7. Type of report (check all that apply)				IND #		( ) study	
( ) 5-day (X) 15-day				PLA #		(X) literature	
( ) 10-day ( ) periodic				pre-1938 ( ) Yes		( ) consumer	
(X) Initial ( ) follow-up #				OTC product (X) Yes		(x) health professional	
9. Mfr. report number				8. Adverse event term(s)		( ) user facility	
0929725A				OVERDOSE		( ) company representative	
E. Initial reporter				ENCEPHALOPATHY		( ) distributor	
1. Name, address & phone #				KIDNEY FAILURE		( ) other:	
[redacted] MD				HYPOTENSION		HEMORRHAGE GI	
[redacted] Centers				HYPO TENSION		LIVER FAILURE	
Suite [redacted] Avenue				HYPO TENSION		COAGULATION DIS	
[redacted]				HYPO TENSION		DEATH	
2. Health professional?		3. Occupation		4. Initial reporter also sent report to FDA			
(X) Yes ( ) No		physician		( ) Yes ( ) No (X) Unk			



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[REDACTED] FATALITY: 1996 [REDACTED]

Case Number: 203  
Age: 35rs  
Substances: Acetaminophen  
acetaminophen/codeine  
Chronicity: Chronic  
Route: Ingestion  
Reason: Ther error  
Pre-Hospital Arrest? No

A 35-year-old male with a history of alcohol abuse and pancreatitis had been taking tylenol and tylenol #3 over a few days for abdominal pain. He was admitted to the hospital for confusion and developed gastrointestinal bleeding, encephalopathy and hepatic and renal failure. He presented with an acetaminophen level of 83 ug/mL, SGPT of 7000 and a bilirubin of 5.2. His coagulopathy and gastrointestinal bleeding progressed with a falling blood pressure and hematocrit that initially responded to treatment with 7 litres of intravenous fluid, 6 units PRBC's and 4 units FFP. However, he continued to be unstable and was intubated. Intravenous N-acetylcysteine was also administered. The patient expired 2 days after admission.