

A. Patient information				C. Suspect medication(s)			
1. Patient identifier Case 195 In confidence	2. Age at time of event: 43 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 Extra Strength TYLENOL Tablets #2		3. Therapy dates (if unknown, give duration) from/to (or best estimate) #1 up to 2 days #2	
B. Adverse event or product problem				2. Dose, frequency & route used #1 perhaps 10 g, po #2		4. Diagnosis for use (indication) #1 unknown #2	
1. X Adverse event and/or Product problem (e.g., defects/malfunctions)				5. Event abated after use stopped or dose reduced #1 () Yes () No (X) N/A #2 () Yes () No () N/A		6. Lot # (if known) #1 Unknown #2	
2. Outcomes attributed to adverse event (check all that apply) (X) death (m/d/y) Unknown () life-threatening (X) hospitalization - initial or prolonged () other:				7. Exp. date (if known) #1 Unknown #2		8. Event reappeared after reintroduction #1 () Yes () No (X) N/A #2 () Yes () No () N/A	
3. Date of event unknown (m/d/y)		4. Date of this report 02/06/98 (m/d/y)		9. NDC # - for product problems only (if known)			
5. Describe event or problem Case # 195 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]			
G. All manufacturers							
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		3. Report source (check all that apply) () foreign () study (X) literature () consumer (X) health professional () user facility () company representative () distributor () other:	
4. Date received by manufacturer (m/d/y) 01/30/98				5. (A) NDA # 17-552 IND # PLA # pre-1938 () Yes OTC product (X) Yes		8. Adverse event term(s) OVERDOSE LIVER FAILURE RESPIRATORY DIS PROTHROMBIN INC THINKING ABNORM HEART ARREST DEATH	
6. If IND, protocol #				7. Type of report (check all that apply) () 5-day (X) 15-day () 10-day () periodic (X) Initial () follow-up #		9. Mfr. report number 0929671A	
6. Relevant tests/laboratory data, including dates See attached case report form provided by [redacted]				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]			
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-1998-0673



3031723-7-00

[REDACTED] FATALITY: 1996 [REDACTED]

Case Number: 195
Age: 43 yrs
Substances: Acetaminophen
Chronicity: Chronic
Route: Ingestion
Reason: Unknown
Pre-Hospital Arrest? No

History: This is a 43 year old alcoholic male who denies the use of any other drugs, he had been taking Extra Strength Tylenol for up to two days and took, perhaps, 20 tablets. A call to the poison center came from his doctor who stated that the patient was already in liver failure, had bilateral pulmonary infiltrates, but, was awake, alert and oriented. At that time his total bilirubin was 3.5, SGOT was 2,000, SGPT was 1,000, PT was 25. We suggested that despite the fact that he was already in significant hepatic failure, he be started on Mucomyst and plans be made to consider a hepatic transplant. He was in a hospital that does do hepatic transplants. The day after the call to the poison center he was found with decreasing mental status, suffered a cardiac arrest and expired before transplant could be conducted.