

# MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

**McNEIL**

McNEIL CONSUMER PRODUCTS FORT WASHINGTON Individual Safety Report

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Approved by FDA on 11/14/93

A. Patient information				C. Submission information(s)	
1. Patient Identifier unknown in confidence	2. Age at time of event: or 6 mo Date of birth:	3. Sex ( ) female ( ) male	4. Weight unk (lbs) or kgs	1. Name (give labeled strength & mfr/labeler, if known) #1 TYLENOL Analgesic Unknown #2	
B. Adverse event or product problem				2. Dose, frequency & route used	
1. X Adverse event and/or Product problem (e.g., defects/malfunctions)				#1 "very high doses", po #2	
2. Outcomes attributed to adverse event (check all that apply)				3. Therapy dates (if unknown, give duration) from/to (or best estimate)	
( ) death (mo./day/yr) unknown ( ) life-threatening ( ) hospitalization - initial or prolonged ( ) other:				#1 unknown #2	
3. Date of event (mo./day/yr) unknown				4. Date of this report (mo./day/yr) 09/16/98	
5. Describe event or problem				4. Diagnosis for use (indication)	
Physician report received via internet of DEATH in a 6 month old infant allegedly associated with one of our TYLENOL® acetaminophen products. According to reporting physician, infant was administered very high doses of Tylenol for a flu-like syndrome after parents reportedly misunderstood directions on the Tylenol bottle. Physician reports at the time of death, patient had been off the high doses of Tylenol for several days and an acetaminophen level was undetectable. Histology of the liver at autopsy revealed diffuse hepatocyte damage (LIVER DAMAGE), but not pathognomic for any disease. Infant's blood was tested & Hepatitis C antibody was positive. Coroner reportedly attributed cause of death to acute Hepatitis C infection (HEPATITIS) although it could not be proven with available data. Infant's mother had no elevation of transaminases & has non-detectable levels of Hepatitis C virus. According to reporting physician, mother was counseled that child did not die from Hepatitis C, but rather the flu-like illness and high doses of Tylenol.				#1 flu-like syndrome #2	
				5. Event abated after use stopped or dose reduced #1 ( ) Yes ( ) No (X) N/A #2 ( ) Yes ( ) No ( ) N/A	
6. Relevant tests/laboratory data, including dates				6. Lot # (if known)	
Hepatitis C antibody (+); histology of liver at autopsy revealed diffuse hepatocyte damage, not pathognomic; acetaminophen level was nondetectable several days after being off the "high" doses of Tylenol				#1 Unknown #2	
7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)				7. Exp. date (if known)	
unknown				#1 Unknown #2	
				8. Event reappeared after reintroduction #1 ( ) Yes ( ) No (X) N/A #2 ( ) Yes ( ) No ( ) N/A	
				9. NDC # - for product problems only (if known)	
				10. Concomitant medical products and therapy dates (exclude treatment of event) unknown	
G. All manufacturers					
1. Contact office - name/address (& mfring site for devices)				2. Phone number	
McNeil Consumer Products Company Medical Affairs 7050 Camp Hill Road Ft. Washington, PA 19034				215-233-7820	
4. Date received by manufacturer (mo./day/yr) 09/15/98				3. Report source (check all that apply)	
5. (A) NDA # 19-872				( ) foreign ( ) study ( ) literature ( ) consumer  (X) health professional ( ) user facility  ( ) company representative ( ) distributor ( ) other:	
6. Mfr. IND, protocol #				IND # PLA # pre-1938 ( ) Yes OTC product (X) Yes	
7. Type of report (check all that apply)				8. Adverse event term(s)	
( ) 5-day (X) 15-day ( ) 10-day ( ) periodic (X) initial ( ) follow-up #				DEATH HEPATITIS LIVER DAMAGE	
9. Mfr. report number				1035634A	
E. Initial reporter					
1. Name, address & phone #					
[REDACTED] DO [REDACTED] [REDACTED] [REDACTED]					
2. Health professional? (X) Yes ( ) No					
3. Occupation physician					
4. Initial reporter also sent report to FDA ( ) Yes ( ) No (X) Unk					