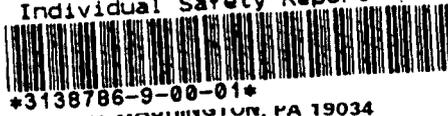


# MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Individual Safety Report



\*3138786-9-00-01\*  
WASHINGTON, PA 19034

Approved by FDA on 11/16/93

Page \_\_\_\_ of \_\_\_\_

FDA use only

A. Patient information				C. Suspect medication(s)			
1. Patient Identifier [Redacted]	2. Age at time of event: 53 yrs or Date of birth: [Redacted]	3. Sex (X) female  ( ) male	4. Weight Unk lbs or kgs	1. Name (give labeled strength & mfr/labeler, if known)			
In confidence				#1 Regular Strength Tylenol		#2	
B. Adverse event or product problem				2. Dose, frequency & route used		3. Therapy dates (if unknown, give duration) from/to (or best estimate)	
				#1 975 mg, Q4H		#1 1/24/95; 1 day	
1. X Adverse event and/or Product problem (e.g., defects/malfunctions)				4. Diagnosis for use (indication)		5. Event abated after use stopped or dose reduced	
2. Outcomes attributed to adverse event (check all that apply)				#1 flu like symptoms		#1 (X) Yes ( ) No ( ) N/A	
( ) death (mo/day/yr)				#2		#2 ( ) Yes ( ) No ( ) N/A	
( ) life-threatening				6. Lot # (if known)		7. Exp. date (if known)	
(X) hospitalization - initial or prolonged				#1 Unknown		#1 Unknown	
( ) other: recovered				#2		#2	
3. Date of event (mo/day/yr)		4. Date of this report (mo/day/yr)		8. Event reappeared after reintroduction			
1/28/95		09/23/98		#1 ( ) Yes ( ) No (X) N/A			
5. Describe event or problem				9. NDC # for product problems only (if known)			
Consumer's written report alleges that the use of one of our TYLENOL® acetaminophen products was associated with HEPATITIS (hepatitis C). According to consumer, she took an unspecified quantity of TYLENOL for the flu and has had hepatitis C for 3 years now.				10. Concomitant medical products and therapy dates (exclude treatment of event)			
Additional written information received on 9/23/98: Consumer indicates she experienced acute fulminant LIVER FAILURE with jaundice secondary to acute hepatitis. According to consumer, injury was secondary to Tylenol ingestion on setting of (unknown at time) chronic hepatitis C. She took three Regular Strength Tylenol every 4 hours on 1/24/95 for flu like symptoms. She was admitted to hospital (1/28/95), transferred to 2nd hospital (2/2/95) & discharged (2/7/95). Patient stopped taking the product and symptoms slowly subsided over months. Patient is now on interferon for chronic hepatitis C and "doing wonderfully". No further information was provided.				Interferon			
6. Relevant tests/laboratory data, including dates				G. All manufacturers			
Unknown				1. Contact office - name/address (& mfring 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		215-233-7820	
Chronic hepatitis C secondary to blood transfusion 20+ years ago				Medical Affairs		3. Report source (check all that apply)	
				7050 Camp Hill Road		( ) foreign	
				Ft. Washington, PA 19034		( ) study	
				4. Date received by manufacturer (mo/day/yr)		( ) literature	
				09/23/98		(X) consumer	
				5. (A) NDA # 19-872		( ) health professional	
				IND #		( ) user facility	
				6. If IND, protocol #		( ) company representative	
				7. Type of report (check all that apply)		( ) distributor	
				( ) 5-day (X) 15-day		( ) other:	
				( ) 10-day ( ) periodic			
				( ) Initial (X) follow-up # 1		8. Adverse event term(s)	
				9. Mfr. report number		LIVER FAILURE	
				1025000A			
				E. Initial reporter			
				1. Name, address & phone #			
				[Redacted]			
2. Health professional?		3. Occupation		4. Initial reporter also sent report to FDA			
( ) Yes ( ) No				( ) Yes ( ) No ( ) Unk			

OCT 17 1998



Facsimile Form 3500A

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.