

# MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM



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Approved by FDA on 11/16/93

FDA use only

A. Patient information				C. Suspect medication(s)			
1. Patient identifier  In confidence	2. Age at time of event: 37 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 Regular Strength <b>TYLENOL</b> Product #2 <b>TEGRETOL</b> ® Tablet 200 mg			
B. Adverse event or product problem				2. Dose, frequency & route used #1 1300 mg/daily, po #2 200 mg, bid, po		3. Therapy dates (if unknown, give duration from/to (or best estimate)) #1 5/22/98-?; unknown duration #2 5/13/98-?; unknown duration	
				4. Diagnosis for use (indication) #1 unknown #2 mood swings		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) ( ) death (mo/day/yr) ( ) life-threatening (X) hospitalization - initial or prolonged ( ) disability ( ) congenital anomaly ( ) required intervention to prevent permanent impairment/damage ( ) other:				6. Lot # (if known) #1 Unknown #2 unknown		7. Exp. date (if known) #1 Unknown #2 unknown	
3. Date of event 9/2/98 (mo/day/yr)		4. Date of this report 09/24/98 (mo/day/yr)		8. Event reappeared after reintroduction #1 ( ) Yes ( ) No (X) N/A #2 ( ) Yes ( ) No (X) N/A			
5. Describe event or problem  Physician report rec'd via manufacturer (Mfr report # 98USA11354) of HEPATITIS, JAUNDICE, and LIVER FUNCTION TESTS ABNORMAL (elevated liver enzymes) allegedly associated with one of our <b>TYLENOL</b> ® acetaminophen products, <b>TEGRETOL</b> ®, alcohol and <b>SEROQUEL</b> ®. Physician reports patient began <b>TEGRETOL</b> on 5/13/98 for mood swings. According to physician, baseline liver enzymes were normal. On 5/22/98, <b>TYLENOL</b> mg q6h was added to the drug regimen, which also included <b>SEROQUEL</b> ®. During the first week of September, patient was reportedly transferred from one hospital to another to be monitored for hepatitis. Lab results at that time revealed patient's ALT=3200, AST=1800, alk phos=215 and GGT=400. Enzyme levels reportedly began to decrease without discontinuing medication. Patient has no history of alcohol abuse but was at a picnic prior to the incident. No further information was provided.				9. NDC # - for product problems only (if known) - - -			
6. Relevant tests/laboratory data, including dates 9/7/98: SGPT (ALT)=3200; SGOT (AST)=1800; alkaline phosphatase=215; GGT=400				10. Concomitant medical products and therapy dates (exclude treatment of event) Sect C#3 alcohol; C#4 <b>SEROQUEL</b> ®, unknown dose, unknown duration (5/22/98-?)			
7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) no history of alcohol abuse				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	
				4. Date received by manufacturer (mo/day/yr) 09/22/98		3. Report source (check all that apply) ( ) foreign ( ) study ( ) literature ( ) consumer  (X) health professional ( ) user facility  ( ) company representative ( ) distributor (X) other: manuf.	
				6. If IND, protocol #		5. (A) NDA # 19-872 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) HEPATITIS JAUNDICE LIVER FUNC ABNO	
				9. Mfr. report number 1040634A			
				E. Initial reporter			
				1. Name, address & phone # [REDACTED] MD [REDACTED] Dr. [REDACTED]			
2. Health professional? (X) Yes ( ) No		3. Occupation health prof		4. Initial reporter also sent report to FDA ( ) Yes ( ) No (X) Unk			

JUL 17 1998

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## Individual Safety Report



\*3138786-9-00-01\*

Approved by FDA on 11/16/93

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FDA use only

### A. Patient information

1. Patient Identifier  In confidence	2. Age at time of event: 53 yrs or Date of birth: _____	3. Sex (X) female  ( ) male	4. Weight Unk lbs or kgs
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### C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)	
#1 Regular Strength Tylenol	#2
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
#2	#2
4. Diagnosis for use (indication)	5. Event abated after use stopped or dose reduced
#1 flu like symptoms	#1 (X) Yes ( ) No ( ) N/A
#2	#2 ( ) Yes ( ) No ( ) N/A
6. Lot # (if known)	7. Exp. date (if known)
#1 Unknown	#1 Unknown
#2	#2
9. NDC # for product problems only (if known)	8. Event reappeared after reintroduction
	#1 ( ) Yes ( ) No (X) N/A
	#2 ( ) Yes ( ) No ( ) N/A
10. Concomitant medical products and therapy dates (exclude treatment of event)	
Interferon	

### B. Adverse event or product problem

1. X Adverse event and/or	Product problem (e.g., defects/malfunctions)
2. Outcomes attributed to adverse event (check all that apply)	
( ) death (mo/day/yr)	( ) disability
( ) life-threatening	( ) congenital anomaly
(X) hospitalization - initial or prolonged	( ) required intervention to prevent permanent impairment/damage
	(X) other: recovered
3. Date of event (mo/day/yr)	4. Date of this report (mo/day/yr)
1/28/95	09/23/98

5. Describe event or problem

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.

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.

6. Relevant tests/laboratory data, including dates
Unknown
7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)
Chronic hepatitis C secondary to blood transfusion 20+ years ago

### 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)	3. Report source (check all that apply)
09/23/98	( ) foreign ( ) study ( ) literature (X) consumer  ( ) health professional ( ) user facility  ( ) company representative ( ) distributor ( ) other:
6. If IND, protocol #	5. (A) NDA # 19-872 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 ( ) Initial (X) follow-up # 1	LIVER FAILURE
9. Mfr. report number	
1025000A	

### E. Initial reporter

1. Name, address & phone #			
OCT 17 1998			
2. Health professional?	3. Occupation	4. Initial reporter also sent report to FDA	
( ) Yes ( ) No		( ) Yes ( ) No ( ) Unk	



Facsimile Form 3600A

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