



3243258-7-00-01

**MEDWATCH**

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM



McNeil Consumer Healthcare  
Fort Washington, PA 19034-2299

Page 1 of 1

Mfr report #
UF/Dist report #
FDA use only

**A. Patient information**

1. Patient identifier In confidence	2. Age at time of event: or 20 yrs Date of birth:	3. Sex (X) female ( ) male	4. Weight unk lbs or kgs
--	---	----------------------------------	-----------------------------------

**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
( ) other:	
3. Date of event (mo/day/yr) unknown	4. Date of this report (mo/day/yr) 04/09/99

5. Describe event or problem

Consumer report received via Internet alleges that the use of an unspecified **TYLENOL** acetaminophen product was associated with **LIVER FAILURE**. According to consumer's Internet report, she recently had a head cold/sinus infection and took **TYLENOL** for 10-12 days. She reportedly was admitted to the ICU of a hospital for liver failure. No further information was provided.



6. Relevant tests/laboratory data, including dates unknown	<div style="border: 1px solid black; padding: 5px; text-align: center;"> <p><b>RECEIVED</b></p> <p>APR 20 1999</p> <p>BY: _____</p> </div>
---	--

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) reports never having any other health issues; consumer's Internet report indicates she was eating and drinking fluids less than normal for an unspecified period of time

**C. Suspect medication(s)**

1. Name (give labeled strength & mfr/labeler, if known)	
#1 <b>TYLENOL Analgesic Unknown</b>	
#2	
2. Dose, frequency & route used	3. Therapy dates (if unknown, give duration) from/to (or best estimate)
#1 unknown dose, po	#1 unknown dates; 10-12 days
#2	#2
4. Diagnosis for use (indication)	
#1 head cold/sinus infection	
#2	
5. Event abated after use stopped or dose reduced	
#1 ( ) Yes ( ) No (X) N/A	
#2 ( ) Yes ( ) No ( ) N/A	
6. Lot # (if known)	7. Exp. date (if known)
#1 unknown	#1 unknown
#2	#2
8. Event appeared 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) one unspecified medication	

**G. All manufacturers**

1. Contact office - name/address (& mfring site for devices)	2. Phone number
McNeil Consumer Healthcare Medical Affairs 7050 Camp Hill Road Ft. Washington, PA 19034	215-273-7820
4. Date received by manufacturer (mo/day/yr) 04/08/99	3. Report source (check all that apply)
5. (A) NDA # 19-872	( ) foreign
6. If IND, protocol #	( ) study
IND #	( ) literature
PLA #	(X) consumer
pre-1938 ( ) Yes	health professional
OTC product (X) Yes	( ) user facility
7. Type of report (check all that apply)	( ) company representative
( ) 5-day (X) 15-day	( ) distributor
( ) 10-day ( ) periodic	(X) other:
(X) Initial ( ) follow-up #	Internet
8. Adverse event term(s)	
LIVER FAILURE	
9. Mfr. report number	
1156108A	

**E. Initial reporter**

1. Name, address & phone #	
<p><b>DSS</b></p> <p>APR 21 1999</p> <p>ADVERSE EVENT REPORTING SYSTEM</p>	
2. Health professional?	3. Initial reporter also reported to FDA
( ) Yes ( ) No	( ) Yes ( ) No ( ) Unk