



Mfr report #
UF/Dist report #
FDA use only

**A. Patient information**

1. Patient identifier	2. Age at time of event: or 39 yrs Date of birth: 03/08/1960	3. Sex (X) female ( ) male	4. Weight lbs or 67 kgs
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**B. Adverse event or product problem**

1. X Adverse event and/or Product problem (e.g., defects/maifunctions)	
2. Outcomes attributed to adverse event (check all that apply)	
(X) death 4/15/99	( ) 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) 4/10/99	4. Date of this report (mo/day/yr) 01/16/01

5. Describe event or problem

Notification received via attorney of DEATH allegedly associated w/use of unspecified TYLENOL® acetaminophen products in his client. Addl info rec'd 1/8/01: Med records indicate that on 4/9/99, pt presented to MD w/hx of 24-48 hrs of fatigue, anorexia, nausea, epigastric pain & fullness & dark urine. On 4/10/99, pt went to ER w/worsening sx's. Pt used TYLENOL & TYLENOL® PM for sinus congestion, 1 wk PTA. Pt reported taking APAP daily-usually 2 tabs 3-4x/d, sometimes more if she developed migraine. Pt had hx of alcohol abuse. On adm, pt slightly icteric, awake but lethargic & intermittently confused w/asterixis. APAP level was less than 2 & ETOH was undetectable. Pt found to have acute LIVER FAILURE, ACUTE KIDNEY FAILURE, gap metabolic ACIDOSIS, COAGULATION DISORDER, HYPOGLYCEMIA, & HYPOKALEMIA. Pt transferred to ICU & then to 2nd hosp on 4/10 for tx consideration. Pt agitated over night. On 4/11, MUCOMYST started. Pt's MS declined & pt intubated, paralyzed, & sedated. On 4/13, path report liver bx: massive LIVER NECROSIS. Findings (See Sect B7)

6. Relevant tests/laboratory data, including dates

4/10/99:AST=6941,ALT=6493,AP=187,GGT=214,amylase=324,Lipase=2420,NH3=117,lactate=7.7,RBC=1.91,Hgb=6.7,Hct=21.7,PT=73.9,INR=7,PTT=50,fibrinogen=96,plts=27,Cl=89,K=2.5,CO2=8,glu=26,Cr=3.1,Tbili=6.7,Dbili=5.3,pH=7.16, APAP less than 2,ETOH=ND

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

migraine, claudication;weekend ETOH intake since 18 yrs ago indicate various etoh hxs, including "a few beers & 1/4-1/2 of a large bottle qd", "several beers/d wine 1 bottle/d" (Sect B5 cont): c/w APAP toxicity. No evidence for acute or chronic alcoholic liver dx. On 4/14, CT showed CEREBRAL EDEMA w/herniation.Pt w/SEPSIS. On 4/15, pt (See Sect C10)

**C. Suspect medication(s)**

1. Name (give labeled strength & mfr/labeler, if known)	
#1 unspecified TYLENOL acetaminophen product	
#2 unspecified TYLENOL PM product (See Sect C10)	
2. Dose, frequency & route used	3. Therapy dates (if unknown, give duration) from/to (or best estimate)
#1 2 tablets, tid-qid, po	#1 #1 week prior to admission"
#2 unknown dose, po	#2 #1 week prior to admission"
4. Diagnosis for use (indication)	
#1 sinus congestion	
#2 sinus congestion	
5. Event abated after use stopped or dose reduced	#1 ( ) Yes ( ) No (X) N/A
6. Lot # (if known)	7. Exp. date (if known)
#1 unknown	#1 unknown
#2 unknown	#2 unknown
8. Event reappeared after reintroduction	
#1 ( ) Yes ( ) No (X) N/A	
#2 ( ) Yes ( ) No (X) N/A	
9. NDC # - for product problems only (if known)	
10. Concomitant medical products and therapy dates (exclude treatment of event) TRIPHASIL®, St. John's Wort, "not every day" (Sect C1 cont) #3 a bottle of wine and several beers daily (Sect B7 cont) had a grim prognosis secondary to fulminant hepatic failure & multi-organ system failure.Pt disconnected from ventilator	

**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	215-273-7303
4. Date received by manufacturer (mo/day/yr) 01/08/01	3. Report source (check all that apply)
6. If IND, protocol #	( ) foreign ( ) study ( ) literature (X) consumer  ( ) health professional ( ) user facility  ( ) company representative ( ) distributor ( ) other:
7. Type of report (check all that apply)	(A) NDA # 19-872 IND # PLA # pre-1938 ( ) Yes  OTC product (X) Yes
8. Adverse event term(s)	DEATH LIVER FAILURE KIDNEY FAIL ACU ACIDOSIS COAGULATION DIS NECROSIS LIVER EDEMA BRAIN SEPSIS
5. ( ) 5-day (X) 15-day ( ) 10-day ( ) periodic ( ) Initial (X) follow-up # 1	
9. Mfr. report number	
1477459A	

**E. Initial reporter**

1. Name, address & phone #		
[Redacted]		
JAN 24 2001		
2. Health professional?	3. Occupation	4. Initial reporter also sent report to FDA
( ) Yes (X) No	attorney	( ) Yes ( ) No (X) Unk
JAN 09 2001		