



3282564-7-00-01

McNeil
 Consumer Healthcare
 McNeil Consumer Healthcare
 Fort Washington, PA 19034-2299

Approved by FDA on 11/15/93

Mfr report #
UF/Dist report #
FDA use only

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page ____ of ____

A. Patient information

1. Patient identifier	2. Age at time of event: 16 yrs or Date of birth:	3. Sex (X) female () male	4. Weight unk lbs or kgs
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B. Adverse event or product problem

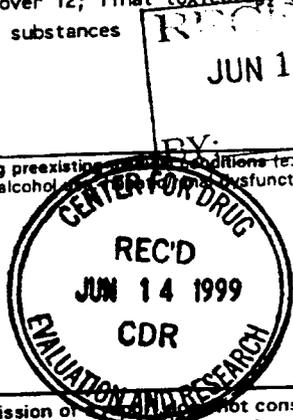
1. X Adverse event and/or Product problem (e.g., defects/malfunctions)	2. Outcomes attributed to adverse event (check all that apply)
3. Date of event 4/19/99 (mo/day/yr)	4. Date of this report 06/04/99 (mo/day/yr)

5. Describe event or problem

Pharmacist report of DEATH in a 16 year old female allegedly associated with the use of an unknown TYLENOL® acetaminophen product. Addl info rec'd 4/29/99: Physician reports pt used an unknown TYLENOL product in combination w/NYQUIL® chronically at least 3-4 days PTA. Physician reports contacting toxicologist to estimate dose of TYLENOL based on acetaminophen level but was unsuccessful obtaining estimated dose. According to physician, on 4/19/99, pt presented to ER with ABDOMINAL PAIN. Later in the day, pt became combative (HOSTILITY), was in & out of consciousness (DELIRIUM) & developed ENCEPHALOPATHY. Pt was treated w/one dose of MUCOMYST® before being transferred to 2nd hospital to await liver transplant. Physician reported that she was unaware if pt rec'd addl doses of MUCOMYST. Pt reportedly died of LIVER FAILURE but physician could not provide autopsy results or the date of death. Addl info rec'd 6/2/99: Physician edited initial MedWatch report. MD changed CoSTART term from SYNCOPE to DELIRIUM to describe loss of consciousness.

6. Relevant tests/laboratory data, including dates
4/19/99 9:30 a.m. acetaminophen level= 52; gall bladder ultrasound (-); identified right upper quadrant pain; Glasgow coma scale never over 12; final toxicology labs: urine (-) for all illicit substances

7. Other relevant history, including preexisting conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, renal/hepatic dysfunction, etc.)
 no known conditions



C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)	2. Dose, frequency & route used	3. Therapy dates (if unknown, give duration from/to (or best estimate)
#1 TYLENOL Analgesic Unknown	#1 unknown dose, po	#1 at least 3-4 days
#2 NyQuil®	#2 unknown dose, po	#2 at least 3-4 days
4. Diagnosis for use (indication)	5. Event abated after use stopped or dose reduced	
#1 pain relief	#1 () Yes () No (X) N/A	
#2 sleep	#2 () Yes () No (X) N/A	
6. Lot # (if known)	7. Exp. date (if known)	8. Event reappeared after reintroduction
#1 unknown	#1 unknown	#1 () Yes () No (X) N/A
#2 unknown	#2 unknown	#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) none	

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)	3. Report source (check all that apply)
06/02/99	() foreign () study () literature () consumer (X) health professional () user facility () company representative () distributor () other:
5. (A) NDA #	6. If IND, protocol #
19-872	
IND #	7. Type of report (check all that apply)
PLA #	() 5-day (X) 15-day () 10-day () periodic () Initial (X) follow-up # 1
pre-1938 () Yes	8. Adverse event term(s)
OTC product (X) Yes	DEATH PAIN ABDOMINAL HOSTILITY DELIRIUM ENCEPHALOPATHY LIVER FAILURE
9. Mfr. report number	
1166476A	

E. Initial reporter

1. Name, address & phone #	DSS JUN 15 1999	
MD Medical Center Avenue		
2. Health professional?	3. Occupation	ADVERSE EVENT REPORTING SYSTEM sent report to FDA
(X) Yes () No	physician	() Yes () No (X) Unk