Individual Safety Report

165504-0-00-01*

For VOLUNTARY reporting
ealth professionals of adverse
ents and product problems

Page ___ of ___ CDER CDER

Form Approved: OMB No. 0910-0291 Expires:12/31/94
See OMB statement on reverse

FDA Use Only

Triage unit sequence # 93566

Patient information

1. Patient identifier: [redacted] in confidence
2. Age at time of event: 23 YEARS or Date of birth: 11/08/71
3. Sex: ☐ female ☒ male
4. Weight: 170 lbs or ___ kgs

B. Adverse event or product problem

1. ☒ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)
2. Outcomes attributed to adverse event (check all that apply)
   - ☒ death 04/24/95 (mo/day/yr)
   - ☐ life-threatening
   - ☐ hospitalization – initial or prolonged
   - ☐ disability
   - ☐ congenital anomaly
   - ☐ required intervention to prevent permanent impairment/damage
   - ☐ other:
3. Date of event (mo/day/yr): 04/15/95
4. Date of this report (mo/day/yr): 11/24/98
5. Describe event or problem: YOUNG, HEALTHY MALE TOOK TYLENOL III, AS PRESCRIBED, FOR WRIST PAIN (10 DAYS) A FEW DAYS AFTER PRESCRIPTION WAS EXHAUSTED, HE PURCHASED TYLENOL TABLETS (OTC), INGESTING less than ONE "VIAL" WITHIN 3 DAYS OF PURCHASE. APPROX. 4 DAYS LATER, HE ADMITTED HIMSELF TO LOCAL HOSPITAL ER, WITH "FLU-LIKE" SIGNS/SYMPTOMS. PATIENT BECAME COMATOSE @ 48HRS AFTER ADMISSION - REMAINED IN COMA UNTIL DEATH.
6. Relevant tests/laboratory data, including dates: 04/17/95 ACETAMINOPHEN NOMOGRAM 27 BY HOSPITAL TESTING. PATIENT ALSO GIVEN 1 gm TYLENOL BY ER. PERSONNEL: 06/-/95 AUTOPSY REPORTED CAUSE OF DEATH AS "ACETAMINOPHEN POISONING."
7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.): PATIENT HAD NO KNOWN PRE-EXISTING MEDICAL HISTORY.

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
   - #1 TYLENOL III
   - #2 TYLENOL OTC TABLETS
2. Dose, frequency & route used
   - #1 AS DIRECTED
   - #2 AS DIRECTED
3. Therapy dates (if unknown, give duration) from/to (or best estimate)
   - #1 03/31/95
   - #2 04/10/95
4. Diagnosis for use (indication)
   - #1 WRIST PAIN
   - #2
5. Event abated after use stopped or dose reduced
   - #1 ☐ yes ☒ no ☐ doesn't apply
   - #2 ☐ yes ☒ no ☐ doesn't apply
6. Lot # (if known)
   - #1
   - #2
7. Exp. date (if known)
   - #1
   - #2
8. Event reappeared after reintroduction
   - #1 ☐ yes ☐ no ☒ doesn't apply
   - #2 ☐ yes ☐ no ☒ doesn't apply
9. NDC # (for product problems only) – –
10. Concomitant medical products and therapy dates (exclude treatment of event): THERA-FLU - ONE PACKAGE USED @ 04/13/95

D. Suspect medical device

1. Brand name
2. Type of device
3. Manufacturer name & address
4. Operator of device: ☐ health professional ☐ lay user/patient ☐ other:
5. Expiration date (mo/day/yr)
6. model # / catalog # / serial # / lot # / other #
7. If implanted, give date (mo/day/yr)
8. If explanted, give date (mo/day/yr)
9. Device available for evaluation? (Do not send to FDA) ☐ yes ☐ no ☐ returned to manufacturer on ___ (mo/day/yr)
10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

[redacted]

2. Health professional? ☒ yes ☐ no
3. Occupation: PILOT / EMT
4. Also reported to: ☐ manufacturer ☐ user facility ☐ distributor
5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box. ☒

PLEASE TYPE USE BLACK INK

FDA

Mail to: MEDWATCH 5600 Fishers Lane Rockville, MD 20852-9787 or FAX to: 1-800-FDA-0178

CTU 93566

FDA Form 3500 (6/93)

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