RECEIVED AT DRUG SAFETY SURVEILLANCE
12-MAR-1998-1090

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ents and product prol

Individual Safety Report
3059170-2-00

E FDA MEDICAL PRODUCTS REPORTING PROGRAM (MEDWATCH) Page ___ of ___

A. Patient information

1. Patient identifier	2. Age at time of event: 64 or ___ Date of birth [redacted]	3. Sex ☒ female ☐ male	4. Weight 130 lbs or ___ kgs
n confidence			

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 11-8-97 (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) 11-8-97
4. Date of this report (mo/day/yr) 2-9-98

5. Describe event or problem
[redacted] WAS ADMITTED TO HOSP. ON 10-29-97. IT WAS DETERMINED THAT 1 KIDNEY WAS NOT FUCTIONING AND THE LIVER SEVERELY DAMAGED DUE TO TYLENOL POISONING. SHE DIED ON 11-8-97 AT 3:00 AM. *SHE HAD TAKEN TYLENOL FOR PAIN. SHE HAD NO IDEA IT COULD CAUSE PROBLEMS OR DEATH. SHE HAD BEEN TAKING 3 OR 4 TYLENOL A TIME FOR SOME WEEKS BEFORE HER HOSPITALIZATION. SHE THOUGHT TYLENOL WAS SAFE.

6. Relevant tests/laboratory data, including dates
10-29-97 TO 11-5-97 VARIOUS DIAGNOSTIC TEST TO FIND OUT WHY [redacted] WAS SICK. TEST DONE AT [redacted] HOSPITAL IN [redacted]

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)
[redacted] SMOKED UNTIL 8-97 WHEN SHE QUIT. SHE HAD HIGH BLOOD PRESSURE EMPHESEMA AND BIPOLAR DESORDER AND CRACKS.

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
#1 TYLENOL EXTRA STRENGTH
#2

2. Dose, frequency & route used
#1 ORAL DOSE 3-4 TABLETS A DAY
#2 OVER SEVERAL WEEKS

3. Therapy dates (if unknown, give duration) from/to (or best estimate)
#1
#2

4. Diagnosis for use (indication)
#1 GENERAL 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 UNKNOWN
#2

7. Exp. date (if known)
#1 UNKNOWN
#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)

D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address
78935

4. Operator of device
☐ health professional
☐ lay user/patient
☐ other:

5. Expiration date (mo/day/yr)

6.
model # REC'D.
catalog # MAR 12 1998
serial #
lot #
other # MEDWATCH

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)

1. Name, address & phone #
[redacted]

2. Health professional? ☐ yes ☒ no

3. Occupation ELECTRICIAN

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. ☐

FDA

Mail to: MEDWATCH
5600 Fishers Lane
Rockville, MD 20852-9787

or FAX to:
1-800-FDA-0178

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.