11/24/99 WED 14:20 FAX [redacted] 001

3409401-1-00-01

[redacted] DRUG INFORMATION for VOLUNTARY reporting by health professionals of adverse events and product problems

CDER

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CDER

FDA Use Only

Triage unit employee #: 113384

FAX to Min Chen

A. Patient information

1. Patient identifier: [redacted] In confidence
2. Age at time of event: 23 or Date of birth:
3. Sex: ☒ female ☐ male
4. Weight: ___ 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 10-29-99 (mo/da/yr)
   - ☐ life-threatening
   - ☒ hospitalization – initial or prolonged
   - ☐ disability
   - ☐ congenital anomaly
   - ☐ required intervention to prevent permanent impairment/damage
   - ☐ other:
3. Date of event (mo/da/yr): 10-22-99
4. Date of this report (mo/da/yr): 11-24-99
5. Describe event or problem

Pt took a hand ful of acetaminophen after an argument. She was taken to outside hospital but did not tell them she had taken APAP; therefore, she was not treated for APAP overdose. Pt was transferred to [redacted]. Pt had fulminant hepatic failure with encephalopathy, coagulopathy and subarachnoid hemorrhage.

10/25

6. Relevant tests/laboratory data, including dates

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

allergy - sulfa; WF

Pt was taking large doses of tylenol (unknown amount) to treat HA.

C. Suspect medication(s)

1. Name (give labeled strength & manufacturer, if known)
   #1 Tylenol
   #2
2. Dose, frequency & route used
   #1 "handful"
   #2
3. Therapy dates (if unknown, give duration)
   #1
   #2
4. Diagnosis for use (indication)
   #1
   #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)
   10/22 - -
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

DSS
NOV 29 1999
ADVERSE EVENT REPORTING SYSTEM

4. Operator of device
   ☐ health professional
   ☐ lay user/patient
   ☐ other:
5. Expiration date (mo/da/yr)
6. model #
   catalog #
   serial #
   lot #
   other # MEDWATCH CTU

REC'D.
NOV 29 1999

7. If implanted, give date (mo/da/yr)
8. If explanted, give date (mo/da/yr)
9. Device available for evaluation? (Do not send to FDA)
   ☐ yes ☐ no ☐ returned to manufacturer on ___ (mo/da/yr)
10. Concomitant medical products and therapy dates (exclude treatment of event)

[redacted] Pharm.D.

E. [redacted] back)

1. [redacted] Hospital
   Drug Resource Center, [redacted]
   [redacted] Street
   [redacted]
2. Health professional? ☒ yes ☐ no
3. Occupation: Pharmacist
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. ☐

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

or FAX to: 1-800-[redacted]-1178

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.

MEDWATCH
THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

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CTU 113384

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