3476445-3-00-01

CDER

VOLUNTARY reporting
ealth professionals of adverse
ents and product problems

Form Approved: OMB No. 0910-0291 Expires: 12/31/00
See OMB statement on reverse

FDA Use Only (AHFS)
Triage unit sequence #: 118882

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page ___ of ___ CDER

A. Patient information

1. Patient identifier: [redacted] In confidence
2. Age at time of event: 7 months or Date of birth:
3. Sex: ☑ female ☐ male
4. Weight: ___ lbs or 8.6 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 ___ (mm/dd/yyyy)
   ☒ life-threatening
   ☒ hospitalization – initial or prolonged
   ☐ disability
   ☐ congenital anomaly
   ☐ required intervention to prevent permanent impairment/damage
   ☐ other: ___
3. Date of event (mm/dd/yyyy): 2/28/2000
4. Date of this report (mm/dd/yyyy): 3/2/2000
5. Describe event or problem

Parents inadvertently gave 1½ tsp (7.5ml) of drops (100mg/ml) instead of 1½ dropperful. It is believed pt recieved 4 doses of this (parents not english-speaking) Pt went into Liver failure was in the intensive care unit.
Pt recovered over about a 1 week period and her enzymes are continuing to decrease.

DRUG MALADMINISTRATION (Include Narrative)

6. Relevant tests/laboratory data, including dates

AST on admission 2869 rose to a high of 9384 (3/1)
ALT on admission 1685 rose to a high of 5768 (3/1)
PT on admission 26.5 rose to a high of 30.0 (3/1)
PT has normalized
AST/ALT are slowly decreasing

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

DSS
MAR 16 2000

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
   #1 Tylenol® 80mg/0.8ml
   #2
2. Dose, frequency & route used
   #1 1½ tsp (7.5ml) q6° x 4
   #2
3. Therapy dates (if unknown, give duration) (mm/dd/yyyy or best estimate)
   #1 2/28/2000
   #2
4. Diagnosis for use (indication)
   #1 ? Fever
   #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)

D. Suspect medical device

1. Brand name
2. Type of device
3. Manufacturer name & address

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MEDWATCH CTU

4. Operator of device
   ☐ health professional
   ☐ lay user/patient
   ☐ other: ___
5. Expiration date (mm/dd/yyyy)
6. model # ___ catalog # ___ serial # ___ lot # ___ other #
7. If implanted, give date (mm/dd/yyyy)
8. If explanted, give date (mm/dd/yyyy)
9. Device available for evaluation? (Do not send to FDA)
   ☐ yes ☐ no ☐ returned to manufacturer on ___ (mm/dd/yyyy)
10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. Name, address & phone #: [redacted] PharmD [redacted] Ave [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. ☐

FDA

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

FDA Form 3500 (6/98)

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

CTU 118882