Individual Safety Report

3742123-6-00-01

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

MEDWATCH Form ■ UPDATES

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For VOLUNTARY reporting by health professionals of adverse events and product problems

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

FDA Use Only (AHFS)

Triage unit sequence # 145688

Page ___ of ___

A. Patient information

1. [redacted]
2. Age at time of event: 7 days or Date of birth: 12-25-13
3. Sex: [X] female [ ] male
4. Weight: ___ lbs or ___ kgs

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): [ ] death ___ (mm/day/yr) [ ] life-threatening [X] hospitalization – initial or prolonged [ ] disability [ ] congenital anomaly [ ] required intervention to prevent permanent impairment/damage [ ] other
3. Date of event (mm/day/yr): 11-11-00
4. Date of this report (mm/day/yr): [illegible]
5. Describe event or problem

[illegible]

6. Relevant tests/laboratory data, including dates

[illegible]

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

[illegible]

C. Suspect medication(s)

1. Name (give labeled strength & mfr labeler, if known): #1 [illegible] #2
2. Dose, frequency & route used: #1 [illegible] #2
3. Therapy dates (if unknown, give duration): #1 [illegible] #2
4. Diagnosis for use (indication): #1 [illegible] #2
5. Event abated after use stopped or dose reduced: #1 [ ] yes [X] 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 [X] 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): [illegible]

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 (mm/day/yr)
6. model # ___ catalog # ___ serial # ___ lot # ___ other # ___
7. If implanted, give date (mm/day/yr)
8. If explanted, give date (mm/day/yr)
9. Device available for evaluation? (Do not send to FDA) [ ] yes [ ] no [ ] returned to manufacturer on ___ (mm/day/yr)
10. Concomitant medical products and therapy dates (exclude treatment of event)

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E. Reporter (see confidentiality section on back)

1. Name, address & phone #: [redacted]
2. Health professional? [X] yes [ ] no
3. Occupation: [illegible]
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.

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AHFS DRUG INFORMATION 93 ■ CURRENT DEVELOPMENTS

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