MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

For VOLUNTARY reporting by health professionals of events and product pro

CDER

Page ___ of ___

Individual Safety Report

3144405-8-00-01

A. Patient information

1. Patient identifier: [redacted] in confidence
2. Age at time of event: 65 or Date of birth: [redacted]
3. Sex: [X] female [ ] male
4. Weight: 145 lbs or ___ kgs

B. Adverse event or product problem

1. [X] Adverse event and/or [X] Product problem (e.g., defects/malfunctions)
2. Outcomes attributed to adverse event (check all that apply)
   - [X] death 3-8-86 (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): 1983
4. Date of this report (mo/day/yr): 10-19-98
5. Describe event or problem

liver disease Related to excessive use of Tylenol. Physicians Refused to perscribe medications for pain, but said to take As many Tylenol as was necessary to control the pain - no limit to the number taken per dose, per day to control pain of osteo Arthritis

OCT 19 '98 9:54

6. Relevant tests/laboratory data, including dates

liver biopsy was conducted several time - Records should be available at Douglas General r Emory Hospitals

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

long history of arthritis, back, knee, wrist pain

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 16-20 daily
   #2
3. Therapy dates (if unknown, give duration) from/to (or best estimate)
   #1 3 yrs
   #2
4. Diagnosis for use (indication)
   #1 Arthritis
   #2
5. Event abated after use stopped or dose reduced
   #1 [ ] yes [ ] no [X] doesn't apply
   #2 [ ] yes [ ] no [ ] doesn't apply
6. Lot # (if known)
   #1 N/A
   #2
7. Exp. date (if known)
   #1 N/A
   #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) NA
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
4. Operator of device
   - [ ] health professional
   - [ ] lay user/patient
   - [ ] other:
5. Expiration date (mo/day/yr)
6. model # REC'D.
   catalog # OCT 19 1998
   serial #
   lot # MEDWATCH CTU
   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)

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

CTU 91260