



VOLUNTARY reporting health professionals of adverse events and product problems Internet Submission - Page 1

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Form Approved: OMB No. 0910-0291 Expires: 03/31/00 See OMB statement on reverse FDA Use Only Triage unit sequence # 122507

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

A. Patient information

1. Patient Identifier: 400345
In confidence

2. Age at time of event: 60 Years
or Date of birth: _____

3. Sex: female male

4. Weight: 195 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 (mm/dd/yyyy) disability congenital anomaly

life-threatening required intervention to prevent permanent impairment/damage

hospitalization - initial or prolonged other: _____

3. Date of event: 12/15/1999 (mm/dd/yyyy)

4. Date of this report: 05/15/2000 (mm/dd/yyyy)

5. Describe event or problem
Hepatitis "probably" secondary to high Tylenol use

6. Relevant tests/laboratory data, including dates
AlkPhos - 643 -12/18/1999-
Acetaminophen - <2 -12/15/1999- +

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

DSS MAY 17 2000

C. Suspect medication(s)

1. Name (Product Name) (Labeled Strength) (Mfr/Labeler)

#1 Acetaminophen / /

#2 / /

2. Dose/Frequency/Route used

#1 "a" / / lot# / /

#2 / /

3. Therapy dates (if unknown, give duration)

#1 From - To (or best estimate)

#2 - -

4. Diagnosis for use (separate indications with commas)

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

#1 #1

#2 #2

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

4. Operator of device

health professional lay user/patient other:

5. Expiration date (mm/dd/yyyy)

6. model # MAY 17 2000

7. If implanted, give date (mm/dd/yyyy)

8. If explanted, give date (mm/dd/yyyy)

9. Device available for evaluation? (Do not send device 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 phone #

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 FAX to: 1-800-FDA-0178

FDA Form 3500

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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