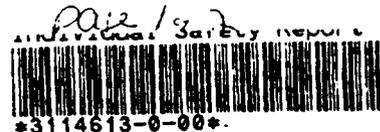




06-AUG-1998-0025

DEP



3114613-0-00

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

by VOLUNTARY
of health professionals of
events and product problems

1000002564

sequence # **87691**

A. Patient information

1. Patient Identifier: [redacted]
2. Age at time of event: [redacted]
or Date of birth: [redacted]
3. Sex: female male
4. Weight: [redacted] lbs or [redacted] 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): 05/20/1998
4. Date of this report (mm/dd/yyyy): 07/31/1998

5. Describe event or problem (up to a total of 6400 characters allowed)
 18 year old male patient admitted 05/20/1998 with acute acetaminophen toxicity presenting as fulminant liver failure. Patient took Tylenol 1000 mg PO q2h x10 doses in 24 hour period. See labs below. Treatment included acetylcysteine 5.8 G PO q4h x17 doses, vitamin K 10 mg SC QD, lactulose 20 G/30 mL PO q4h, & empiric antibiotic therapy. Patient considered for OLT and workup was completed; however, patient was discharged 05/23/1998 for followup in clinic. Patient lost to followup at our facility.

6. Relevant tests/laboratory data, including dates (a total of 1000 characters allowed)
 acetaminophen level 5/21: 9 mcg/mL; 5/22 9 mcg/mL-----SGPT 5/20: 11,100; 5/21: 7am 8,040 and 11pm 5,761-----SGOT 5/20: 9,182

7. Other relevant history, including preexisting medical conditions (up to a total of 500 characters allowed)
 NKDA: hypercholesterolemia/lipidemia; [redacted]

C. Suspect medication(s)

1. Name (Product Name) (Labeled Strength) (Mfr/Labeler)
 #1 Tylenol / 500 mg / OrthoMcNeil
 #2 _____

2. Dose/Frequency/Route used
 #1 1000 / q2h / Oral
 #2 _____

3. Therapy dates (if unknown, give duration)
 From To (or best estimate)
 #1 05/19/1998-05/20/1998
 #2 _____

4. Diagnosis for use (separate indications with commas)
 #1 unspecified
 #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 _____

8. Event reappeared after reintroduction
 #1 yes no doesn't apply
 #2 yes no doesn't apply

9. NDC # (for product problems only)
 #1 _____ #1 _____
 #2 _____ #2 _____

10. Concomitant medical products and therapy dates (up to a total of 1000 characters)
 Zocor NOS

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 # _____ MEDWATCH CTU
 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 device to FDA)
 yes no returned to manufacturer on (mm/dd/yyyy) _____

10. Concomitant medical products and therapy dates (up to a total of 1000 characters)

E. Reporter (see confidentiality section on back)

1. Name _____ phone # _____
 Address _____ E-mail (for electronic acknowledgment) _____

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-FDA-0178

FDA Form 3500 (WWW)

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

CTU 87691



06-AUG-1998-0013

1000002564

DER MEDWATCH

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87691

For VOLUNTARY reporting by health professionals of adverse events and product problems
Detail Reporter page - Page 2

E1. Reporter (detail information)

Last Name First Name Middle Initial

Title
Pharmacist

Organization Department

Medical Center Pharmacy

Mailing Address - Street name, number, PO Box, rural route, mail route code designator, etc.

City State Zip Code Country (if not USA)

Telephone Country Code Area Code Phone Number Extension

Fax Country Code Area Code Phone Number Extension

E-mail Address



3114613-0-00

Mail to: MEDWATCH or FAX to:
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Rockville, MD 20852-9787

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