



OLUNTARY reporting
lth professionals of adverse
its and product problems

Form Approved: OMB No. 0910-0291 Expires: 12/31/04
See OMB statement on reverse

FDA Use Only

Triage unit
sequence #

120334

Page 1 of 2

CDER

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

A. Patient information

1. Patient Identifier # confidence 54010	2. Age at time of event: or Date of birth: 5/27/53	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight 140 lbs or kgs
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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)

<input type="checkbox"/> death (mortality)	<input type="checkbox"/> disability
<input checked="" type="checkbox"/> life-threatening	<input checked="" type="checkbox"/> congenital anomaly
<input checked="" type="checkbox"/> hospitalization - initial or prolonged	<input checked="" type="checkbox"/> required intervention to prevent permanent impairment/damage
	<input type="checkbox"/> other:

3. Date of event (mortality): 12/1/99

4. Date of this report (mortality): 2/5/00

5. Describe event or problem

4610: ACETAMINOPHEN TOXICITY
46 YOF with Hep C, EtOH abuse adm 12/1 with nausea, dizziness, and coffee ground emesis X 3. Pt admitted to ingesting large amts of Acetaminophen and Ibuprofen for > 1 month for ankle pain. APAP level 42 and pt started on Acedylcysteine. Pt worsened throughout the day with dec MS, inc LFTs, inc Tbili. Lactulose started for hepatic encephalopathy. Pt progressed to liver failure and DIC. Pt expired 12/5.

6. Relevant tests/laboratory data, including dates

Date	ALT	AST	TBili	Alk Phos	GGT	INR
12/2	96	170	13.0	-	-	2.5
12/3	71	304	8.9	66	55	2.8
12/4	575	3855	17.3	89	106	3.1
12/5	372	1756	19.4	74	97	-

APAP 12/2 42, 36

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

~~Motrin, Goldenseal~~
Hepatitis C, jaundice, Alcohol Hepatitis, Chronic Liver disease, EtOH use

NKDA
STULLOBBY

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, # known)

#1 Acetaminophen

#2

2. Dose, frequency & route used

#1 2g, daily, po

#2

3. Therapy dates (if unknown, give duration) from/to (or best estimate)

#1 ~1 month

#2

4. Diagnosis for use (indication)

#1 ankle 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)

#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)

Motrin, Goldenseal

D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address

DSS
APR 11 2000

4. Operator of device

health professional
 lay user/patient
 other:

5. Expiration date (mortality)

6. model #

7. If implanted, give date (mortality)

8. If explanted, give date (mortality)

9. Device available for evaluation? (Do not send to FDA)

yes no returned to manufacturer on (mortality)

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 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