



VOLUNTARY reporting
health professionals of adverse
events and product problems

Form Approved: OMB No. 0910-0281 Expires: 12/31/04
See OMB statement on reverse

FDA Use Only
Triage unit sequence # **133626**

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

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CDER

A. Patient information

1. Patient Identifier 4913 <small>In confidence</small>	2. Age at time of event: or Date of birth: 12/9/71	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight ____ 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	<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 (month/day/yr) **6/17/00**

4. Date of this report (month/day/yr) **6/20/00**

5. Describe event or problem

28 YOM adm 6/17 for w/u of fulminant hepatic failure. On 6/15, pt adm to psych hospital after fight w/ neighbors. Adm for agitation/hallucinatory behavior, unclear if psych illness or drug abuse. On 6/16, SBP 50 and bx to OSH. Pt became obtunded w/ ARF. Pt adm to taking # 10-15 ES APAP(per Chart "2 bottles") on 6/14 for hangover. Pt EtOH abuse since age 15. Pt started on Acetylcysteine and bx here for tpt eval. Tbili = 8.2. Per MD, acute hepatitis on top of chronic liver disease second to inadvertant APAP OD. Tox screen + 6/17

C. Suspect medication(s)

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

#1 **Acetaminophen**

#2 _____

2. Dose, frequency & route used

#1 **10-15 tabs/24° PO**

#2 _____

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

#1 **6/14/00**

#2 _____

4. Diagnosis for use (indication)

#1 **hangover, muscle aches**

#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)

none

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 (month/day/yr)

6. model # _____

7. If implanted, give date (month/day/yr)

8. If explanted, give date (month/day/yr)

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

yes no returned to manufacturer on _____ (month/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 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.

CTU 133626

8. Relevant tests/laboratory data, including dates

	6/6	6/7	6/8	6/17 APAP = 23
AST 13797		1833		
ALT 6210				
GGT		252	210	
LDH		2280		
Tbili	8.2		2.7	
Dbili	6.6		3.7	
TP	5.7		4.8	
Albumin	2.3			

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

RN → hives

EtOH abuse since age 15

No DT's

Kidney stones

drug abuse (LSD, marijuana)



Mail to: MEDWATCH
5600 Fishers Lane
Rockville, MD 20852-6787

OR FAX to:
1-800-FDA-0178