

Individual Safety Report



3589394-7-00-01

OLUNTARY reporting
 lth professionals of adverse
 its and product problems

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

FDA Use Only H Pad
 Triage unit sequence # **130495**
DBFH FN

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page ___ of ___ **CDER CDER**

A. Patient information

1. Patient identifier 	2. Age at time of event: or Date of birth: 52 5/4/48	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight ___ lbs or 30 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)

<input checked="" type="checkbox"/> death 9/18/00 <small>(mo/day/yr)</small>	<input type="checkbox"/> disability
<input type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
	<input type="checkbox"/> other: _____

3. Date of event **9/14/00**
(mo/day/yr)

4. Date of this report **10/3/00**
(mo/day/yr)

5. Describe event or problem

Patient with alcoholic cirrhosis, malnutrition, emphysema, chronic pancreatitis and anemia admitted to hospital for rectal bleeding. Patient stated she had been taking "8 tylenol per day" for 2 weeks. Found to have APAP level of 157.6. Treated with acetylcysteine, level fell to 53.9 later that day. Pt expired 4 days later. Causes of death listed as ① sepsis ② hepatic failure ③ acetaminophen toxicity

6. Relevant tests/laboratory data, including dates

Acetaminophen level:	157.6	9/14	06:28
	53.9	9/14	21:15

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

see above

DSS
OCT 06 2000

CTV/130495

FDA Mail to: MEDWATCH 5600 Fishers Lane Rockville, MD 20852-9787 or FAX to: 1-800-FDA-0178

C. Suspect medication(s)

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

#1 **Acetaminophen - strength unknown**

#2 _____

2. Dose, frequency & route used

#1 **8 tabs/day**

#2 _____

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

#1 **9/1/00 - 9/14/00**

#2 _____

4. Diagnosis for use (indication)

#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)

#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)

#1 _____

#2 _____

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

RECEIVED
OCT 06 2000
MEDWATCH CTU

4. Operator of device

health professional
 lay user/patient
 other: _____

5. Expiration date (mo/day/yr)

6. Model #

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 #

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.