

Individual Safety Report



55605-7-00-01*

VOLUNTARY reporting
alth professionals of adverse
nts and product problems

CDER

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

FOIA Use Only

Trisge unit
sequence #

127719

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

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A. Patient information

1. Patient identifier [redacted] 4787 In confidence	2. Age at time of event: or Date of birth: [redacted]	3. Sex <input checked="" type="checkbox"/> female <input 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 (mortality)	<input type="checkbox"/> disability
<input checked="" type="checkbox"/> life-threatening	<input 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 (m/d/yyyy) 3/30/00

4. Date of this report (m/d/yyyy) 4/4/00

5. Describe event or problem

ae_id	adr_desc
4787	42 YOF transfer from [redacted] on 3/31 with acute liver failure. Since 3/18, pt related taking 2-3 Percocet and 2-3 beers/day secondary to depression over husband's death. This progressively inc to 6-8 Percocet day and 3-6 beers until 3/26. On 3/26, pt d/vlp N/V/Abd pain/malaise and went to [redacted] diag with acute liver failure. INR 9.3, Tbili 6.5 and APA level 16.3 on 3/30. Pt RX with Mucomyst and transferred. Pt awaiting liver transplant.

6. Relevant tests/laboratory data, including dates

3/30 APAP level = 16.3 pH = 7.19
 INR = 9.3
 AST = 8956
 ALT = 4764
 ALK Phos = 65
 Tbili = 6.5

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

NKDA
 MS dx'd 1993; bipolar disorder

CTU 127719

C. Suspect medication(s)

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

#1 Percocet

#2 _____

2. Dose, frequency & route used

#1 2-8/day PO

#2 _____

3. Therapy dates (if unknown, give duration) (m/d/yyyy)

#1 3/18 - 3/26/00

#2 _____

4. Diagnosis for use (indication)

#1 abuse

#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)

alcohol

D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address

DSS
AUG 23 2000

4. Operator of device

health professional
 lay user/patient
 other: _____

5. Expiration date (m/d/yyyy)

6. model #

7. If implanted, give date (m/d/yyyy)

8. If explanted, give date (m/d/yyyy)

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

yes no returned to manufacturer on _____ (m/d/yyyy)

10. Concomitant medical products and therapy dates (exclude treatment of event)

RECEIVED

AUG 23 2000

MEDWATCH CTU

E. Reporter (see confidentiality section on back)

1. Name, address & phone #

[redacted] PharmD
 [redacted]
 [redacted]
 [redacted]
 [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.



Mail to: MEDWATCH
 5600 Fishers Lane
 Rockville, MD 20852-9787

or FAX to:
 1-800-FDA-0178