



MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

✓ VOLUNTARY reporting by health professionals of adverse events and product problems

CDER

Internet Submission - Page 1

Form Approved: OMB No. 0910-0281 Expires: 8/31/00
311 OMB statement on reverse

FDA Use Only

Frage unit sequence #

125758
Filed to C. Krawski

A. Patient information

1. Patient identifier [REDACTED]	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 checked="" type="checkbox"/> death 06/27/2000 (mm/dd/yyyy)	<input type="checkbox"/> disability
<input type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input checked="" type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
	<input type="checkbox"/> other: _____

3. Date of event (mm/dd/yyyy) 06/25/2000

4. Date of this report (mm/dd/yyyy) 07/17/2000

5. Describe event or problem

Patient was found unresponsive at home and taken to [REDACTED] Hospital. Spouse reported that patient had taken 40 Vicodin over past 2 days. Patient was acidotic and hypotensive and had an acetaminophen level of 137. Patient also was found to be bleeding both from Foley catheter site, as well as from NG tube and endotracheal tube site. Therapy with Mucomyst was initiated. Patient was transferred to Univ. of [REDACTED] Hospital and admitted to Critical Care Medical Unit for further management. Later determined that support would be replaced by comfort care. Patient died at 1:20 p.m. on 6/27/2000 due to irreparable hepatic and multi-organ failure related to overdose of Tylenol and Vicodin.

6. Relevant tests/laboratory data, including dates

6/25/2000 - [REDACTED]: Acetaminophen level 137, AST >9000, ALT > 4000, Glucose < 20, positive opiate screen.

6/26/2000 - [REDACTED]: Acetaminophen 114, AST > 7000, ALT > 3000, INR 2.1, PT 21.5, PTT 43.0

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

African American. No tobacco or alcohol use. Positive opiate use for past 3 years.

C. Suspect medication(s)

1. Name (Product Name) (Labeled Strength) (Mfr/Labeler)
#1 Tylenol / unknown / McNeil Consumer Healthcare
#2 / / /
2. Dose/Frequency/Route used
#1 unkno / /
#2 / / /
3. Therapy dates (if unknown, give duration)
#1 From 06/22/2000 To (or best estimate) 06/25/2000
#2 -
4. Diagnosis for use (separate indications with commas)
#1 chronic abdominal pain
#2
5. Event abated after use stopped or dose reduced
#1 <input type="checkbox"/> yes <input checked="" type="checkbox"/> no <input type="checkbox"/> doesn't apply
#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply
6. Lot # (if known)
#1
#2
7. Exp. date (if known)
#1
#2
8. Event reappeared after rein. / junction
#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply
#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply
9. NDC # (for product problems only)
-
10. Concomitant medical products and therapy dates (exclude treatment of event)
Vicodin -6/22/2000 - 6/25/2000-

D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer's address

DSS

JUL 18 2000 RECEIVED

4. Operator of device

health professional
 lay user/patient
 other: _____

5. Expiration date (mm/dd/yyyy)

6. Model # JUL 17 2000

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 (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. Name [REDACTED] phone # [REDACTED]

[REDACTED] Drive [REDACTED] Box [REDACTED]

[REDACTED]

United States

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 REPORTING PROGRAM
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Rockville, MD 20852-9787 1-800-FDA-0178

CTV125758