



MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Endo Pharmaceuticals Inc.

FDA Form 1085 (Rev. 07/28/99)

Life report #	Percocet2001-00127
UM/DML report #	
FDA Use Only	

Page 1 of 2

A. Patient information

1. Patient Identifier [Redacted]	2. Age at time of event: 47.000 or Date of Birth:	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight ____ lbs or ____ 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):
 death 01/13/1996
 life threatening
 hospitalization - initial or prolonged
 disability
 congenital anomaly
 required intervention to prevent permanent impairment/damage
 other: _____

3. Date of event (m/d/yy): 01/13/1996
 4. Date of this report (m/d/yy): 06/04/2001

5. Describe event or problem

Initial notification (5/29/2001):
 A coroner reported that a 47-year old, obese white male was found DEAD on his living room floor on 1/13/96. The drugs found in the body included Tylenol, Restoril, Phentermine and oxycodone. The patient was a U.S. marine veteran, who was wounded in the Vietnam war and was receiving Percocet prescribed for pain in his legs due to the land mine wound. When the Veteran's Administration medical service stopped these prescriptions, he obtained his subsequent prescriptions from a local doctor. His last prescription dated 1/09/96 was for 60 tablets. Three days later, when he was found dead, there were only 4 remaining tablets in the container. The autopsy showed an advanced, apparently (cont. on following page)

6. Relevant tests/laboratory data, including dates

Test	Value	Units	Date
Oxycodone (blood) level	0.15	mcg/mL	01/19/1996

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

Per autopsy: viral hepatitis, multiple healed fractures and numerous healed surgical scars from injuries received in Vietnam. Had taken Percocet [oxycodone/acetaminophen] for the past 20 years for pain related to these injuries.

C. Suspect medication(s)

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

#1 Percocet	Endo
#2 Tylenol	

2. Dose, frequency & route used

#1 UNK	#1 Unknown
#2 UNK	#2 Unknown

3. Therapy dates (if unknown, give duration)

4. Diagnosis for use (indication)

#1 Pain
#2 UNK

5. Event abated after use stopped or dose reduced

#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 checked="" type="checkbox"/> doesn't apply

6. Lot # (if known) 7. Exp. date (if known)

#1	#1
#2	#2

8. Event reappeared after reintroduction

#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 checked="" type="checkbox"/> doesn't apply

9. NDC # - for product problems only (if known)

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

G. All manufacturers

1. Contact office -name/address (& mailing site for devices)

Endo Pharmaceuticals Inc.
 223 Wilmington West Chester Pike
 Chadds Ford, PA 19317

2. Phone Number
(610) 558-9800

3. Report source (check all that apply)

foreign
 study
 literature
 consumer
 health professional
 user facility
 company representative
 distributor
 other

4. Date received by manufacturer (m/d/yy): 05/29/2001

5. (A) NDA # 85-106

6. If IND, protocol #

7. Type of report (check all that apply):
 5-day 15-day
 10-day periodic
 Initial follow-up # _____

8. Adverse event term(s)
 Hepatic cirrhosis NOS
 Overdose NOS

9. Mfr. report number
 Percocet2001-00127

JUN 06 2001

E. Initial reporter

1. Name & address phone #
 [Redacted]

2. Health professional?
 yes no

3. Occupation
 Med Director

4. Initial reporter also sent report to FDA
 yes no unk



Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

11/13/2001



MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Endo Pharmaceuticals Inc.

Page 2 of 2

FDA Form 3500A, Rev. 07/2013	
Mfr report #	Percocet2001-00127
UR/DRUG report #	
FDA Use Only	

Section B5, Description of event/problem continuation (as necessary):

POST-NECROTIC CIRRHOSIS without varices, jaundice or other indication of fatal complication. No other significant natural disease was found. Forensic laboratory findings were as follows: oxycodone (blood) 0.15 micrograms/mL [therapeutic range 0.01-0.04; toxic range 4-14], oxycodone (urine) 5 micrograms/mL, acetaminophen 16 micrograms/mL [therapeutic range 10-20], temazepam (blood) 0.8 micrograms/mL [therapeutic range 0.2-0.9], caffeine (blood) 3 micrograms/mL, phentermine (blood) 0.26 micrograms/mL [peak level following single oral dose average 0.09], phentermine (urine) 5 micrograms/mL. The coroner stated in his report that although several substances (oxycodone, acetaminophen, tenazepam [temazepam], caffeine and phentermine) were identified in his blood in small amounts, the levels either individually or in combination were not sufficient to have caused the death in a large adult male who had HABITUATED to two of them for more than 20 years. He further concluded that therefore, he could not adequately determine the cause of death in this case.

This adverse event report was received from Purdue Pharma as a periodic safety report in FDA Form 3500A with Mfr report number 2011721.

Section B6, Relevant tests/laboratory data continuation (as necessary):

Test	Value	Units	Date
Oxycodone (urine) level	5	mcg/mL	01/19/1996
Acetaminophen	16	mcg/mL	01/19/1996
Temazepam (blood)	0.8	mcg/mL	01/19/1996
Caffeine (blood)	3	mcg/mL	01/19/1996
Phentermine (blood)	0.26	mcg/mL	01/19/1996
Phentermine (urine)	5	mcg/mL	01/19/1996

Section B7, Other relevant history continuation (as necessary):

Sections C1-8, Suspect medication(s) continuation (as necessary):

Name	Dose, frequency & route used	Therapy dates	Diagnosis for use	Lot # Exp. date	Event abated/ Event reappeared
Restoril	UNK	Unknown	unk		NA NA
Phentermine	UNK	Unknown	UNK		NA NA

Section C10, Concomitant medical products continuation (as necessary):

Name	Therapy dates
------	---------------

Section G8, Adverse event term(s) continuation (as necessary):

Drug dependence

JUN 06 2001