



29-MAY-1998-0320

FDA MEDICAL PRODUCTS REPORTING PROGRAM



3084945-3-00

A. Patient information			
1. Patient Identifier [REDACTED]	2. Age at time of event or 16 YRS Date of birth:	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight lbs or kgs 67.6
B. Adverse event or product problem			
1. <input checked="" type="checkbox"/> Adverse event and/or <input type="checkbox"/> Product problem			
2. Outcomes attributed to adverse event (check all that apply)			
<input type="checkbox"/> death		<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:		<input type="checkbox"/> other:	
3. Date of event 05/30/97	4. Date of this report 05/26/98		
5. Describe event or problem			
A PHYSICIAN REPORTED THAT TWO PATIENTS EXPERIENCED ADVERSE EVENTS WHILE TAKING SERZONE (NEFAZODONE HCL). THIS REPRESENTS PATIENT #2. THIS PATIENT WAS AN 18 YEAR OLD FEMALE TAKING NEFAZODONE HCL FOR THE TREATMENT OF DEPRESSION. THE TOTAL DURATION OF NEFAZODONE HCL THERAPY WAS 4 MONTHS. THE PATIENT DEVELOPED HEPATITIS DURING THE LAST 3 WEEKS OF THERAPY. A LABORATORY ANALYSIS (UNITS NOT REPORTED) SHOWED BILIRUBIN 29, ALBUMIN 2 AND PROTHROMBIN TIME 19. THE PATIENT WAS NOT TAKING ANY OTHER MEDICATIONS.			
CROSS REFERENCE FILE M067540.			
SUPPLEMENTAL INFORMATION WAS RECEIVED FROM A SECOND PHYSICIAN ON JULY 14, 1997. THE PATIENT WAS 16 YEARS OLD AND NOT 18 YEARS OLD AS ORIGINALLY REPORTED. THE			
(CONTINUED)			
6. Relevant tests/laboratory data			
BILIRUBIN 29			
PROTHROMBIN TIME 19			
ALBUMIN 2			
HEPATITIS PROFILE NEGATIVE			
CYTOMEGALOVIRUS TITER NEGATIVE			
EPSTEIN BARR VIRUS NEGATIVE			
(CONTINUED)			
7. Other relevant history, including preexisting medical conditions			
OBESE			

C. Suspect medication(s)			
1. Name			
#1. SERZONE TABS			
#2. ACETAMINOPHEN			
2. Dose, frequency & route used		3. Therapy dates	
#1. 300 MG BID ORAL		#1. 02/00/97-05/30/97	
#2. ORAL		#2. NI	
4. Diagnosis for use		5. Event abated after use stopped or dose reduced	
#1. DEPRESSION		#1. <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
#2. UNK		#2. <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply	
6. Lot #	7. Exp. date		8. Event reappeared after reintroduction
#1. NI	#1. NI		#1. <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply
#2. NI	#2. NI		#2. <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply
9. NDC # NOT REPORTED			
10. Concomitant medical products NONE			
G. All manufacturers			
1. Contact office - name/address		2. Phone number	
JUDITH R. SZMYD		609-818-3737	
BRISTOL-MYERS SQUIBB COMPANY			
WORLDWIDE SAFETY & SURVEILLANCE			
MAIL LOCATION HW 19-1.01			
P.O. BOX 5400			
PRINCETON, NEW JERSEY 08543-5400			
4. Date received by manufacturer 05/13/98		5. (A) NDA # 20-152	
6. If IND, protocol # NA		IND # _____	
7. Type of report (check all that apply)		PLA # _____	
<input type="checkbox"/> 5-day <input checked="" type="checkbox"/> 15-day		pre-1998 <input type="checkbox"/> yes	
<input type="checkbox"/> 10-day <input type="checkbox"/> periodic		OTC product <input type="checkbox"/> yes	
<input type="checkbox"/> Initial <input checked="" type="checkbox"/> follow-up# 2		8. Adverse event term(s) HEPATITIS	
9. Mfr. report number M067616		NECRO LIVER	
E. Initial reporter			
1. Name, address & phone number			
[REDACTED], M.D. [REDACTED], USA			
2. Health professional? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no		3. Occupation PHYSICIAN	
4. Initial reporter also sent report to FDA <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> 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.

JUN 0 1 1998



29-MAY-1998-0321

THE FDA MEDICAL PRODUCT REPORT

Approved by FDA: 11/01/93



3984945-3-00

A. Patient information			
1. Patient Identifier In confidence	2. Age at time of event: or _____ Date of birth: _____	3. Sex <input type="checkbox"/> female <input type="checkbox"/> male	4. Weight _____ lbs or _____ kgs
B. Adverse event or product problem			
1. <input type="checkbox"/> Adverse event and/or <input type="checkbox"/> Product problem			
2. Outcomes attributed to adverse event (check all that apply)			
<input type="checkbox"/> death _____	<input type="checkbox"/> disability	<input type="checkbox"/> congenital anomaly	
<input type="checkbox"/> life-threatening	<input type="checkbox"/> required intervention to prevent permanent impairment/damage		
<input type="checkbox"/> hospitalization-normal or prolonged	<input type="checkbox"/> other: _____		
3. Date of event _____	4. Date of this report _____		
5. Describe event or problem			
PATIENT STARTED TAKING NEFAZODONE HCL AND WITHIN ONE MONTH SHE APPEARED JAUNDICED. NEFAZODONE HCL CONTINUED TO BE ADMINISTERED FOR ANOTHER MONTH AND THE LIVER BECAME NECROTIC. THE TOTAL DURATION OF NEFAZODONE HCL THERAPY WAS 2 MONTHS AND NOT 4 MONTHS AS ORIGINALLY REPORTED. THE PATIENT UNDERWENT A LIVER TRANSPLANT PROCEDURE. SUPPLEMENTAL INFORMATION WAS RECEIVED FROM THE SECOND PHYSICIAN ON AUGUST 8, 1997. NEFAZODONE HCL THERAPY WAS HALTED ON MAY 30, 1997. THE PATIENT EXPERIENCED PROGRESSIVE LIVER FAILURE DESPITE DRUG DISCONTINUATION. A LABORATORY ANALYSIS SHOWED HEPATITIS A,B AND C NEGATIVE, CYTOMEGALOVIRUS NEGATIVE, EPSTEIN-BARR VIRUS NEGATIVE, CERULOPLASMIN DECREASED AND LIVER COPPER NORMAL. THE REPORTER CONCLUDED THAT THE LIVER FAILURE (CONTINUED)			
6. Relevant tests/laboratory data			
CERULOPLASMIN DECREASED LIVER COPPER NORMAL			
7. Other relevant history, including preexisting medical conditions			

C. Suspect medication(s)	
1. Name _____	
2. Dose, frequency & route used _____	3. Therapy dates _____
4. Diagnosis for use _____	
5. Event abated after use stopped or dose reduced	
<input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
<input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
6. Lot # _____	7. Exp. date _____
8. Event reappeared after reintroduction	
<input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
<input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
9. NDC # _____	
10. Concomitant medical products _____	
G. All manufacturers	
1. Contact office - name/address _____	
2. Phone number _____	
3. Report source (check all that apply)	
<input type="checkbox"/> foreign	
<input type="checkbox"/> study	
<input type="checkbox"/> literature	
<input type="checkbox"/> consumer	
<input type="checkbox"/> health professional	
<input type="checkbox"/> user facility	
<input type="checkbox"/> company representative	
<input type="checkbox"/> distributor	
<input type="checkbox"/> other: _____	
4. Date received by manufacturer _____	5. (A)NDA # _____
6. If IND, protocol # _____	IND # _____
7. Type of report (check all that apply)	PLA # _____
<input type="checkbox"/> 5-day <input type="checkbox"/> 15-day	pre-1938 <input type="checkbox"/> yes
<input type="checkbox"/> 10-day <input type="checkbox"/> periodic	OTC product <input type="checkbox"/> yes
<input type="checkbox"/> Initial <input type="checkbox"/> follow-up# _____	8. Adverse event term(s) _____
9. Mfr. report number _____	
E. Initial reporter	
1. Name, address & phone number _____	
2. Health professional?	3. Occupation _____
<input type="checkbox"/> yes <input type="checkbox"/> no	
4. Initial reporter also sent report to FDA	
<input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> unk	



29-MAY-1998-0322

FDA MEDICAL PRODUCTS REPORTING PROGRAM

Approved by FDA: 11/31/93

Mfr report # **M06781**
 Individual Safety Report



3084945-3-00

A. Patient information

1. Patient Identifier	2. Age at time of event: or _____ Date of birth: _____	3. Sex <input 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

2. Outcomes attributed to adverse event (check all that apply)

<input type="checkbox"/> death	<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

4. Date of this report

5. Describe event or problem
WAS DUE TO NEFAZODONE HCL THERAPY.

SUPPLEMENTAL INFORMATION WAS RECEIVED FROM A THIRD PHYSICIAN ON MAY 13, 1998. THE PATIENT WAS AN OBESE FEMALE. SHE STARTED TAKING NEFAZODONE HCL 50 MG TWICE DAILY IN FEBRUARY 1997. THE DOSE WAS TITRATED UP TO 300 MG TWICE DAILY. THE PATIENT WAS ALSO TAKING ACETAMINOPHEN. THE PATIENT STARTED TO EXPERIENCE STOMACH PAIN. THE PATIENT THEN BECAME JAUNDICED AND WAS DIAGNOSED WITH ACUTE LIVER FAILURE. SHE UNDERWENT A LIVER TRANSPLANT. THIS REPORTING PHYSICIAN CONCLUDED THAT THE EVENTS WERE DUE TO OVERUSE OF ACETAMINOPHEN.

8. Relevant tests/laboratory data

7. Other relevant history, including preexisting medical conditions

C. Suspect medication(s)

1. Name

2. Dose, frequency & route used

3. Therapy dates

4. Diagnosis for use

5. Event abated after use stopped or dose reduced
 yes no doesn't apply

6. Lot #

7. Exp. date

8. Event reappeared after reintroduction
 yes no doesn't apply

9. NDC #

10. Concomitant medical products

G. All manufacturers

1. Contact office - name/address

2. Phone number

3. Report source (check all that apply)

<input type="checkbox"/> foreign
<input type="checkbox"/> study
<input type="checkbox"/> literature
<input type="checkbox"/> consumer
<input type="checkbox"/> health professional
<input type="checkbox"/> user facility
<input type="checkbox"/> company representative
<input type="checkbox"/> distributor
<input type="checkbox"/> other: _____

4. Date received by manufacturer

5. (A)NDA # _____
 IND # _____
 PLA # _____
 pre-1939 yes
 OTC product yes

6. If IND, protocol #

7. Type of report (check all that apply)

<input type="checkbox"/> 5-day	<input type="checkbox"/> 15-day
<input type="checkbox"/> 10-day	<input type="checkbox"/> period.c
<input type="checkbox"/> initial	<input type="checkbox"/> follow-up

8. Adverse event term(s)

9. Mfr report number

E. Initial reporter

1. Name, address & phone number

2. Health professional?
 yes no

3. Occupation

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