

Individual Safety Report



3358780-2-00-01

CDER

Triage unit sequence #

110401

A. Patient Information

1. Patient Identifier | 2. DOB: [REDACTED] | 3. Sex | 4. Weight
| AGE: 50 yrs | MALE | 0.0

B. Adverse Event or Product Problem

1. [X] Adverse Event [] Product problem
2. Outcomes attributed to adverse event
[] death [] disability
[X] life-threatening [] congenital anomaly
[X] Hospitalization [] required intervention to
initial or prolonged prevent impairment/damage
[] other

3. Date of event | 4. Date of this report
01/06/99 | 09/09/99

5. Describe event or problem
LIVER DYSFUNCTION

6. Relevant test/laboratory data, including dates

7. Other relevant History, including preexisting medical conditions

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

or FAX to:
1-800-FDA-0178

FDA Form 3500

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

C. Suspect Medication(s)

1. Name
#1: ACETAMINOPHEN

2. Dose, frequency & route used | 3. Therapy dates
#1: | #1:

4. Diagnosis for use (indication) | 5. Event abated after use
#1: | #1: [N/A]
stopped or dose reduced?

6. Lot # (if known) | 7. Exp. date | 8. Event reappeared after
#1: | #1: | #1: []
reintroduction

9. (Not applicable to adverse drug event reports)

10. Concomitant medical products/therapy dates (exclude treatment)

D. Suspect Medical Devices

Note: Please use the actual MedWatch form if the event involves a suspected device as well as a suspect drug

E. Reporter

1. Name, address & phone #: [REDACTED]

2. Health professional? | 3. Occupation | 4. Reported to Mfr.
[YES] | PHARMACIST | [NO]

5. If you don't want your identity disclosed to the Manufacturer, place an "X" in the box. [X]

REC'D.

10/28/99

MEDWATCH CTU

SEP 28 1999

CTU 110401